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Proposed Re-evaluation Decision PRVD2016-13

Captan

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Overview

General Introduction

In Canada, pesticides are regulated under the *Pest Control Products Act*, administered by Health Canada's Pest Management Regulatory Agency (PMRA). All pesticides are registered (that is, approved) if a rigorous scientific assessment indicates that the health and environmental risks are acceptable and the products have value. The *Pest Control Products Act* also contains provisions for post-market reviews of registered pesticides namely, re-evaluation and special reviews, to assess whether pesticides continue to meet Health Canada's health and environmental standards, and whether they can continue to be used in Canada.

As part of the decision making process, before making a final decision, the PMRA consults with the members of the public and other interested stakeholders on all proposed major decisions such as new registrations, re-evaluations and special reviews. The PMRA encourages the public and stakeholders to participate in the consultation process. The proposed decisions are made based on the information available at the time, and the PMRA will consider the comments and information received during consultation using a science-based approach before making a final decision. The final decision will be published on the Pesticides and Pest Management portion of Health Canada's website and it will include a summary of the comments received during the consultation and PMRA's responses to the comments.

The registration status of products and conditions of use of pesticide products on the market are not impacted by proposed re-evaluation or special review decisions. This may be the case only when final decisions are made. However, at any point during the re-evaluation or special review of a pesticide, the *Pest Control Products Act* allows the PMRA to cancel or amend the registration of registered pest control products, if there are reasonable grounds to believe this is necessary to deal with a situation that endangers human health or safety or the environment.

What is the Proposed Re-evaluation Decision?

An evaluation of available scientific information has determined that, under currently labelled conditions of use, certain uses of captan products have value in the food and crop industry, and do not pose risks of concern to human health or the environment, when new risk mitigation measures proposed in this document are included on labels of captan products. These uses include:

Commercial class products:

- Greenhouse use as soil treatment, rhubarb in forcing sheds, and greenhouse potted flowers;
- Cucumbers (revised rate), potatoes, pumpkin (young), squash (young) at 1 application;
- Ornamental outdoor potted flowers;
- Commercial seed treatment use of liquid and wettable powder formulation products;

- On-farm seed treatment use of liquid formulation or wettable powder formulation (applied as a liquid) products;
- On-farm seed treatment use of wettable powder formulation products as a dry hopper box treatment on corn.
- Golf courses;
- Sod farms.

Domestic class products:

- Fruit trees (except apples, apricots, cherries at rate of 2 g a.i./L);
- Ornamental trees and shrubs (except at rate of 2 g a.i./L);

As well, additional studies are required under Section 12 of the *Pest Control Products Act* to confirm assumptions that were used in risk assessments.

The evaluation also determined that under the currently labelled conditions of use the estimated human health risks for certain other uses of captan do not meet current standards. Therefore, the cancellation of these captan uses is proposed at this time. Uses of captan being proposed for cancellation are:

Commercial class products:

- Greenhouse uses (except soil treatment, rhubarb in forcing sheds, and potted flowers);
- Tree fruits (apple, pear, cherry, plum, prune, peach, nectarine, and apricot);
- Grapes:
- Ornamental stem dip and flower bulb dip;
- Pumpkin, squash (mature);
- Field tomato;
- Berries (strawberry, loganberry, blueberry, blackberry, raspberry);
- Field cut flowers;
- On-farm seed treatment use of wettable powder formulation products as a dry hopper box treatment on beans.

Domestic class products:

- All dust product uses;
- Fruit (blackberries, strawberries);
- Vegetables (cucumbers, peppers, tomatoes);
- Flowers;
- Outdoor ornamental trees and shrubs (rate of 2 g a.i./L);
- Fruit trees (apples, apricots, cherries) (rate of 2 g a.i./L).

Consideration of any additional data/information submitted during the consultation period to further refine the health risk assessment may or may not result in a change to this proposal.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for captan and presents the reasons for the proposed re-evaluation decision. The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides details on the risk assessments conducted for captan.

Before making a final re-evaluation decision on captan, the PMRA will accept and consider written comments on this proposal received up to 90 days from the date of its publication. Please forward all comments to Publications (see contact information on the cover page of this document).

Once the final re-evaluation decision is made, registrants will be instructed on how to address any new requirements.

What Does Health Canada Consider When Making a Re-evaluation Decision?

Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents details of the re-evaluation activities and program structure. The key objective of the *Pest Control Products Act,* to prevent risks of concern to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[2] The Act also requires that products have value[3] when used according to the label directions. Requirements of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as rigorous and modern policies. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. The re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information.

For more information on how the PMRA regulates pesticides, as well as the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

3 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

What is Captan?

Captan is a contact fungicide with a multi-site mode of action (BCPC, 2014). It is used to control a broad range of diseases on a variety of use sites including greenhouse (food and non-food crops), seed treatment (food, feed and non-food), terrestrial feed and food crops, outdoor ornamentals, and turf (golf courses and sod farms only). Formulations include dusts, wettable powders, wettable granules, suspensions and solutions. Domestic class products for use by the general public include foliar and a dust applications. Commercial class captan products can be applied using airblast, backpack, field and aerial sprayers, by dipping of cuttings, bulbs and corms of ornamentals, by incorporating into the soil, and by treating seed (slurry machines or hand mixing with a paddle or shovel in a container or seed box and commercial seed treatment facilities) by farmers, farm workers, professional applicators and nursery workers.

Health Considerations

Can Approved Uses of Captan Affect Human Health?

Additional risk-reduction measures are required on captan labels. Captan is unlikely to affect your health when used according to the revised label directions.

Potential exposure to captan may occur through the diet, when handling and applying products containing captan, or when entering or contacting treated sites. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, captan was of low acute oral and dermal toxicity and of slight acute toxicity from the inhalation route. It was minimally irritating to the skin but was severely irritating to the eyes resulting in irreversible effects. Following dermal exposure, captan caused an allergic skin reaction in animals and humans.

Registrant-supplied short, and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature were assessed for the potential of captan to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment included fetal loss and malformations. There was evidence that young animals were slightly more sensitive than adult animals to captan toxicity as demonstrated by reduced offspring body weight

at a dose that was not toxic to the mothers. Inhalation exposure resulted in irritation and degenerative effects of the respiratory tract. The risk assessment approach ensures that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

The acute dietary exposure estimate (in other words, to captan and tetrahydrophthalimide (THPI), the principal metabolite of captan, from food and drinking water) for females 13-49 years of age at the 99.9th percentile represents 36% of the acute reference dose when using drinking water concentrations generated from water modelling. The chronic dietary exposure estimate for this subpopulation represents 4% of the chronic reference dose. Chronic dietary exposure estimates for all other subpopulations range from 2 to 8% of the chronic reference dose. Thus, acute and chronic dietary risks are not of concern.

Canadian MRLs for captan are currently specified for some commodities (MRL database). Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specific MRL, are regulated under Subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues do not exceed 0.1 ppm. The current MRLs for captan can be found in Appendix VII of this document. An amendment of the residue definition is being proposed as a result of this re-evaluation. Consequently, it is proposed that MRLs be reassessed (through an *ad hoc* submission) on the basis of the amended residue definition. Details can be found in the Science Evaluation section of this document.

The thiophosgene metabolite

The metabolism of captan in plants and animals produces thiophosgene ($SCCl_2$), a highly reactive, short-lived intermediate. Thiophosgene is likely responsible for the sustained duodenal irritation that progresses to the development of duodenal tumors. As the thiophosgene metabolite is common to both captan and the closely related chemical folpet, cumulative risk from captan and folpet will be assessed concomitantly with the folpet risk assessment.

Risks in Residential and Other Non-Occupational Environments

Certain residential uses are not of concern when used according to label directions. Risk mitigation is required for those uses with risks of concerns.

Residential exposure may occur from application of products containing captan to residential fruit trees, berries, vegetables and ornamental gardens including flower bulbs and soil, as well as golf courses. Residential handler exposure would occur from mixing, loading and applying domestic-class captan products. These products can be applied either as a dust or as a liquid when mixed with water.

Residential postapplication exposure may occur while performing activities on treated areas. Treated areas include areas treated by residential handlers, as well as residential areas treated by commercial applicators. Exposure would be predominantly by the dermal route.

For domestic class products applied as a dust, risks of concern were identified for most uses. To mitigate risks, cancellation is proposed for all domestic class products formulated as a dust. For domestic class products applied as a liquid, homeowner applicator risk estimates are not of concern.

Postapplication risks were not of concern for golfers. Postapplication risk from application of domestic or commercial class products is not of concern for application to residential fruit trees and ornamental trees and shrubs. However, risks of concern were identified for postapplication activities in residential gardens (berries, vegetables, flowers). To mitigate risks, it is proposed that all uses on berries, vegetables, and flowers be removed from the domestic class product labels.

For those residential scenarios where dermal and inhalation risks were not of concern, exposure was aggregated with background (chronic) dietary exposure (food and drinking water). For most uses, the resulting aggregate risk estimates were not of concern. The aggregate risk estimate for domestic class products applied to residential fruit trees and ornamental trees and shrubs was of concern at the high label rate (2 g a.i./L). To mitigate risks, it is proposed that this rate be removed from the domestic class product labels.

Non-occupational risks from bystander drift exposure are not of concern.

Agricultural application of captan may result in spray drift. Studies that sampled the air in agricultural areas in Canada during the spray season indicate that captan can be present in the air. Bystander risk based on the highest level of captan measured in the air was not of concern.

Aggregate risk where exposure from food and drinking water was combined with possible inhalation exposure from drift was not of concern.

Occupational Risks from Handling Captan

The majority of handler risks are not of concern provided additional risk reduction measures are observed. Risk mitigation is required for uses with risks of concerns.

Occupational handler risk assessments consider exposure to workers who mix, load, and apply the pesticide. Most handler risks are of concern for agricultural scenarios based on the current label statements. However, if engineering controls and/or additional personal protective equipment are used, the majority of uses have no risk concerns. These measures are needed to minimize potential exposure and protect workers' health. For uses that continue to have health risk concerns, further mitigation is proposed, such as limiting the amount of product handled in a day.

The use of captan in seed treatment is of concern for the commercial and on-farm application of liquid and wettable powder formulation products (applied as a liquid), based on the current use pattern. However, using surrogate data, when necessary, most uses are not of concern when engineering controls and/or additional personal protective equipment are used. The on-farm application to beans with wettable powder formulations as a dry hopper box treatment is of concern. To address this risk concern, it is proposed that this use be cancelled. To confirm assumptions for uses proposed for continued registration, information and studies on occupational exposure for seed treatment are required.

Adequate data were not available to assess occupational exposure from the use of captan as a flower bulb and ornamental stem dip. These uses are proposed for cancellation.

Postapplication risks are not of concern provided additional mitigation measures are established. Cancellation is proposed for uses where the mitigation measures are not agronomically feasible, unless there is information/data submitted during the consultation period that would alter the risk assessment.

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture. Based on the current use pattern for agricultural scenarios, postapplication risks to workers performing activities, such as thinning, pruning and harvesting of most crops, did not meet current standards and require mitigation. When the proposed mitigation measures such as lengthened restricted-entry intervals (REIs), and restricting the number of applications are considered, the risks to postapplication workers may not be of concern. However, some of the proposed REIs are not considered to be agronomically feasible, and are not a viable risk mitigation option.

For those crops where risks were identified (greenhouse crops (except soil treatment, potted flowers and rhubarb in forcing sheds)) or the REIs are very long and not agronomically feasible (for example: up to 94 days; for crops such as fruit trees and grapes), it is proposed that these uses be cancelled.

PMRA is aware that changes to the apple orchard architecture may potentially result in lower exposures. The extent of this change for all postapplication activities will be further evaluated after completion of the consultation process, which will include consideration of information that is provided during this process.

Environmental Considerations

What Happens When Captan Is Introduced Into the Environment?

When used according to label directions, captan is not expected to pose risks of concern to the environment.

Captan can enter non-target terrestrial and aquatic habitats through spray drift and can enter aquatic habitats through run-off. Captan is not persistent in soil or water. Captan is not to expected to move through the soil profile and enter groundwater, however, the transformation product THPI does have the potential to reach groundwater. Captan is not expected to accumulate in plant and animal tissue.

Under controlled laboratory conditions, captan can be toxic to some non-target species such as terrestrial plants, wild mammals, aquatic invertebrates, amphibians and fish. If captan is used at labelled rates without any risk reduction measures, it may cause adverse effects in the organisms listed above. Therefore, mitigation measures are required in order to reduce potential exposure of non-target organisms and reduce environmental risk. When captan is used in accordance with the label and the required mitigation measures, the resulting environmental risk is considered to be acceptable.

Value Considerations

What is the Value of Captan?

Captan is an effective broad spectrum fungicide with a multi-site mode of action that provides control of a number of major fungal diseases and is important for resistance management.

Captan has been registered and widely used in Canada for use on food and non-food crop sites for over 50 years due to its effectiveness and multi-site mode of action. Currently, it is registered for use on field, greenhouse and orchard crops, greenhouse and outdoor ornamentals, and turf (golf courses and sod farms only) as a foliar treatment to control a number of major fungal diseases that can have significant negative economic impact on crop revenue. Captan contributes to pest management and sustainability by playing an important role in disease and resistance management when used in rotation, or as a tank mix partner with single-site fungicides on crops where resistance is known or at risk of developing resistance. The majority of the alternatives to captan have single-site mode of action. Other multi-site fungicides are registered for some of the crops but they are not necessarily as effective as captan against certain plant diseases.

Captan is of particular importance to control apple scab on apples; downy mildew, Phomopsis cane and leaf spot on grapes; Botrytis blight and fruit rot on blueberry; Botrytis fruit rot on raspberry and strawberry; brown rot on sweet cherries; and many diseases of ornamentals including Botrytis flower blight, fungal leaf spot, damping-off and fungus root rot.

Captan is also applied as a dip to cuttings, bulbs and corms of ornamentals, as a soil treatment of some ornamentals and vegetables, and as a seed treatment at planting or before storage to control storage rot, soil-borne fungal seed rots, damping-off, seedling blights and root rot on some pulse, vegetable, grain, oilseed and specialty crops.

Proposed Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

Risk-reduction measures are being proposed to address potential risks identified in this assessment. These measures, in addition to those already identified on existing captan product labels, are designed to further protect human health and the environment. The following additional key risk-reduction measures are being proposed.

Key Risk-Reduction Measures

Human Health

To protect homeowners and those entering treated residential areas:

- Require restricted-entry interval of ‘until spray has dried’ to all domestic class products.
- Remove dust applications from labels of all domestic class products.
- Remove berries, vegetables and flowers from labels of all domestic class products.
- Remove the high rate (2.0 g a.i./L) from domestic class products.

To protect mixer/loader/applicators:

- Require additional protective equipment and engineering controls when mixing/loading and applying to all crops.
- Repackage all commercial wettable powders and wettable granules products to water soluble packaging.
- Limit the amount of captan used per day for mechanically pressurized handguns in greenhouses.

To protect workers entering treated sites:

- Revise or establish REIs for some crops.
- Require restrictions on number of applications allowed per season for some crops.
- Require label statements to clarify the acceptable greenhouse uses of captan,
- Remove crop uses with agronomically unfeasible REIs from commercial class products (in other words, fruit trees, grapes, berries, some field vegetable crops, field cut flowers, and greenhouse crops (except soil treatment, potted flowers and rhubarb in forcing sheds)).

To protect workers involved in seed treatment:

- Require additional protective equipment for workers who treat and handle seeds treated with captan.
- Remove on-farm seed treatment use of wettable powder formulation products as a dry hopper box treatment on beans.
- Remove the commercial flower bulb dip and ornamental stem dip use.

To protect bystanders from spray drift:

- Require a statement to promote best management practices to minimize human exposure from spray drift or spray residues resulting from drift.

Environment

- Advisory statements to inform users that captan is toxic to non-target organisms including plants, small mammals, aquatic invertebrates, fish, algae and frogs.
- Advisory statements to inform users of conditions that may favour run-off and leaching.
- Spray buffer zones to protect aquatic and terrestrial habitats from drift.
- A statement advising that transformation products could potentially reach groundwater, particularly in areas where soils are permeable and/or the depth to the water table is shallow.

What Additional Scientific Information is Being Requested?

The following information and studies are proposed as a condition of continued registration under Section 12 of the *Pest Control Products Act* to confirm assumptions for those uses proposed for continued registration:

Human Health

Dietary residue chemistry data:

- A laboratory study which quantifies the individual recovery efficiency for captan and its metabolites by typical multiresidue methods used in food surveillance programs.

Occupational exposure data (seed treatment):

- Comparative laboratory dust-off data for captan treated seeds to determine if the surrogate exposure studies address potential captan exposure. If captan treated seeds are shown to produce more dust compared to seeds used in the surrogate studies, additional exposure data may be required, as exposure may be underestimated.
- Use Description/Scenario for commercial seed treatment of vegetable seeds in Canada, as the method of treatment may be different from that in the surrogate exposure studies. If the treatment method is different, additional exposure and comparative dust-off data may be required.
- Use Description/Scenario for amounts of seed treated in commercial facilities for alfalfa, broccoli, Brussels sprouts, cabbage, cauliflower, clover, and sugar beet.

Next Steps

Before making a re-evaluation decision on captan, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision Document, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments. Based on the final outcome of the re-evaluation, registrants will be expected to revise product labels to include new required risk-reduction measures. Timelines for submission of required data and cancellations of affected products will determined at the time of the final decision.

During the comment period for the PRVD, registrants are asked to submit or commit to submitting the additional scientific information identified in this document for the purposes of confirming or refining the current risk assessment.

Other Information

At the time that the re-evaluation decision is made, the PMRA will publish an Evaluation Report on captan in the context of this re-evaluation decision (based on the Science Evaluation of this consultation document). In addition, the test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

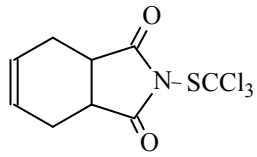
Science Evaluation

1.0 Introduction

Captan is a broad spectrum contact protectant fungicide with a multi-site mode of action belonging to Resistance Management Mode of Action (MoA) group M4 (BCPC, 2014). It belongs to the group of fungicides commonly known as the phthalimides. Following the re-evaluation announcement for captan the technical registrants and primary data providers in Canada indicated that they intended to provide continued support for all uses included on the labels of Commercial Class end-use products (EPs) except turf (lawn seed beds, ornamental, sport). Additionally, the technical registrants indicated that they do support continued domestic/homeowner use of Domestic Class products containing captan and registered for use in Canada. On 24 March 2014 the technical registrants submitted a proposed use pattern which was considered in the assessments.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient.

Common name		Captan
Function		Fungicide
Chemical Family		Phthalimide
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	*N*-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide
2	**Chemical Abstracts Service (CAS)**	3a,4,7,7a-tetrahydro-2-[(trichloromethyl)thio]-1*H*-isoindole-1,3(2*H*)-dione
CAS Registry Number		133-06-2
Molecular Formula		$C_9H_8Cl_3NO_2S$
Structural Formula		

Molecular Weight 300.6

Registration Number	Purity of the Technical Grade Active Ingredient
18221	88% minimum
21107	95% nominal
27904	95% nominal
29963	95.2 % nominal

Identity of relevant impurities of human health or environmental concern:

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

While some manufacturing impurities present in technical captan demonstrate hazardous properties, they are unlikely to impact the risk profile for captan for the following reasons:

i) they are present at very low levels;
ii) their toxicity profiles are similar to captan either qualitatively or quantitatively; and,
iii) the assessment accounts for the contribution of these contaminants to risk given that toxicology studies were conducted with technical captan (including the manufacturing impurities)

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result	Interpretation
Vapour pressure at 25°C	<1.3 mPa	Relatively non-volatile under field conditions
Ultraviolet (UV)/visible spectrum	No absorption above 350 nm	Low potential for direct phototransformation
Solubility in water at 25°C	3.3 mg/L	Low water solubility
n-Octanol/water partition coefficient at 25°C (log K_{ow})	Log K_{ow}= 2.8	Not expected to bioconcentrate
Dissociation constant (pKa)	None, the product does not have dissociating functional groups	N/A

2.3 Description of Registered Captan Uses

Appendix I lists all captan products that are registered under the authority of the Pest Control Products Act. Appendix IIa lists all Commercial Class uses for which Captan is presently registered, while Appendix IIb lists all Domestic Class uses for which captan is presently registered. All uses except turf (ornamental, lawn seed beds, sport) were supported by the registrant at the time of re-evaluation initiation and were, therefore, considered in the health and environmental risk assessments of captan. On 24 March 2014 the technical registrants submitted a registrant proposed use pattern which was considered in the assessments.

Uses of captan belong to the following use-site categories (USC): greenhouse food and non-food, seed treatment food, feed and non-food, terrestrial feed and food, outdoor ornamentals and turf (golf courses and sod farms only).

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Captan is a chloroalkylthio fungicide sharing structural similarities to folpet, another fungicide of the same chemical class. It also demonstrates some similarity to the fungicide captafol in that both compounds have a similar ring structure and accordingly share the tetrahydrophthalimide (THPI) metabolite.

A detailed review of the toxicological database for captan was conducted. The conduct of available studies spans a wide time range with the vast majority of studies being conducted since the mid-1980s. The database for captan is extensive and includes the full array of toxicity studies currently required for hazard assessment purposes, as well as mechanistic data. Published studies were also incorporated into the hazard assessment. Overall, results from the studies are consistent and indicate a contact irritation mechanism targeting mucosal membranes.

Captan was readily absorbed orally by rats following single or repeat exposure to low doses of radiolabelled compound. Studies indicate that the processes leading to absorption of captan in the small intestine reach a point of saturation at moderate to high dose levels. Captan remains in parent form in the stomach until reaching the alkaline regions of the duodenum, at which point it is largely converted to THPI and thiophosgene by hydrolysis and reaction with thiols. Metabolic studies indicate that further metabolism occurs in the small intestine. THPI undergoes hydroxylation and epoxide formation. Thiophosgene has not been quantified in studies due to its highly reactive state but is considered an intermediate to the formation of the metabolites carbon dioxide, thiazolidine-2-thione-4-carboxylic acid (TTC), dithio-bis-methanesulphonic acid (DMS) and its epoxide (DMS-O). Distribution of radiolabel to tissues was minimal with the greatest accumulation occurring in the liver, kidneys and intestines.

At low doses, excretion of radiolabel was rapid and occurred primarily through the urine, with smaller quantities in the feces and expired air. Urinary metabolites in rats included THPI, 3-OH-THPI (3-hydroxy-1,2,6-trihydrophthalimide), 5-OH-THPI (5-hydroxy-1,2,6-trihydrophthalimide), THPAM (cis-1-carboxy-2-carboxamido-4-cyclohexene), TTC, DMS and DMS-O. No captan was detected in the urine in most studies; however, a compound suspected to be captan was detected at a minimal level in urine (<2%) in one oral study using high doses. The fecal metabolic profile was very similar to that of the urine, suggesting that biliary excretion occurred. At high doses, greater fecal elimination and expiration was observed. Rats receiving high doses showed notable levels of captan in the feces.

Absorption occurred more rapidly in mice than in rats, with a similar quantity of captan absorbed in both species over time. Transit through the gastrointestinal tract, as well as excretion, appeared to be more rapid in the mouse. As in the rat tissues, there was no notable distribution of captan metabolites in the murine tissues. There were no significant sex-related differences in the toxicokinetics of captan in either species.

Recently published toxicokinetic data investigated the fate of captan in humans following oral and dermal dosing. The studies were conducted in volunteers, followed informed consent procedures and were approved by a university research ethics committee. The studies showed rapid absorption of the biomarker THPI, a single-exponential model for THPI elimination from plasma and urine, and no significant tissue storage based on the relatively small volume of distributions. Toxicokinetic modelling suggested that only a small fraction of THPI reaches the blood following oral or dermal exposure to captan, and measured data indicated only a small amount of THPI in the urine. Biological matrices were not examined for the presence of captan in these studies.

Captan was of low acute toxicity to rats via the oral and dermal routes, and low acute toxicity to mice via the oral route. Slight acute toxicity was noted in rats exposed to captan via inhalation. In rabbits, captan was severely irritating to the eyes resulting in irreversible corneal opacity but it was only minimally irritating to the skin. Dermal sensitization was observed in both guinea pig Maximization assays and in a human patch test.

In repeat-dose oral toxicity studies in which mice, rats and dogs were administered captan, the most sensitive species was the mouse with the small intestine as the target organ. The effects of captan on the intestinal tract of mice were thoroughly investigated. In short-term studies, distention of the duodenal lumen was observed one day following ingestion of high doses of captan. Pathological effects observed following several weeks of exposure were primarily limited to the proximal region of the duodenum and included the shortening and disorganization of villi, inflammation of the lamina propria, the presence of immature enterocytes at the tip of the villi, and hyperplasia of the crypt cells. As crypt cells replicate, they move up the villi and mature in order to replace the epithelial lining of the intestine. Epithelial cells that comprise the villi are damaged by the irritant properties of captan and are sloughed off into the intestinal lumen at an elevated rate. The hyperplastic condition of the crypt cells is caused by the need to rapidly regenerate the damaged villi as suggested by a decrease in villi height, decreased cell maturity, increased crypt cell mitotic figures and increased crypt cell: villi ratios. The increase in hyperplasia of the crypt stem cells has the potential to increase the incidence of neoplastic

lesions due to spontaneous initiation, both by increased cell turnover and a decrease in the time available for cellular repair of DNA damage. Similar pathology of the gastro-intestinal tract was not observed in rats or dogs.

Consistent liver weight effects were observed in rats following repeated dietary exposure to captan, typically in the absence of correlative histopathology although hepatocellular hypertrophy has been observed in one study. There was no evidence of toxicity to the nervous, endocrine or immune system in any of the tested species. A Hershberger assay in rats did not indicate androgenic or anti-androgenic activity following gavage dosing.

Repeat-dose studies indicated that the toxicity of captan was greatest from the inhalation route of exposure and the least from dermal exposure. Following exposure to captan via inhalation for 3-12 weeks, severe irritation was observed in the respiratory tract which led to histological changes including necrosis. The severity of effects increased with increasing duration of exposure. The only significant systemic effect observed following inhalation exposure, which was consistent with repeat oral dosing, was decreased body weight, suggesting low absorption via the respiratory tract. Animals exposed dermally to high levels of captan experienced diarrhea, as well as decreased body weight gain and food consumption.

Captan was administered to mice via the diet in four chronic studies. In all these studies, intestinal lesions progressed to not only hyperplasia, but adenomas and carcinomas, almost exclusively localized in the proximal region of the duodenum. The combined results of the four studies suggested that a threshold response for both hyperplasia and tumours appeared to occur between 60 and 120 mg/kg bw/day. In one study in which varying treatment and recovery periods were employed, decreases in the incidences of duodenal hyperplasia were observed in animals allowed to recover. Tumours, which were observed as early as 24 weeks, did not regress with cessation of treatment. At very high dose levels, mice also exhibited hyperplasia of the stomach and jejunum, as well as tumours of the jejunum.

There were no treatment-related tumors identified in the rat; the reason for the differences in species susceptibility to the gastrointestinal findings is uncertain. One study indicated that the pH of the duodenum was slightly lower in rats than mice, but the study was limited by small animal numbers. Although duodenal pH can vary with time of day and feeding conditions, the pH of the duodenum is relatively similar among humans, rats and mice. In humans, the pH of the duodenum is not likely to drop below 3.5, with the upper range being limited by the pH of sodium bicarbonate excretions (pH 8.0). More importantly, the human relevance of the mouse duodenal lesions cannot be dismissed on the basis of intraspecies/interspecies variability in duodenal pH.

Duodenal tumors were also observed in mice (but not rats) following chronic administration of the structurally similar fungicide, folpet (PMRA #2063223). Toxicokinetic studies indicate that folpet is metabolized to thiophosgene in the duodenum (PMRA #2063223). Thiophosgene, a principal metabolite of both captan and folpet, is the likely causative agent of the irritation to mucosal membranes such as the eyes, the respiratory tract and the gastrointestinal tract observed with both compounds. The data indicate that the gastrointestinal tumors arise secondary to prolonged, continuous gastrointestinal irritation following captan exposure at high dose levels.

Although it is possible that these effects could be reproduced in humans, the dose levels used to establish the dietary reference doses are well below the threshold for irritation and are therefore considered protective of potential neoplastic effects.

Numerous in vivo and in vitro genotoxicity studies of varying quality have been identified for captan. An extensive battery of in vitro gene mutation assays using prokaryotic organisms (bacteria) have generally yielded a positive response. This response was decreased or eliminated in the presence of glutathione, blood, cysteine or metabolic activation, likely as a result of the detoxification of the highly reactive thiophosgene metabolite via the available reactive thiol groups. The transformation product THPI was negative in a gene mutation assay. In eukaryotic cells, captan yielded mostly positive responses in the absence of metabolic activation in in vitro assays assessing gene mutation, chromosome aberration, sister chromatid exchange and unscheduled DNA synthesis. In vitro studies also indicated DNA damage in the absence of metabolic activation; however, captan did not appear to bind covalently to DNA.

Mixed results were observed in in vivo germ and somatic cell clastogenicity assays; positive results were typically associated with high doses of captan. Captan was negative in an in vivo study investigating unscheduled DNA synthesis. A novel nuclear aberration assay designed to assess the clastogenic potential of captan to villi crypt cells of the small intestine was negative. Overall, the genotoxicity database suggests that it is unlikely that the duodenal tumours observed in mice are produced through a genotoxic mechanism. The Australian National Registration Authority (1997), the U.S. Environmental Protection Agency (2004) and the European Food Safety Authority (2009) have reached the same conclusion.

Two rat dietary reproductive toxicity studies conducted with captan were available. In these studies, body weight effects were the most sensitive effect with the pups being slightly more sensitive than the parental animals. An increase in early neonatal death was observed at levels that were toxic to the mothers. The cause of this mortality was not specified. F1 generation females from one of these studies were selected for use in a developmental toxicity study. In this study, single incidences of cleft palate were noted at 100 and 250 mg/kg bw/day as well as a single incidence of hydrocephaly at 250 mg/kg bw/day; these doses were maternally toxic. Other than a single incidence of tail anomaly, there were no major malformations in the high-dose group of 500 mg/kg bw/day. In a gavage developmental toxicity study in rats, there was no evidence of treatment-related malformations at doses comparable to those tested in the dietary study.

Four developmental toxicity studies in rabbits were conducted by gavage with captan. A fifth study cited by the registrant was considered unacceptable for evaluation. Although no clear evidence of malformations was noted in the earliest two of these studies, these studies were limited by inadequate numbers of dams at the higher dose levels as a result of non-pregnancy, intubation error or litter loss. Increased post-implantation loss was noted in one of these studies at maternally-toxic dose levels. In a third study, the incidences of major external/visceral and skeletal defects were clearly elevated at the top dose of 100 mg/kg bw/day along with an increase in post-implantation loss. The incidences of minor external/visceral defects and late resorptions were increased at 30 mg/kg bw/day and above. Most of the malformations were seen as single occurrences in the mid- and high-dose groups; however, when grouped by type of malformation,

an increase in craniofacial malformations was seen at 30 mg/kg bw/day (2 fetuses in 2 litters) and 100 mg/kg bw/day (3 fetuses in 2 litters), in addition to forepaw flexure malformations. Historical data indicated that these effects were rarely observed in control animals. In the most recent rabbit study, an increase in post-implantation loss was evident at the highest dose tested (45 mg/kg bw/day). Additional malformations were noted at this dose level, in particular, absent kidney and ureter. Effects on fetal viability and development in the third and fourth study were only noted in the presence of materrnal toxicity. A gavage developmental toxicity study in rabbits was submitted for THPI. While no developmental toxicity was seen at the highest dose tested of 22.5 mg/kg bw/day, it was questionable whether adequate doses were used in the study as maternal animals only showed marginal effects on weight gain and food consumption.

In a gavage developmental toxicity study conducted with captan in the hamster, numerous fetal effects were seen at the highest dose level of 400 mg/kg bw/day. This dose level also produced significant maternal toxicity as evidenced by mortality. At the highest dose level, there were increased post-implantation losses and an increase in the overall number of malformations. Malformations seen in the high-dose group, but not in controls, included cleft palate, limb and tail anomalies and fetal anasarca. Two high-dose fetuses from the same litter exhibited multiple malformations; both had exencephaly (one incidence seen in controls) and facial anomalies and one also showed spina bifida.

An older gavage study in monkeys was available but was considered supplemental due to limited study design (lack of control group, did not cover significant periods of organogenesis, lack of detail etc.). Although no malformations were reported in the study, two of seven females at the high-dose level (25 mg/kg bw/day) had abortions and an additional female had a resorption. The resulting fetal mortality exceeded the historical control data for the colony. It is unknown whether the aborted fetuses or placental remnants were examined for malformations.

Malformations and embryo-fetal lethality were also noted in rabbit developmental toxicity studies conducted via gavage with folpet and captafol. In one study with folpet (PMRA # 1347668), no treatment-related soft tissue malformations were evident but increased post-implantation loss was seen at the highest dose (160 mg/kg bw/day). In a second study with folpet (PMRA # 1347666), hydrocephaly was seen at the highest dose of 60 mg/kg bw/day and was often accompanied by irregular-shaped fontanelles; post-implantation loss appeared to be unaffected. In a follow-up study to the second study (PMRA # 1347667) with pulse dosing, at 60 mg/kg bw/day, hydrocephaly was seen in a single fetus from a dam treated with folpet on gestation day 10-12 as well as another dam treated on day 16-18. The fetal incidence of irregular-shaped fontanelle was also increased at this dose level. Post-implantation loss was unaffected in this study.

Two rabbit developmental toxicity studies via gavage were available with captafol. In the first study (PMRA # 1197973), increased incidences of hydrocephaly were noted at 16.5 mg/kg bw/day. At the high-dose level of 50 mg/kg bw/day, single incidences were recorded for hydrocephaly, heart malformation and abnormal flexure of the forepaw. In addition to maternal mortality, post-implantation loss was increased in the high-dose group. In the second study (PMRA # 1197961), maternal mortality and increases in mean number of resorptions at the high-dose level of 50 mg/kg bw/day led to a reduced number of viable fetuses available for

examination. Consequently, the incidences of domed head, cleft palate, clubbed foot, fluid on the cranium, small brain, enlarged fontanelle and distended lateral ventricle at the mid-dose of 16 mg/kg bw/day were of greater significance. A single incidence of distended lateral ventricle was the only cranio-facial malformation of note at the high dose.

The registrant contended that the fetus is not exposed to captan given the rapid and extensive breakdown of captan in the gut (PMRA # 2383644). While there is some potential for absorption of captan, albeit slight, the developing fetus would be primarily exposed to THPI and other metabolites. While THPI did not show evidence of treatment-related malformations or resorptions in a rabbit developmental toxicity study, a sufficiently high dose may not have been used. Furthermore, other metabolites have not been tested for developmental toxicity. Consequently, the captan studies are considered relevant for risk assessment in that all metabolic degradates are considered.

In conclusion, the captan data are suggestive of developmental toxicity at doses ≥ 30 mg/kg bw/day. The effects are not likely a species-specific response (in other words, bacteriogenic action in the rabbit) as suggested by the registrant (PMRA # 2383644) given the findings in hamsters and rats. Although craniofacial and limb anomalies are recurring observations in the developmental toxicity sudies, the lack of consistent structural targets suggests that they may be secondary to maternal toxicity as opposed to a direct teratogenic effect. Studies on folpet and captafol suggest a similar response. Time-course data in mice receiving a high dose of captan (~450 mg/kg bw/day) demonstrate duodenal effects as early as one day post-dosing (luminal distension) followed by pathology three days post-dosing. Although gastrointestinal disturbance is likely a common stressor in pregnant animals of all species at high-dose levels, data to support this contention at lower dose levels are limited, other than for non-specific effects on body weight and food consumption. Regardless, the impact of maternal stress is not species-specific and therefore the animal findings are relevant to humans.

The registrant contended that the toxicity of THPI was sufficiently characterized to show that it is orders of magnitude less than captan. It is acknowledged that THPI is likely to be of lower toxicity than captan due to the metabolic removal of the reactive groups; however, acute oral studies on THPI were either unavailable or of insufficient quality. The most recent developmental toxicity studies in the rabbit with captan and THPI offer the best comparison of toxicity as they were conducted by the same laboratory around the same time. Maternal animals treated with captan at 10 mg/kg bw/day or THPI at 22.5 mg/kg bw/day showed effects on body weight gain and food consumption although the effects were less pronounced with THPI. Overall, the toxicity of THPI is not well characterized and the data are limited, but it would appear that THPI could be half as toxic as captan based on the comparison of the captan and THPI developmental tyoxicity studies. Furthermore, no data are available on other metabolites such as 3-OH-THPI, 5-OH- THPI and THPAM.

Results of the toxicological studies conducted on laboratory animals with captan and THPI are summarized in Appendix IV. The toxicology endpoints for use in the human health risk assessment are summarized in Appendix III.

Epidemiology

Numerous studies were identified which explored the potential health effects of captan exposure (among other pesticides) in human populations. The health outcomes examined included colorectal cancer (PMRA # 2533859; PMRA # 2533850), prostate cancer (PMRA # 2533059; PMRA # 2533850, PMRA # 2533061), breast cancer (PMRA # 2533062), non-Hodgkin's Lymphoma (PMRA # 2533860; PMRA # 2533850), multiple myeloma (PMRA # 2533855), wheeze (PMRA # 2533851; PMRA # 2533852; PMRA # 2533853), chronic bronchitis (PMRA # 2533865), asthma (PMRA # 2533854), rhinitis (PMRA # 2533863; PMRA # 2533864), neural tube defects (PMRA # 2533862), Parkinson's disease (PMRA # 2533857), retinal degeneration (PMRA # 2533856; PMRA # 2533858), and type II diabetes (PMRA # 2533861). Studies reporting positive associations with captan exposure are detailed below. The remaining studies did not observe important relationships between captan exposure and adverse health outcomes; however, small numbers of exposed cases and/or limitations in study design preclude definitive conclusions.

Retinal Degeneration

A case-control study was conducted of pesticide exposure and retinal degeneration among male pesticide applicators in the Agricultural Health Study (AHS) cohort (PMRA # 2533856). Cross-sectional data on pesticide exposure and retinal degeneration were collected through enrollment and take-home questionnaires completed by 17,958 men (99% farmers) between 1993 and 1997. Men were included in the study if they completed both the enrollment and take-home questionnaires. There were 154 applicators who reported diagnosis with retinal/macular degeneration at the beginning of the study; the remaining applicators served as controls. After adjusting for age, sex, education, and state of residence, applicators with greater than 51 days of captan exposure had a significantly increased risk of retinal degeneration (Odds Ratio (OR) = 4.0, 95%CI: 2.0, 8.1) . Although the use of prevalent cases and self-reported exposure and disease information are limitations of this study, the findings suggest a possible relationship between captan exposure and retinal degeneration in pesticide applicators. Neither ophthalmological examinations nor histopathological examinations in several test animal species provided evidence to suggest captan may cause retinal degeneration in humans via systemic exposure.

Breast Cancer

An examination of breast cancer incidence among wives of private pesticide applicators was undertaken in the AHS cohort (PMRA # 2533062). Incident breast cancer cases were identified from enrollment through December, 2000 by matching cohort members to state cancer registries in Iowa and North Carolina. Self-reported pesticide exposure data were collected from women and their husbands through an enrollment questionnaire. In total, 30,354 women participated in the study. After adjusting for age, race, and state of residence, breast cancer incidence was increased among non-exposed women whose husbands used captan (Rate Ratio (RR) =2.7, 95% CI: 1.7, 4.3) but rate ratios were inconsistent when analysed according to state of residence and menopausal status. Breast cancer incidence was not increased among wives that also used captan (RR = 0.5, 95% CI: 0.2, 1.2). In general, the reported findings do not provide definitive evidence

of a relationship between captan exposure and breast cancer incidence among wives of pesticide applicators. There was no evidence in the toxicological assays to support an increase in mammary tumours related to captan exposure.

Multiple Myeloma

A case-control study was conducted of men residing in six Canadian provinces to explore associations between pesticide exposure and four different types of cancer; this paper focussed on multiple myeloma (PMRA # 2533855). A total of 342 multiple myeloma cases diagnosed between 1991 and 1994 from provincial cancer registries or hospital records were included along with 1506 frequency age-matched controls. Information on pesticides used was obtained from all participants via a postal questionnaire. Phone interviews were conducted with subjects reporting ≥ 10 hours/year of pesticide use as well as with a subset (15%) of subjects randomly selected from the remaining sample. After adjusting for age, province of residence, use of a proxy respondent, personal and family medical history and smoking history, individuals exposed to captan had a significantly increased risk of multiple myeloma (OR = 2.96, 95% CI:1.40, 6.24). When analyzed by frequency of use, individuals with more days of exposure to captan (> 2 days) had a lower OR of 2.00 (95% CI: 0.60, 6.67) compared to the OR of 4.50 (95% CI: 1.60, 12.63) for individuals with exposure >0 and ≤ 2 days. The data were limited by the lack of an exposure response pattern, the small number of multiple myeloma cases with reported captan exposure (14) and the self-reported exposure information. The study authors acknowledged that it was possible that the observed associations were due to chance and noted that no similar association was observed between the highest level of captan exposure and cancer in the AHS. There was no evidence in the toxicological assays to support an increase in multiple myeloma as a result of captan exposure.

Prostate Cancer

A case-control study was conducted of 1153 men with prostate cancer drawn from the British Columbia Cancer registry for the years 1983 – 1990, and 3999 age-matched internal controls with cancer at other tissue sites (excluding lung cancer and cancers of unknown primary site) (PMRA # 2533061). Lifetime occupational history was obtained through a self-administered questionnaire and used in conjunction with a job exposure matrix to estimate cumulative exposure to various pesticides. After adjusting for education, smoking, alcohol consumption, ethnicity and use of a proxy respondent, a significant increased risk of prostate cancer (OR = 1.56. 95% CI: 1.12, 2.17) was reported for those exposed to captan. The 62 captan-exposed cases were split approximately in half representing a low and high exposure group. The high-exposure group had a non-significant lower OR of 1.39 (95% CI: 0.87, 2.22) compared to the significant OR of 1.76 (95% CI: 1.12, 2.78) for the low-exposure group. Limitations of the data included lack of familial history, misclassification of exposure due to the use of a job exposure matrix, the use of cancer controls and the potential for false positives given the number of multiple comparisons undertaken in the study. The authors noted that the findings were in contrast to those of the AHS which showed no excess of prostate cancer risk associated with captan. There was no evidence in the toxicological assays to support an increase in prostate cancer as a result of captan exposure.

Rhinitis

An analysis was undertaken of cross-sectional data on rhinitis over a 12-month period and pesticide use from 21,958 Iowa and North Carolina farmers enrolled in the Agricultural Health Study over 1993 – 1997 (PMRA # 2533864). Information on pesticide exposure (ever used, use during the past year, frequency of use, number of years used) and rhinitis symptoms were gathered via two self-administered questionnaires. ORs were adjusted for age, race, education, state of residence, body mass index, currently working on a farm, years mixing pesticides and other general farming variables and the number of episodes of rhinitis in the past year was characterized (1, 2, 3-6, 7-12 and 13+). Captan was reported to be significantly associated with increased number of rhinitis episodes (data not provided).The strongest association between captan use and rhinitis was noted for 7-12 episodes (OR = 1.32, 95% CI: 1.17, 1.49). Exposure-response was not assessed due to the small numbers of exposed individuals. Limitations of the study included self-reporting of rhinitis, inclusion of those with upper respiratory infections and inability to distinguish between allergic and non-allergic rhinitis. In a similarly designed study assessing 2245 Iowa commercial pesticide applicators in the AHS, no significant association was noted between captan use and rhinitis (PMRA # 2533863). Given captan's irritant properties on mucosal membranes, rhinitis is considered a biologically plausible observation.

Overall, the findings in the epidemiological studies were often limited by small numbers, self-reporting and/or lack of reproducibility. The lack of reliable characterization of exposure was considered an important weakness in most studies. Those studies that attempted to address exposure by characterizing frequency of use failed to demonstrate an exposure-response relationship. Furthermore, most of the reported associations lacked biological plausibility. In conclusion, the available epidemiology data for captan did not further inform the current risk assessment.

Pest Control Products Act Hazard Consideration

For assessing risks from potential residues in food or from products used in or around homes and schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, as well as potential pre-and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database, data available on captan included two reproductive toxicity studies in rats, and numerous developmental toxicity studies in hamsters, rats and rabbits.

With respect to potential pre- and post-natal toxicity of captan, sensitivity of the young was observed in the reproductive toxicity assays as evidenced by slightly greater decreases in body weight in the young when compared to the adult animals. Serious effects were noted throughout the database in the form of embryo-fetal loss, early post-natal death and malformations. Increased post-implantation loss was observed in hamsters, rabbits (3 of 4 studies) and monkeys, although these findings were typically observed at dose levels causing toxicity in the dams. Early

post-natal death was also observed in rats at levels that produced maternal toxicity. Low incidences of malformations were noted in hamsters and in one of two rat developmental toxicity studies. Malformations were also noted in the most recent two of four rabbit studies. No malformations were seen in the older two rabbit studies; however, limited animals at the highest dose tested may have reduced the power of these studies to detect low incidence findings. Malformations were noted in all species at maternally toxic levels. No malformations were noted in the rabbit developmental toxicity study with THPI but dosing may not have been conducted at sufficiently high levels.

Overall, the database is adequate for determining the sensitivity of the young. The fetal/pup effects (in other words, post-implantation loss, post-natal death and malformations) were considered serious endpoints although the concern was tempered by the presence of maternal toxicity. Therefore, the *Pest Control Products Act* factor was reduced to 3-fold for both acute- and repeat-exposure scenarios when using developmental toxicity endpoints to establish the point of departure for women of child bearing age. In exposure scenarios for children, the risk was considered well characterized and the *Pest Control Products Act* factor was reduced to 1-fold.

3.2 Dietary Exposure and Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet. Exposure to captan and its metabolites from potentially treated imported foods is also included in the assessment. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors).

For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The PMRA considers limiting use of a pesticide when risk exceeds 100% of the reference dose. The PMRA Science Policy Note SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide*, presents detailed acute, chronic and cancer risk assessment procedures.

Residue estimates used in the dietary risk assessment may be based conservatively (in other words, use upperbound estimates) on the maximum residue limits (MRLs) or the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency's (CFIA) National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program (USDA PDP). Specific and empirical processing factors as well as specific information regarding percent of crops treated may also be incorporated to the greatest extent possible.

In situations where the need to mitigate dietary exposure has been identified, the following options are considered. Dietary exposure from Canadian agricultural uses can be mitigated through changes in the use pattern. Revisions of the use pattern may include such actions as reducing the application rate or the number of seasonal applications, establishing longer pre-harvest intervals (PHIs), and/or removing uses from the label. In order to quantify the impact of such measures, new residue chemistry studies that reflect the revised use pattern would be required. These data would also be required in order to amend maximum MRLs to the appropriate level. Imported commodities that have been treated also contribute to the dietary exposure and are routinely considered in the risk assessment. The mitigation of dietary exposure that may arise from treated imports is generally achieved through the amendment or specification of MRLs.

Acute and chronic exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™, Version 2.14), which incorporates consumption data from the United States Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994 to 1996 and 1998. For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendices VI, VII, VIII and IX.

3.2.1 Determination of Acute Reference Dose

Acute Reference Dose (ARfD), Females 13-49 Years of Age

To estimate acute dietary risk (1 day), a NOAEL of 20 mg/kg bw/day from a rabbit developmental toxicity study with captan was selected for risk assessment. At an oral dose of 45 mg/kg bw/day, absent kidney and ureter were noted in fetuses in the presence of maternal toxicity as well as an increase in early resorptions. Increases in malformations of the forepaw and cranio-facial region were also noted in a second rabbit study with captan at doses of 30 mg/kg bw/day and greater in the presence of maternal toxicity. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed under the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* was reduced to 3-fold. The composite assessment factor is 300.

$$\text{ARfD} = \frac{20 \text{ mg/kg bw/day}}{300} = 0.07 \text{ mg/kg bw captan}$$

Acute Reference Dose (ARfD), General Population (Excluding Females 13-49 Years of Age)

An endpoint relevant for establishing an ARfD for the general population was not identified in the available database. Effects on food consumption and distention of the duodenal lumen were observed in mice following one day of exposure in a 28-day dietary study investigating duodenal histopathology; however, this study was deemed unacceptable for use in establishing an ARfD as only one dose (450 mg/kg bw/day) group was used in the study and examination was limited. Therefore, an acute dietary risk assessment for the general population is not required.

3.2.2 Acute Dietary Exposure and Risk Assessment

The acute dietary risk (from food and drinking water) was calculated considering the highest ingestion of captan that would be likely on any one day, and using food consumption and food residue values. The expected intake of residues is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, the acute dietary exposure is not of concern.

The probabilistic acute dietary exposure assessment was conducted for females aged 13-49 years. The assessment was performed by using combined residues of captan and its metabolite THPI expressed as captan. Most of the residue values were taken from available CFIA and PDP surveillance data. MRLs or U.S.Tolerances were used for commodities for which no surveillance data was available. In addition, the following inputs were used: available percent crop treated (%CT) information in Canada and in the United States; crops for which no %CT information was available were considered 100% treated; available information on the proportion of domestic production and import supply; DEEM default processing factors; and the drinking water estimated environmental concentration (EEC) for combined residues of the parent captan and the metabolite THPI from modelling (see Section 3.4 below for details). Most of the commodities in the PDP surveillance programs were measured for both captan and THPI. For commodities which were not measured for THPI, the THPI contribution to the residue was estimated by using a statistical approach based on a data correlation procedure (see Appendix VIII for details). CFIA residue monitoring data were reported as the combined residue of captan and the metabolite THPI.

The acute dietary exposure estimate (at the 99.9th percentile) for females aged 13-49 years is approximately 36% of the ARfD and is not of concern. An acute dietary risk assessment for other population groups is not required.

3.2.3 Determination of Acceptable Daily Intake

Acceptable Daily Intake (ADI), Females 13-49 Years of Age

To estimate the risk of repeated dietary exposure, a NOAEL of 20 mg/kg bw/day from a rabbit developmental toxicity study conducted with captan was selected for risk assessment. At a dose of 45 mg/kg bw/day, absent kidney and ureter were noted in fetuses in the presence of maternal toxicity along with increased post-implantation loss and skeletal variants. Increases in malformations of the forepaw and cranio-facial region, skeletal variants and post-implantation loss were also noted in a second rabbit study at doses of 30 mg/kg bw/day and greater in the presence of maternal toxicity. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed under the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* was reduced to 3-fold. The composite assessment factor is 300.

$$\text{ADI} = \frac{20 \text{ mg/kg bw/day}}{300} = 0.07 \text{ mg/kg bw/day captan}$$

Acceptable Daily Intake (ADI), General Population (Excluding Females 13-49 Years of Age)

To estimate the risk of repeated dietary exposure for the general population, two reproductive toxicity assays in rats were selected for risk assessment. A combined-study offspring NOAEL of 12.5 mg/kg bw/day was established, with decreases in body weight and body weight gain being observed in the young at the LOAEL of 25 mg/kg bw/day. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed under the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. The composite assessment factor is 100.

$$\text{ADI, general population} = \frac{12.5 \text{ mg/kg bw/day}}{100} = 0.13 \text{ mg/kg bw/day captan}$$

This ADI provides a margin of 460 to the NOAEL for pre-neoplastic lesions of the duodenum in mice. A non-genotoxic mode of action for gastrointestinal tumor formation was established which includes the formation of pre-neoplastic lesions as a result of GI tract irritation, with subsequent formation of tumors. The use of a threshold approach to risk assessment was therefore deemed appropriate. A reference dose established below dose levels causing pre-neoplastic lesions was considered protective of duodenal tumours. The selection of the ADI (general population and females 13-49 years of age) is considered to be protective of all sub-populations, including children and females 13-49 years of age.

3.2.4 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated by using the average consumption of different foods and the average residue values on those foods. This expected intake of residues was then compared to the ADI. When the expected intake of residues is less than the ADI, the chronic dietary exposure is not of concern.

Chronic dietary exposure (from food and drinking water) assessments were performed for all population subgroups by using average residues from the same CFIA and USDA PDP residue surveillance data used in the acute assessment; Canadian MRLs, American tolerances or Codex MRLs (whichever was greater) for all other commodities; average %CT in Canada and in the US, as well as import statistics when available; 100 %CT for all other commodities; and DEEM default processing factors. In addition, a chronic drinking water estimated environmental concentration (EEC) for combined residues of captan and THPI (from modelling) was used as a point estimate that was incorporated directly in the dietary assessment.

The chronic dietary exposure estimate for females aged 13-49 years is approximately 4% of the ADI. Exposure estimates for other population subgroups range from 2 to 8% of the ADI. Thus, chronic dietary exposure is not of concern for any of the population subgroups.

3.2.5 Cancer Assessment

Dietary administration of captan resulted in gastrointestinal tumors in mice. No treatment-related tumors were seen in rats. The tumors in mice arose via a non-genotoxic mode of action involving gastrointestinal irritation. Cancer risk (threshold) was addressed through the selected toxicology endpoints.

3.2.6 Dietary Cancer Exposure and Risk Assessment

A separate quantitative cancer assessment was not required (See Section 3.2.5).

3.3 Exposure from Drinking Water

Residues of captan and its metabolite tetrahydrophthalimide (THPI) in potential drinking water sources were estimated from modelling.

3.3.1 Concentrations in Drinking Water

EECs of combined residues of captan and its transformation product THPI in potential sources of drinking water were calculated using PRZM/EXAMS and LEACHM models for surface and groundwater, respectively. Level 2 (refined) modelling was carried out using typical rates for the uses on cherries and apples. The highest surface water reservoir daily peak EEC value of 0.141 ppm and groundwater yearly average EEC value of 0.082 ppm for combined residues of captan and THPI were used in the acute and the chronic dietary exposure assessments, respectively.

3.3.2 Drinking Water Exposure and Risk Assessment

Drinking water exposure estimates were combined with food exposure estimates, with EEC point estimates incorporated directly in the dietary (food + drinking water) assessments. Please refer to sections 3.2.2 and 3.2.4 for details.

3.4 Occupational and Non-Occupational Exposure and Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

3.4.1 Toxicology Endpoint Selection for Occupational and Non-Occupational Risk Assessment

Non-Dietary Oral Ingestion, Children (Short-term)

For short-term non-dietary oral risk assessment, two reproductive toxicity assays in rats were selected. A combined-study offspring NOAEL of 12.5 mg/kg bw/day was established on the basis of decreases in pup body weight and body weight gain at the LOAEL of 25 mg/kg bw/day. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed under the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. The target MOE is 100.

Short-term Dermal Risk Assessment, Children

For the short-term dermal risk assessment for children, two reproductive toxicity assays in rats were selected. Studies investigating dermal toxicity in the young were not available. A combined-study offspring NOAEL of 12.5 mg/kg bw/day was established, on the basis of decreases in pup body weight and body weight gain at the LOAEL of 25 mg/kg bw/day. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed under the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. The target MOE is 100.

Dermal Risk Assessment, All Durations, Adults

For short-, intermediate- and long-term dermal risk assessment, the NOAEL of 20 mg/kg bw/day for developmental toxicity was selected from a developmental toxicity study in rabbits conducted with captan. Although a repeat-dose dermal toxicity study was available, this study was not selected as it is not designed to address the endpoint of concern, namely developmental toxicity. Based on the collective results of the rabbit developmental toxicity studies, increases in malformations, post-implantation loss and skeletal variants were observed in the presence of maternal toxicity at doses of 30 mg/kg bw/day and above. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. For residential scenarios, as discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 3-fold, resulting in a target MOE of 300. For occupational scenarios, the target MOE was also 300 reflecting the use of an additional 3-fold factor to protect the unborn children of exposed female workers.

Short-term Inhalation Risk Assessment

For short-term inhalation risk assessment, the 21-day rat inhalation toxicity study NOAEC of 5.3 µg/L (equivalent to 1.4 mg/kg bw/day) was selected based upon irritative and degenerative effects on the respiratory tract including ulceration and necrosis of both the laryngeal and nasal epithelium at concentrations of 24.8 µg/L. The target MOE is 100, accounting for standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies

variability. As the endpoint of concern for this risk assessment was considered a portal of entry effect, the young were not expected to be more sensitive than the adult population. For the residential risk assessment, the *Pest Control Products Act* factor was reduced to 1-fold as discussed in the *Pest Control Products Act* Hazard Characterization section. This MOE is considered to be protective of all populations including nursing infants and the unborn children of exposed women.

Intermediate- and Long-Term Inhalation Risk Assessment

For intermediate- and long-term inhalation risk assessment, the 90-day rat inhalation study LOAEC of 0.13 µg/L (equivalent to 0.04 mg/kg bw/day) was selected based upon irritative and degenerative effects on the respiratory tract epithelium at and above this dose concentration. A NOAEC was not established in this study. The target MOE is 300 for intermediate-term exposure, accounting for standard uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and an additional 3-fold uncertainty factor for lack of a NOAEC. For the long-term exposure scenario, the target MOE is 1000 as an additional 3-fold uncertainty factor was applied to account for the potential for an increase in severity of irritative/degenerative response with prolonged exposure. As the endpoint of concern for this risk assessment was considered a portal of entry effect, the young were not expected to be more sensitive than the adult population. For the residential risk assessment, the *Pest Control Products Act* factor was reduced to 1-fold as discussed in the *Pest Control Products Act* Hazard Characterization section. This MOE is considered to be protective of all populations including nursing infants and the unborn children of exposed women.

Dermal Absorption

A dermal absorption value of 25% was chosen for the re-evaluation of captan based on the *in vivo* studies available in the literature as well as studies submitted to the PMRA.

3.4.2 Occupational Exposure and Risk Assessment

Workers can be exposed to captan through mixing, loading or applying the pesticide, and when entering a treated site to conduct activities such as scouting and/or handling treated crops or seeds.

Mixer, Loader and Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, and applicators. As per the supported uses, the following activities were assessed:

- Mixing/loading liquids;
- Mixing/loading wettable powders;
- Mixing/loading wettable granules;
- Airblast application to apple, apricot, cherry (sweet, sour), grape, nectarine, pear, peach, plum, prune, blackberry, blueberry, loganberry, raspberry;

- Groundboom application to field soil, field flowers, strawberry, raspberry, blackberry, blueberry, loganberry, cucumbers, pumpkin, squash, potato, field tomato, golf courses and sod farms;
- Aerial application to apple, apricot, cherry (sweet, sour), grape, nectarine, pear, peach, plum, prune, blueberry, strawberry, cucumber, potato, field tomato;
- Mixing/loading/applying by backpack to greenhouse soil, greenhouse flowers, greenhouse tobacco seedlings, rhubarb in forcing sheds, field soil, field flowers, strawberry, raspberry, blackberry, loganberry, blueberry, field tomato, golf courses and sod farms;
- Mixing/loading/applying by manually pressurized handwand to greenhouse soil, greenhouse flowers, greenhouse tobacco seedlings, rhubarb in forcing sheds, field soil, field flowers, strawberry, raspberry, blackberry, loganberry, blueberry, field tomato;
- Mixing/loading/applying by mechanically pressurized handgun to field soil, greenhouse soil, greenhouse flowers, and field flowers;
- Mixing/loading/applying by turf gun to golf courses and sod farms;
- Commercial slurry seed treatment for alfalfa, bean, broccoli, Brussels sprouts, cabbage, cauliflower, chickpea, clover, corn, lupin, lentil, pea, soybean, sugar beet;
- On-farm seed slurry treatment for bean, chickpea, corn, lentil, lupin, pea, soybean, sugar beet;
- On-farm dry hopper box seed treatment for bean, corn;
- Planting treated seeds;

Based on the number of applications and timing of application, workers applying captan would generally have a short-term (<30 days) duration of exposure. Custom applicators may have intermediate-term (up to several months) exposure for those crops with multiple applications. For workers in greenhouses, there is potential for intermediate-term (up to several months) duration of exposure.

The PMRA estimated handler exposure based on different levels of personal protective equipment (PPE):

- Baseline PPE: Long pants, long-sleeved shirt and chemical-resistant gloves (unless specified otherwise). For groundboom application, this scenario does not include gloves, as the data quality was better for non-gloved scenarios than gloved scenarios.
- Mid-Level PPE: Cotton coveralls over long pants, long-sleeved shirt, and chemical-resistant gloves.
- Engineering Controls: Represents the use of appropriate engineering controls, such as closed cab tractor or closed loading systems. Engineering controls are limited for handheld application methods.
- Chemical Resistant Headgear. Chemical resistant headgear that covers the neck (for example, Sou'Wester hat, rain hat).
- Respirator: a respirator with NIOSH approved organic-vapour removing cartridge

with a prefilter approved for pesticides.

- NIOSH approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. .

Chemical-specific exposure studies available in the literature and studies submitted to the Agency were considered in the risk assessment. However, due to study limitations or limitations with the study scenario, they were not used quantitatively in the risk assessment (in other words, refinements of exposure scenarios not possible). These studies did support the overall results of the risk assessment, which was based primarily on generic data. Biomonitoring studies were also available in the literature; however, these were not used quantitatively in the risk assessment due the lack of adequate characterization of the captan pharmacokinetics.

Dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database Version 1.1 (PHED), Agricultural Handlers Exposure Task Force (AHETF) and Outdoor Residential Exposure Task Force (ORETF) studies. The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of personal protective equipment (PPE). The open cab airblast scenario from AHETF was used in the risk assessment. The professional turf gun application scenario from ORETF was used in the risk assessment. While there are limitations in the use of generic data, these exposure data represent the most reliable information currently available. In most cases, PHED and AHETF did not contain appropriate data sets to estimate exposure to workers wearing coveralls, or a respirator. This was estimated by incorporating a 75% clothing protection factor for coveralls, an 80% protection factor for N95 filtering facepiece respirators (dust masks), and a 90% protection factor for a respirator (such as full and half-face air purificying and supplied air) into the unit exposure data.

Captan is registered for seed treatments. PHED scenarios were not considered to be representative of exposure to workers treating or handling seed. Surrogate commercial and on-farm seed treatment exposure studies, as well as exposure studies for planting treated seeds, were used to estimate worker exposure. These are the best data available for the assessment of worker exposure during the treatment of seeds. See Appendix IX, Table 19 for a description of these studies and unit exposure values used in this assessment. As these studies were conducted on a limited number of seed types, comparative dust-off data will be required (see Section 8.2.1.2 for more information).

For commercial bulb treatment and planting of treated bulbs and for commercial ornamental stem dip and planting of treated stems, adequate data to estimate exposure were not available. These uses are proposed for cancellation unless adequate data is submitted and an updated risk assessment supports the registrantion of this use.

For agricultural and turf uses, calculated MOEs exceeded target MOEs for mixing, loading, and application scenarios and are not of concern, provided engineering controls, personal protective equipment, and limitations on amount handled per day are used as summarized in Section 8.1.1.3 and Appendix XII.

MOEs did not reach the target MOE for intermediate-term inhalation exposure for custom applicators; however, this is expected to be addressed by mitigation proposed for the postapplication scenarios by reducing rates and/or the frequency of applications. Appendix IX, tables 1–5, summarizes the calculated MOEs for mixers/loaders and applicators.

For on-farm and commercial seed treatment, calculated MOEs exceeded target MOEs for most uses and are not of concern, provided engineering controls and PPE are used as summarized in Section 8.1.1.3 and Appendix XII. Appendix IX, tables 6–8, summarizes the calculated MOEs for commercial and on-farm seed treatment, as well as for planting treated seed. Target MOEs were not met and are of concern for on-farm dry hopper box treatment of wettable powder products for beans. To mitigate this risk, cancellation of this use on bean seeds is proposed .

Postapplication Worker Exposure and Risk Assessment

The postapplication occupational risk assessment considered exposures to workers entering treated sites to conduct agronomic activities involving contact with treated material (for example foliage, soil). Based on the captan use pattern, there is potential for short-term (<30 days) postapplication exposure to captan residues for workers. For greenhouse uses, there is potential for long-term (> 6 months) postapplication exposure.

Activity-specific transfer coefficients (TCs) from the Agricultural Re-entry Task Force (ARTF) were used to estimate postapplication exposure resulting from contact with treated turf and foliage at various times after application. A TC is a factor that relates worker exposure to dislodgeable residues. TCs are specific to a given crop and activity combination (for example, hand harvesting apples, scouting late season corn) and reflect standard clothing worn by adult workers. Postapplication exposure activities include (but are not limited to): scouting, weeding, and transplanting.

Dislodgeable foliar residue (DFR) and turf transferrable residues (TTR) refer to the amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant or turf. Chemical-specific DFR studies available in the literature and submitted to the PMRA were considered in the postapplication risk assessment. DFR for registered Canadian crops were calculated, where possible, using the study ‘peak DFR’ and predicted’ daily dissipation’ calculated from the linear equation of plotting the natural logarithm (ln) of DFR versus dissipation time (postapplication interval) following the final application. Estimated DFR values were adjusted proportionally for maximum Canadian application rates. As no TTR studies were available, default assumptions were used (peak TTR residue of 1% of the application rate with 10% dissipation per day). There were no DFR studies available for greenhouses, so the default peak residue of 25% was used. As the dissipation rate inside greenhouses is unknown, the dissipation of residues over time could not be estimated. The studies and values used to estimate dislodgeable foliar and turf transferable residues on registered Canadian crops are summarized in Appendix IX, Table 20.

Tetrahydrophthalimide (THPI) residues were considered in the risk assessment for postapplication exposure since this compound was measured in DFR studies. Exposure to the

thiophosgene metabolite was not considered to be relevant for dermal exposure, as it is not formed through these routes of exposure.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely enter after application. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures above the target MOE(> 300).

The PMRA is primarily concerned with the potential for dermal exposure for workers performing postapplication activities in crops treated with a foliar spray. Based on the vapour pressure of captan, inhalation exposure is not likely to be of concern provided that the minimum 12-hour REI is followed.

To achieve the target MOEs for postapplication workers in agricultural scenarios, most current REIs would need to be significantly increased in length. Calculated REIs ranged from 12 hours to 94 days for outdoor uses, which are agronomically unfeasible for some crops. For greenhouse uses, only rhubarb in forcing sheds and potted flowers had MOEs greater than the target MOE. To mitigate these risks, all greenhouse uses (except potted flowers, soil treatment, and rhubarb in forcing sheds) are proposed for cancellation. Table 9 in Appendix IX summarizes the postapplication exposure and risk assessment.

The proposed REIs are not considered to be agronomically feasible for some crops, for example, fruit trees (38-day REI), juice/wine grapes (70-day REI), and table grapes (94-day REI). Even with registrant proposed rates and the apple tank mix rate, REIs were not considered to be agronomically feasible for fruit trees (25-33 day REI). To mitigate the risks on crops with agronomically unfeasible REIs, these uses are proposed for cancellation (fruit trees, grapes, berries, field cut flower and some field vegetable crops). PMRA is aware that changes to the apple orchard architecture may potentially result in lower exposures. The extent of this change for all postapplication activities will be further evaluated after completion of the consultation process, which includes considering information that is provided during this process.

For pre-plant applications to soil, postapplication exposure was assessed using an approach outlined in the USEPA Risk Assessment Guidance for Superfund (RAGS) document for dermal exposure to soil. Calculated MOEs exceeded the target MOE and are not of concern. See Appendix IX, Table 10 for more information.

3.4.3 Non-Occupational Exposure and Risk Assessment

Non-occupational risk assessment involves estimating risks to the general population, including youths and children, during or after pesticide application.

The United States Environmental Protection Agency (USEPA) has generated standard default assumptions for developing residential exposure assessments for both applicator and postapplication exposures when chemical- and/or site-specific field data are limited. These assumptions may be used in the absence of, or as a supplement to, chemical- and/or site-specific data and generally result in high-end estimates of exposure. These assumptions are outlined in

the Standard Operating Procedures (SOPs) for Residential Pesticide Exposure Assessments (2012). The following sections from the Residential SOPs were used to assess residential exposure to captan:

- Section 3: Lawns and Turf
- Section 4: Gardens and Trees

Residential Handler Exposure and Risk Assessment

A residential applicator would be an adult who purchased a domestic-class captan product for outdoor residential use.

Residential applicators are assumed to be wearing shorts, short-sleeved shirts, shoes and socks. Based on label directions and survey information from ORETF, domestic-class captan products are assumed to be applied two times per year (with a seven-day interval); therefore they would have potential for short-term (1-30 days) exposure during application to fruit trees, berries, vegetables and outdoor ornamentals, as well as dust application to flower bulbs and soil. Domestic class products can be applied either as a dust or as a liquid when mixed with water.

Based on the typical use pattern, the major scenarios identified were:

- Mixing and loading wettable powder
- Plunger duster, bulb duster, shaker can, electric/power duster and hand crank duster (dust) application to gardens (berries, vegetables, flowers) and trees (fruit trees, ornamental trees and shrubs)
- Manually-pressurized handwand, backpack, hose-end sprayer, and sprinkler can (liquid) application to gardens (berries, vegetables, flowers) and trees (fruit trees, ornamental trees and shrubs)

Calculated dermal and inhalation MOEs for wettable powder formulation products applied as a liquid exceeded the target MOEs and are not of concern. Target MOEs were not met for wettable powder formulation products applied as a dust. To mitigate this risk, it is proposed that all label uses for dust application be removed from domestic class product labels. See Appendix IX, Table 11 for more information.

Residential Postapplication Exposure and Risk Assessment

Residential postapplication exposure refers to an exposure scenario in which an individual is exposed through dermal, inhalation, and/or incidental oral (non-dietary ingestion) routes as a result of being in a residential environment that has been previously treated with a pesticide. The area could have been treated by a residential applicator using a domestic-class product or a commercial applicator hired to treat the residential area.

There is potential for short-term exposure to adults, youth (11 to < 16 years old), and children (6 to < 11 years old) through contact with foliar residues following commercial applications of

captan to golf courses and residential fruit trees, as well as following domestic applications of captan to gardens (berries, vegetables, flowers) and trees (fruit trees, ornamental trees and shrubs). Adults, youth and children have the potential for postapplication dermal exposure.

The following scenarios were assessed for the postapplication exposure to captan:

- Lawns/Turf
  - Adult, youth, and children (6 <11 years old) dermal exposure resulting from golfing on treated turf
- Gardens and Trees
  - Adult, youth, and children (6 <11 years old) dermal exposure resulting from activities in gardens, on trees and indoor plants

The PMRA is primarily concerned with the potential for dermal exposure to these populations conducting postapplication activities in treated areas. Based on the vapour pressure of captan, inhalation exposure is not likely to be of concern.

Postapplication dermal exposure using activity-specific TCs was calculated using estimates for foliar or turf residue, leaf-to-skin or turf-to-skin residue transfer for individuals contacting treated foliage or turf during certain activities, and exposure time. A TC is a factor that relates exposure to dislodgeable foliar residues (DFR) or turf transferrable residues (TTR). It is the amount of treated surface that a person contacts while performing activities in a given period (usually expressed in units of cm^2 per hour) and is specific to a particular population.

For the residential postapplication assessment of captan, transfer coefficients were derived in the Residential SOPs for activities conducted on gardens and trees, as well as while golfing. Chemical-specific DFR studies were used to calculate foliar residues for gardens and trees, while default assumptions were used for estimating residues on turf as no chemical-specific TTR studies were available (1% of the application rate).

Calculated dermal MOEs for residential postapplication exposure to captan exceed the target MOE for golfers and some residential scenarios (wettable powder applied as a liquid to fruit trees, ornamental trees and shrubs) and are therefore not of concern. Calculated MOEs for residential postapplication exposure to captan in gardens (berries, vegetables, and flowers) were below the target MOE. To mitigate these risks, it is proposed that all uses on berries, vegetables, and gardens be removed from the domestic class product labels. See Appendix X, Table 13 for more information.

Postapplication exposure following application of captan dust formulations to soil (flower beds) was assessed using an approach outlined in the USEPA Risk Assessment Guidance for Superfund (RAGS) document for dermal exposure to soil. Calculated MOEs exceeded the target MOE and are not of concern. See Appendix IX, Table 12 for more information.

Adequate data were not available to estimate postapplication exposure from handling flower bulbs treated with domestic-class dust formulations of captan. However as residential application to bulbs is proposed for cancellation, this exposure scenario is not considered further.

There is also potential postapplication exposure to homeowners who may purchase and plant commercially-treated bulbs and seed. As commercial treatment to bulbs is proposed for cancellation, this exposure scenario is not considered further.

Exposure to homeowners who apply captan and conduct postapplication activities in treated areas or with treated plants or soil on the same day, along with potential dietary exposure, are considered in Section 3.5 – Aggregate Exposure and Risk Assessment.

Bystander Exposure

Captan residues were detected in the air in Canadian agricultural settings in BC and Quebec during the spray season in 2004. Based on the current use pattern of captan, potential bystander exposure was assumed to be of intermediate-term duration (in other words, several months). The peak air concentration was used to estimate exposure, thus resulting in conservative (upper bound) exposure estimates. THPI was not measured in these studies but would not be expected to be present in the air in significant quantities, based on occupational postapplication air monitoring studies. As noted in Appendix IX, Table 14, MOEs were greater than the target MOE for all subpopulations and are not of concern.

3.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation). Risk estimates were performed for those scenarios where the individual exposure routes met the target MOEs and were not of concern. The likelihood of co-occurrence was considered prior to aggregation of these scenarios.

3.5.1 Toxicology Endpoint Selection for Aggregate Risk Assessment

Aggregate exposure to captan may be comprised of food, drinking water and residential exposures. The irritative properties, as observed by the gastrointestinal and respiratory lesions, are believed to be due to the dissociation and formation of thiophosgene as a site-specific reaction and therefore are not relevant to an aggregate exposure risk assessment.

For females 13-49 years of age, the relevant endpoint for aggregate assessment is developmental toxicity. This endpoint is applicable to all routes of exposure for all durations. The two most recent rabbit developmental toxicity studies conducted with captan were selected in which doses of 30 mg/kg bw/day and greater resulted in an increased incidence of malformations, post-implantation loss and skeletal variants in the presence of maternal toxicity. A combined-study NOAEL of 20 mg/kg bw/day was established. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act*

factor was reduced to 3-fold resulting in a target MOE of 300. This MOE is considered to be protective of pregnant women and their unborn children.

For the general population (including children, but excluding females 13-49 years of age), the most relevant endpoint for aggregate assessment is decreased body weight and body weight gain in pups from the rat reproductive toxicity studies. A combined NOAEL of 12.5 mg/kg bw/day was established with effects being observed in the young at the LOAEL of 25 mg/kg bw/day. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor has been reduced to 1-fold. The target MOE is 100.

For all adult and youth aggregate assessments, only the female 13-49 years of age endpoint was considered, as it represents the worst case scenario for these sub-populations.

3.5.2 Aggregate Exposure and Risk Assessment

Residential Exposure

The dermal and inhalation exposures from use of captan in residential and recreational areas were assumed to co-occur with background (chronic) dietary (food and drinking water) exposure for adults, youth, children (6<11 years old), and toddlers (6<12 months old). Homeowner applicator exposure is considered likely to co-occur with postapplication exposure on residential fruit trees and ornamental trees and shrubs treated with the same domestic-class formulation.

As noted in Appendix IX, tables 15 and 16, aggregate (residential application and postapplication exposure plus exposure from food and drinking water) MOEs exceeded the target MOE for all scenarios and sub-populations, except for domestic class products at the high label rate (2 g a.i./L) on fruit trees and ornamental trees and shrubs. To mitigate risks, it is proposed that this rate be removed from the domestic class product labels for fruit trees and ornamental trees and shrubs.

Bystander Exposure

To calculate intermediate-term aggregate exposure to captan for potential inhalation exposure following application to agricultural areas, inhalation exposure was considered likely to co-occur with background (chronic) dietary (food and drinking water) exposure for adults, youth, and infants (6<12 months old).

As noted in Table 17, Appendix IX, aggregate MOEs exceeded the target MOE for all scenarios and are not of concern.

3.6 Cumulative Risk Assessment

The Pest Control Products Act requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. The metabolism of captan in plants and animals produces thiophosgene (SCCl2), a highly reactive, short-lived intermediate.

Thiophosgene is likely responsible for the sustained duodenal irritation that progresses to the development of duodenal tumors. As the thiophosgene metabolite is common to both captan and the closely related chemical folpet, cumulative risk from captan and folpet will be assessed concomitantly with the folpet risk assessment.

3.7 Incident Reports Related to Human Health

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA, including adverse effects to Canadian health or the environment. Incident reports involving the active ingredient captan were reviewed.

As of 14 August 2015, the PMRA has received reports of five human incidents and four domestic animal incidents that involved a pest control product with the active ingredient captan. In one of the human incidents, an individual experienced dermal symptoms after spilling the concentrate on themselves. In another incident, several workers developed a rash after picking strawberries that had been sprayed with a captan product. In a third human incident, more than one individual experienced mild respiratory irritation after a nearby field was sprayed with a captan product. In two of the domestic animal incidents, dogs were reported to have experienced gastrointestinal symptoms following accidental ingestion of the product. In the four other incidents (involving two humans and two dogs), either exposure to the pesticide was unlikely to have occurred, or there was insufficient information provided in the report to evaluate the incidents.

The incident report data were incorporated into the re-evaluation of captan.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Available fate and physical chemistry data indicate that captan is rapidly broken down in terrestrial and aquatic environments and is unlikely to persist (Appendix X, tables 1–3). Phototransformation and volatilization are not expected to be important routes of dissipation in terrestrial or aquatic systems. Hydrolysis is expected to be a major transformation route for captan in aquatic systems. The major transformation product, THPI, is more persistent and has potential to leach to groundwater. Captan is unlikely to bioaccumulate due to its relatively low K_{ow} and short environmental half-life.

Captan is transformed by microorganisms under both anaerobic and aerobic conditions in soil. In aerobic soils captan was found to have DT50 of 0.9 days which classifies captan as non-persistent. The major transformation products THPAm and THPI were formed and are slightly persistent with DT50s up to 22 days. In anaerobic soils captan is also non-persistent having a DT50 of less than7 days. Major transformation products identified in the anaerobic soil transformation study include THPAm, THPI, THCY and THPAL. Under anaerobic conditions, transformation products tend to accumulate over time and some appear to be stable.

An assessment of captan's leaching potential indicates that it is not expected to leach to groundwater. Captan does not appear to be mobile in soil based on soil column leaching studies and field dissipation studies. Captan satisfies only 3 of the criteria set out by Cohen et. al. (1984), therefore, there is a low potential for captan to leach in soils. The calculated Groundwater Ubiquity Score (GUS) for captan is 1.5-1.7, which classifies it as a non-leacher. Captan has certain properties that do not favor leaching (low solubility and short half life in soil and water) which also indicates it has a low potential to reach groundwater. Groundwater modeling outputs similarly predict no groundwater contamination by the parent. However, the transformation product THPI does have the potential to reach groundwater based on the available information. The GUS score for THPI is 2.2-4.1, classifying this transformation product as a borderline leacher to leacher. Soil column studies as well as soil adsorption studies indicate that THPI has very high mobility. Furthermore, a large percentage of the applied parent chemical (66%) is transformed to THPI in aerobic soils and groundwater modelling results show that captan residues such as THPI can reach ground water.

Captan may be carried away from the area of application through runoff. Limited data available from monitoring studies indicates that captan is detected in surface water infrequently and at low concentrations. Modeled surface water concentrations resulting from runoff vary widely by region and crop use.

No Canadian specific field dissipation studies are available, however, rapid dissipation is expected in terrestrial and aquatic systems based on the available laboratory fate data. Field dissipation studies conducted in the United States with similar conditions to Canada indicate that captan and THPI were detected only in the upper 7.6 cm of soil through the end of the studies. Captan was not detected after seven days following the last treatment. The DT50 for captan residues in these studies ranged from 3 to 4 days. According to the classification of Goring et al. (1975), captan would be non-persistent in the tested soils. No leaching was observed and the results are consistent with the soil thin layer chromatography studies, GUS, Cohen criteria and modelling scenarios.

In aquatic systems, aerobic biotransformation is the main route of transformation of captan (t1/2 < 1 d). The major transformation products observed were THPI with a DT50 ranging from 5 to 18 days and THPAm with a DT50 of 18 days, indicating that the two compounds ranged from slightly persistent to non-persistent. Captan is not expected to accumulate in sediments

A search for captan water monitoring data in Canada revealed that routine analysis for captan is not conducted and some samples were collected in areas of low use or where no use occurs. The rate of detections across provinces was generally low (0-10%) with the exception of one apple growing region in Quebec where stream water samples showed a detection frequency of 56.5%. Monitoring data for THPI was not available.

4.2 Risk to Non-Target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects to non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects

occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the transformation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted using uncertainty factors to account for potential differences in species sensitivity as well as varying protection goals (protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risk to Terrestrial Organisms

A risk assessment of captan to terrestrial organisms was based upon an evaluation of toxicity data on bees, earthworm, two standard test species of birds and small mammals, as well as terrestrial plants. A summary of terrestrial toxicity data for captan is presented in Appendix X, Table 6. For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with captan.

Invertebrates

The screening level risk assessment indicated that the levels of concern for terrestrial invertebrates such as bees, earthworms or beneficial insects were not exceeded at the maximum application rates. No data is available on chronic effects to bees such as hive/brood studies or other field studies, however, based on lack of toxicity from acute laboratory exposures and considering the mode of action of captan fungicide, chronic effects on pollinators such as bees are not expected. Appendix X, Table 6 summarise the risk quotients for terrestrial invertebrates.

Birds and Small Wild Mammals

Standard exposure scenarios on vegetation and other food sources based on correlations in Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher *et al.* (1994) were used to determine the concentration of pesticide (EEC) on various food items (on a dry weight basis) in the diet of birds and small wild mammals, and are expressed as an estimated daily exposure (EDE). Exposure is dependent on the body weight of the organism and the amount and type of food consumed. In the screening level assessment a set of generic body weights was used for birds (20, 100, 1000g) and small wild mammals (15, 35, 1000 g) to represent a range of bird and small wild mammal species. The screening level assessment uses relevant food categories for each size group consisting of 100% of a particular dietary item. These items include the most conservative residue values for plants, grains/seeds, insects, and fruits.

Birds and Mammals

Foliar application:

The avian and mammalian risk assessment is summarized in Appendix X, Table 7. Birds can be exposed to captan through the consumption of contaminated food (for example, seeds, insects, vegetation), as well as from drinking water and dermal contact, although in the present assessment only food sources are considered. From Table 7, there is apparent risk to both birds and mammals for most of the feeding guilds and size classes, as RQs generally exceed the LOC. This case applies to both on and off field and maximum and minimum residue exposure scenarios.

While potential risks have been identified based on the determination of risk quotients, they are in large part driven by the assumptions (i) that the maximum application rates as well as the maximum number of applications per season will be used and (ii) that adverse effects will occur at the exposure concentrations identified by toxicity tests.

It should be noted that the maximum rate used for cherries (5 × 7.2 kg a.i./ha) represent a conservative exposure scenario as a more likely application scenario involves switching to fungicides having other modes of action for resistance management. Another relatively high exposure scenario would be the rate for apples and strawberries of 6 × 3.6 kg a.i./ha. Here too, resistance management initiatives would likely preclude 6 applications per year. This scenario results in a similar risk pattern but with lower RQs and less exceedances of the LOC.

It should also be noted that both the acute and dietary toxicity endpoints for both species of birds tested are greater than the highest dose tested. Therefore, although the calculated RQs based on these values indicate exceedances of the LOCs in many cases, these are based on the conservative assumption that the relevant effects endpoints are equal to the highest concentration tested. Reported acute RQs are best interpreted as "<" (less than) values. Thus, avian acute and dietary risk from actual use of captan in the field is not expected to be as high as the calculated RQs would suggest and acute risk to birds is not expected to be of concern. Similarly in the case of small mammals, the acute toxicity data showed no adverse effects at the highest dose tested,

and thus the acute risk to mammals is interpreted the same way as for birds. Acute risk to mammals is also not expected to be of concern.

The reproductive risk quotients also exceeded the level of concern for both birds and mammals. For birds, there were no adverse reproductive effects in laboratory studies up to the highest test concentration, (NOEL = 100 mg/kg dw). Because of this, the reproductive risk for birds is considered to be low. Conversely, there was a true adverse effect determined in the reproduction study with small mammals (NOEL = 100 mg/kg bw/d based on a reduction of pup weight). Given that the reproductive endpoint is based on an environmentally relevant effect, the exceedances of the LOC observed for mammals are of potential concern. As a result, a hazard label statement will be included on the label.

Seed treatment:

The risk assessment for seed treatments is presented in Appendix X, tables 8 and 9.

As was the case with foliar applications, acute risk quotients are based on toxicity data that are greater than the highest dose tested. Given the low acute toxicity of captan, acute risk for birds and mammals is considered to be low. The level of concern is also exceeded on a reproductive basis for smaller sizes of birds and mammals. Reproductive risk to birds is considered to be low given that no reproductive effects were observed in laboratory studies at the highest test level. Conversely, for small mammals, true reproductive effects were observed in laboratory studies. The actual risk of reproductive adverse effects in small mammals from the ingestion of treated seed is, however, considered to be low given that the reproductive risk quotient exceeds the LOC by a slight margin for smaller sizes of mammals and is below the level of concern for larger mammals and given the conservative exposure scenario used for the risk assessment (assumed that the diet is comprised exclusively of treated seeds). Although the level of concern is exceeded by a slight margin, it is possible that spilled seeds may be consumed in a large enough quantity to result in exposures exceeding the threshold level for toxicity and a precautionary label statement will be added to end-use products for seed treatment and treated seeds.

Terrestrial Plants

Non-target terrestrial vascular plants could be exposed to residues of captan as a result of spray drift from the site of application when products containing captan are used. The screening level risk assessment indicated that level of concern was exceeded for terrestrial plants depending on the type of application equipment being used. Risk quotients varied from < 0.24 using groundboom to < 2.9 for early season airblast application. As plant toxicity tests were only conducted up to an application rate of 9 kg ai./ha, the NOEC was greater than this rate as no effects were detected. However, captan is registered at rates up to 36 kg ai./ha, and the potential for adverse effects cannot be ruled out at rates above 9 kg a.i./ha. Therefore, the risk to plants was determined based on the assumption that NOEC = 9 kg a.i./ha. As such a buffer zone of 1m is required due to the slight exceedance of the LOC.

4.2.2 Effects on Aquatic Organisms

Risk to aquatic organisms is based on evaluation of toxicity data for captan on fourteen species (one invertebrate; seven fish; one macrophyte; four algae and one estuarine/marine species (diatom)). A summary of aquatic toxicity data for captan is presented in Appendix X, Table 4. For the assessment of risk, toxicity endpoints chosen from the most sensitive taxonomic groups were used as surrogates for the wide range of species that can be potentially exposed following treatment with captan (Appendix X, Table 10). For the screening level scenario, expected environmental concentrations were determined based on a direct overspray of an 80 cm deep body of water for fish and invertebrate assessments and a 15 cm depth was used to estimate risk to amphibians.

Captan is not expected to be persistent in aquatic systems near treated areas given that it has a half-life of less than 1 day, however, based on the high frequency and volume of use on some crops, repeated exposure of non-target aquatic organisms may result in chronic exposure.

The screening level assessment for aquatic organisms (see Appendix X, Table 10) indicates that the acute levels of concern were exceeded for freshwater fish, algae and amphibians but not for aquatic invertebrates or vascular plants. A species sensitivity distribution (SSD) was used for freshwater fish to determine the hazardous concentration to five percent of species (HC_5), which was used in the risk assessment. Chronic LOCs were also exceeded for aquatic invertebrates and fish. Similarly, the acute LOC was exceeded for marine fish, invertebrates and algae; no chronic data is available for these organisms.

Refined Aquatic Assessment

Runoff. For the refined aquatic assessment, estimated environmental concentrations (EECs) of captan from runoff into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. For the refined assessment, the water body consists of a 1 ha wetland with an average depth of 80 cm and a drainage area of 10 ha. A 15 cm deep seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level.

Two crop uses representing six standard regional scenarios were initially modelled to represent different regions of Canada. Several application dates between early April and late July were modelled. The EECs represent concentrations of pesticide resulting from runoff only; potential deposition from spray drift is not included. The highest EECs in the 80 cm water body and in the 15 cm water body of all selected runs of a given use pattern/regional scenario are reported in Appendix XI, tables 3-1 and 3-2.

Results of the risk assessment for runoff are presented in Appendix X, Table 10. For runoff EEC estimation, the use patterns for potatoes and peas were evaluated. Potato represents a high cumulative application crop, with lower individual application rates, while peas represent a crop with a single application per season, but with a higher application rate than potato. The modelling indicates that the potato foliar application use pattern produces the highest EECs in

surface runoff. The application rate on peas is representative of several other vegetable crops that are treated with captan. Additional PRZM/EXAMS modeling was done for peas to assess risks due to runoff from crops with higher single pre-plant application rates using a soil incorporated application method. This modeling used soil incorporation through a defined uniform distribution depth of 8 cm. The Tier II refined runoff EECs are presented in Table 3-3 of Appendix XI.

For use on potatoes, the LOC for acute effects was exceeded for amphibians (RQ = 28.8), freshwater fish (RQ = 5.4), algae (RQ = 1.4), marine invertebrates (RQ = 87) and marine algae (RQ = 1.6). Runoff EECs did not exceed chronic effects endpoints. For use on peas, the LOC for acute effects was exceeded for marine invertebrates only (RQ = 1.9).

Aquatic organisms, such as freshwater fish and especially marine bivalves such as the Eastern oyster may be at risk from exposure to captan in runoff. Label advisory statements will be required to inform users of conditions that may favour run-off (Appendix XII).

Spray Drift. The risk to aquatic organisms due to spray drift can also be assessed taking into consideration the percent deposition from different application methods (ground boom (6% drift), aerial application (23% drift) and orchard airblast (59-74% drift) based on a spray quality of *ASAE medium*) into an adjacent water body 1 m downwind from the site of application. The water body used for the spray drift refinement is the same as is used for the runoff refinement.

Appendix X, Table 11 summarizes the refined risk to aquatic organisms resulting from exposure to spray drift for ground boom and airblast applications of captan. From ground boom applications on potatoes, a typical application rate for many crops, the LOC is exceeded only for marine invertebrates (RQ = 5). For orchard airblast applications at the high rate of 5 × 7200 g a.i./ha the acute LOC is exceeded for all late and early season use scenarios, with RQs ranging up to 6.3-403 for marine fish and invertebrates, respectively. Mitigation in the form of buffer zones will be required (Appendix XII).

Incident Reports Related to the Environment

There are some listed incident reports for captan fungicide from the United States in the Ecological Incident Information System (EIIS) data base; there are no Canadian incident reports. Of the nine incident reports available, three are undetermined as to the identity of the chemical, five are reported as misuse (accidental exposure) and one is reported as a registered use of captan but the causative agent being unlikely to be captan. In the registered use report from North Carolina in 1991 it is stated that a bird kill was observed where captan was used as seed treatment on potatoes. However, the grower had also used aldicarb on his field, which was confirmed by soil sampling; the North Carolina Agriculture Department ruled the event a misuse. Given the very low acute toxicity to captan fungicide, it is not expected to have caused the bird kill in this event.

5.0 Value

5.1 Commercial Class Products

The PMRA solicits feedback on the availability, effectiveness and extent of use of pesticidal alternatives to captan and of production practices (for example, application timing) for the uses which have risk concerns that cannot be mitigated using currently proposed mitigation measures, or where risk assessments cannot be further refined due to a lack of adequate data.This information will allow the PMRA to refine sustainable pest management approaches for site and pest combinations with identified risk concerns.

For most of the large crops and commercially important diseases several alternative active ingredients are registered in Canada. Alternative active ingredients cited in the value section of this document are mainly taken from crop profiles developed for Agriculture and Agri-Food Canada, provincial authorities and other published literature. Crop profiles are documents that provide crop production and pest management information on a commodity basis. They are developed through an extensive consultative process and are reviewed by industry and provincial specialists. The PMRA has not commented on the availability, extent of use and viability of these alternatives. Furthermore, the PMRA has not searched all end use product labels for alternatives, does not endorse any of the options listed, and only some regulatory status changes since the date of publication of crop profile documents, such as voluntary discontinuation from registrants, have been incorporated in this document.

For some of the uses identified in crop profiles for which captan is registered, there are one or few other registered alternatives. Additionally, many of the listed alternative active ingredients are in the process of being re-evaluated by Health Canada such as chlorothalonil, ferbam, folpet, iprodione, mancozeb, metiram, myclobutanil, propiconazole, thiophanate-methyl and triforine.

5.1.1 Commercial Class Uses for Which Information on the Value of Captan is Sought

The PMRA solicits feedback on the availability, effectiveness and extent of use of pesticidal alternatives to captan and of pest management practices for uses that are identified as having risk concerns, or where risk assessments cannot be further refined due to a lack of adequate data. This information will allow the PMRA to refine sustainable pest management options for site and pest combinations with identified risk concerns.

The PMRA is also soliciting scientific information during the PRVD comment period to support product efficacy at lower than registered rates proposed by the registrants on 24 March 2014 (in other words, efficacy trials, use history, scientific rationales, published information) for apples, pears, strawberry, for mature plants of cucumber and tomatoes and ornamentals (dip application).

5.2 Domestic Class Products

All Domestic Class uses of captan are supported by the registrant and are listed in Appendix IIb. While the PMRA has no information about the extent of use of the captan Domestic Class products, there are risk concerns for all dust applications and liquid applications on berries, flowers and vegetables at the higher rate.

5.3 Value of Captan

5.3.1 Uses

Captan is an integral component of many pest management programs to slow down or prevent the development of pest resistance to higher resistance-risk fungicides. Currently, it is registered for use on field, greenhouse and orchard crops, greenhouse and outdoor ornamentals, and turf (golf courses and sod farms only) as a foliar treatment to control a number of major fungal diseases. These include apple scab on apples; downy mildew, Phomopsis cane and leaf spot on grapes; Botrytis blight and fruit rot on blueberry; Botrytis fruit rot on raspberry and strawberry; brown rot on sweet cherries; and many diseases of ornamentals including Botrytis flower blight, fungal leaf spot, damping-off and fungus root rot. Captan is also applied as a dip to cuttings, bulbs and corms of ornamentals, as a soil treatment of ornamentals and vegetables, and as a seed treatment at planting or before storage to control storage rot, soil-borne fungal diseases that cause seed rots, damping-off, seedling blights and root rot on some pulse, vegetable, grain, oilseed and specialty crops.

5.3.2 Apple scab

Apple scab (Venturia inaequalis) is the most serious fungal disease of apple and is a significant economic threat in all apple growing regions of Canada. Captan is widely-used fungicide for controlling apple scab due to its effectiveness and multi-site mode of action. Alternative multi-site mode of action fungicides are registered to control scab but they are also under re-evaluation (i.e mancozeb and metiram). The majority of the alternatives to captan have single-site mode of action. The need of captan is based on the need for different fungicides with single and multi-site mode of action, which are used at different times during the crop season to target various plant diseases and for resistance management. This is necessary as part of an Integrated Pest Management (IPM) program. Captan's broad spectrum of activity includes the simultaneous control of minor diseases as a result of spraying for apple scab, such as flyspeck and sooty blotch, thereby reducing the need for farmers to apply multiple costly sprays of different fungicides.

5.3.3 Botrytis blight and fruit rot of blueberry

In blueberries, Botrytis blight and fruit rot can be a serious problem (AAFC, 2008). Although, there are several end use products registered for these uses, captan with a multi-site mode of action, is important as a rotational partner with the other fungicides to control Botrytis blight and fruit rot and to manage fungicide resistance development.

5.3.4 Downy mildew, Phomopsis cane and leaf spot of grapes

Downy mildew (Plasmopara viticola), Phomopsis cane and leaf spot (Phomopsis viticola) are major diseases of grapes in Ontario, Quebec and Nova Scotia (AAFC, 2006a). Captan is important to Canada's IPM program in grapes as a protectant fungicide for downy mildew and Phomopsis cane and leaf spot. Downy mildew can cause economic loss due to direct fruit loss, uneven fruit maturity and reduced sugar content when foliar infections are severe (AAFC, 2006a). Growers rely on broad spectrum, inexpensive fungicides such as captan for the season long control of downy mildew and as a rotational partner with the other fungicides to help manage fungicide resistance development. Active ingredients registered on grapes for control of downy mildew include multi-site active ingredients copper, mancozeb and metiram as well as single-site active ingredients such as boscalid/pyraclosclostrobin, fosetyl-Al, fluopicolide, kresoxim-methyl and mandipropamid. Folpet is the only alternative to captan registered for Phomopsis cane and leaf spot in Canada.

5.3.5 Brown rot of sweet cherries

Brown rot is a major disease of sweet cherries in British Columbia and Ontario. There is no tolerance for brown rot infected fruit in the market. In addition to captan, other multi-site fungicides registered for this disease are chlorothalonil, ferbam and sulphur. Chlorothalonil and ferbam are under re-evaluation. Sulphur is not widely recommended because it causes skin irritation to fruit pickers and kills beneficial mites (AAFC 2006b). Single-site fungicides which are registered for this disease are boscalid and pyraclostrobin, fenbuconazole, fenhexamid, iprodione, myclobutanil, propiconazole and triforine . Triforine and iprodione are under Re-evaluation. Single site fungicides are at risk of developing resistance. Captan is particularly valuable in brown rot IPM programs designed to delay the development of fungicide resistance as it is alternated with resistance-prone single site fungicides so as to reduce the frequency of their use.

5.3.6 Botrytis fruit rot of raspberry and strawberry

Botrytis fruit rot is a major disease of raspberry and strawberry. Control of Botrytis fruit rot is a high priority for raspberry and strawberry production and resistance to this plant pathogen is already present to many of the other registered active ingredients. Since captan has a multi-site mode of action it is important as a protectant fungicide and also as a rotational partner with other fungicides to help manage fungicide resistance development.

5.3.7 Ornamentals

Ornamental horticulture represents the largest segment of horticultural production, representing over 40% of horticulture's $5.4 billion in annual farm gate receipts (COHA, 2009). In the floriculture industry there are few registered alternatives to captan for the control of diseases of greenhouse and field ornamentals. Many of the registered fungicides are specific for selected plants or flowers. Captan, being a broad spectrum fungicide having a multi-site mode of action, is an essential tool for maintaining the continued utility of many other fungicides with single-site mode of action, that are at risk of developing resistance. Resistance management through

fungicide rotation is particularly important for sites that have only a few registered alternative fungicides, particularly if they are at high risk to develop resistance.

5.3.8 Resistance management

Captan is effective as a broad spectrum contact fungicide that controls the target pathogens upon direct contact and can be used as a protectant fungicide. Captan has a multi-site mode of action; therefore, it is less susceptible to the development of resistance compared to fungicides with single-site mode of action. Resistance builds up through the survival and spread of initially rare mutant strains (Brent and Hollomon, 2007). Captan is used in rotation, or as a tank mix, with other fungicidal active ingredients thus it prolongs the effective life of single-site mode of action fungicides which are prone to the development of resistance to plant pathogens.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

During the review process, captan and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[4] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Captan does not meet Track 1 criteria, and is not considered a Track 1 substance. See Appendix X, Table 12 for comparison with Track 1 criteria.
- Captan is not expected to form any transformation products that meet all Track 1 criteria

The use of captan is not expected to result in the entry of TSMP Track-1 substances into the environment (Appendix X, Table 12).

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and*

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4 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

4 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

4 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New *Pest Control Products Act*.

4 DIR2006-02, *PMRA Formulants Policy*.

4 DIR2006-02, *PMRA Formulants Policy*

Contaminants of Health or Environmental Concern maintained in the *Canada Gazette*[5]. The list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including DIR99-03 and DIR2006-02[7], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Captan fungicide and its associated end use products contain carbon tetrachloride (as a micro-contaminant of the manufacturing process of captan), a known ozone depleting substance (ODS). The manufacturers/registrants of captan have indicated that current production techniques have decreased the amount of carbon tetrachloride to below the maximum acceptable level set out by the European Union (0.01%). The PMRA has reviewed available data and has determined that the levels of this contaminant are at acceptable levels.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02[8].

7.0 Summary

7.1 Human Health and Safety

7.1.1 Toxicology

The toxicology database submitted for captan was adequate to define the majority of toxic effects that may result from human exposure to captan. Captan is not expected to be genotoxic or carcinogenic under environmental conditions. Captan has the potential to cause irritation of the mucous membranes upon contact. The most sensitive endpoints for risk assessment included fetal loss and malformations. There was evidence that young animals were slightly more sensitive than adult animals to captan toxicity as demonstrated by reduced offspring body weight at a dose that was not toxic to the mothers. Inhalation exposure resulted in irritation and degenerative effects of the respiratory tract. The risk assessment protects against the effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

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5 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

6 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New Pest Control Products Act.

7 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.1.2 Dietary Risk from Food and Drinking Water

There were no dietary risk concerns from the acute and chronic dietary risk assessments (food and drinking water) for the general population and all population subgroups, including infants, children, youths, adults and seniors.

7.1.3 Non-Occupational Risk

Risks to residential applicators are not of concern, with the exception of domestic products applied as a dust. Residential postapplication risk is not of concern for golfers and liquid application to fruit trees and ornamental trees and shrubs.

To mitigate risks, it is proposed that all label uses for dust application and gardens (berries, vegetables, flowers) be removed from domestic class product labels.

Bystander exposure to captan is not of concern.

See Appendix IX, Table 18 for a summary of the proposed mitigation and data requirements for captan.

7.1.4 Occupational Risk

Risk estimates associated with mixing, loading and applying activities for agricultural label uses are not of concern for most uses, provided engineering controls, personal protective equipment, and additional mitigation measures as listed in Section 8.1.1.2 and Appendix XII are implemented.

Adequate data were not available to assess exposure from use of captan for commercial ornamental stem dips and commercial flower bulb dip. These uses are proposed for cancellation.

Worker risk estimates for commercial and on-farm seed treatment are not of concern for most crops, provided engineering controls and personal protective equipment as listed in Section 8.1.1.3 and Appendix XII are implemented. On-farm application of wettable powder formulated products as a dry hopper box treatment is of concern for beans and is proposed for cancellation.

Postapplication risks for workers were not of concern for some crops when the proposed mitigation measures are applied. However, a number of proposed REIs or reduction in the number of applications may not be considered agronomically feasible. All possible risk mitigation measures were considered. For those crop uses where MOEs did not reach the target or the REIs are agronomically unfeasible (most greenhouse uses, fruit trees, grapes, berries, some field vegetable crops, field cut flowers), cancellation is proposed. PMRA is aware that changes to the apple orchard architecture may potentially result in lower exposures. The extent of this change for all postapplication activities will be further evaluated after completion of the consultation process, which will include consideration of information that is provided during this process.

See Appendix IX, Table 18 for a summary of the proposed mitigation and data requirements for captan.

7.1.5 Aggregate Risk

Since exposure to captan can occur from residential uses, an aggregate risk assessment that also considers exposure from food and drinking water was conducted. Aggregate risk estimates were calculated for those scenarios where the individual exposure routes met the target MOEs and there is a likelihood of co-occurence of scenarios (ie. domestic class product application and postapplication exposure). The aggregate MOEs met the target MOE in all cases, except for the high label rate (2 g a.i./L) for application to fruit trees and ornamental trees and shrubs. Label directions are proposed to be modified to remove this rate from domestic class products. For all other uses, aggregate risk was not of concern.

7.2 Environmental Risk

The fungicide captan is not persistent in the envrionment, having a short half-life in soil and aquatic systems under aerobic conditions. Captan has low solubility in water and, based on lab/field studies and modelling, is not expected to leach into groundwater. Bioconcentration is unlikely to occur in non-target organisms due to the low K_{ow} value and very short environmental half-life.

The terrestrial risk assessment indicates that captan may pose a risk to small mammals and terrestrial plants, but is not expected to pose a risk to pollinators, beneficial insects and birds.

The aquatic risk assessment indicates that captan may pose a risk to freshwater fish, amphibians, algae, marine invertebrates and marine algae from exposure to runoff. Similarly, spray drift may pose a risk to amphibians, fish, alge and marine invertebrates.

Buffer zones and label statements are required to reduce exposure to terrestrial and aquatic organisms.

7.3 Value

Captan is widely used in Canada for use on field, greenhouse and orchard crops, greenhouse and outdoor ornamentals, and turf (golf courses and sod farms only) for the control of a broad range of major fungal diseases. Captan is particularly important for the control of apple scab of apples, Botrytis blight and fruit rot of blueberry, downy mildew, Phomopsis cane and leaf spot of grapes, brown rot of sweet cherries, botrytis fruit rot of raspberry and strawberry and many diseases of ornamentals.

Captan has a multi-site mode of action, thus it is an essential tool for maintaining the continued availability of many other fungicides with single-site mode of action that are at high risk of developing resistance. Other multi-site fungicides are registered for some of the crops but they are not necessarily as effective as captan against certain plant diseases.

Captan contributes to pest management and sustainability by playing an important role in resistance management when used in rotation, or as a tank mix, with many other fungicidal active ingredients on sites where resistance is known or that are at risk for it to develop.

8.0 Organisation for Economic Co-operation and Development Status of Captan

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups member countries and provides a forum in which governments can work together to share experiences and seek solutions to common problems.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member country to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Captan is currently acceptable for use in other OECD member countries, including the United States, Australia and European Union Member States. As of September 11th , 2015, no decision by an OECD member country to prohibit all uses of captan for health or environmental reasons has been identified.

9.0 Proposed Regulatory Decision

After a thorough re-evaluation of the fungicide captan, Health Canada's PMRA, under the authority of the *Pest Control Products Act,* is proposing continued registration of certain uses of captan with mitigation measures and removal of other uses based on risk associated with human health.

9.1 Proposed Regulatory Actions

9.1.1 Proposed Regulatory Action Related to Human Health

9.1.1.1 Uses Proposed for Cancellation

Due to risks of concern the following uses are proposed for cancellation: For these uses, mitigation measures were considered and were unable to sufficiently reduce the risks or were not considered to be agronomically feasible.

<u>Commercial Class Products:</u>

- Greenhouse uses (except soil treatment, rhubarb in forcing sheds, potted flowers)
- Tree fruits (apple, pear, cherry, plum, prune, peach, nectarine, apricot):
- Grapes;
- Pumpkin, squash (mature);

- Field tomato:
- Berries (strawberry, loganberry, blueberry, blackberry, raspberry)
- Field cut flowers;
- Ornamental stem dip and flower bulb dip;
- On-farm seed treatment use of wettable powder formulation products as a dry hopper box treatment on beans.

Domestic Class Products:

- All dust product uses;
- Fruit (blackberries, strawberries);
- Vegetables (cucumbers, peppers, tomatoes);
- Flowers;
- Outdoor ornamental trees and shrubs (rate of 2 g a.i./L);
- Fruit trees (apples, apricots, cherries) (rate of 2 g a.i./L).

9.1.1.2 Proposed Label Amendments

The following is a summary of the proposed label amendments for captan products. Refer to Appendix XII for specific label statements and details.

- Label amendments for the captan technical product labels under WARNINGS.
- Statements to distinguish and clarify greenhouse and non-greenhouse uses.
- Further precautionary statements and personal protective equipment for restricted-entry intervals and early entry.
- There may be potential for exposure to bystanders from drift following pesticide application to agricultural areas. In the interest of promoting best management practices and to minimize human exposure from spray drift or from spray residues resulting from drift, a label statement is proposed under Use Precautions.
- It is proposed that all captan products currently formulated as wettable powders or wettable granules be reformulated in water soluble packaging. Label language would need to be clarified to indicate directions for the use of water soluble packaging.
- Label directions for engineering controls and personal protective equipment in order to mitigate handler exposure to captan.
- Addition of restricted-entry intervals (REIs) and limits to numbers of applications in order to mitigate postapplication exposure to captan.
- Addition of a minimum rotational crop plantback interval.
- Addition of precautionary statements on domestic-class labels
- Removal of uses which the registration did not support for re-evaluation.

9.1.1.3 Residue Definition for Risk Assessment and Enforcement

The residue definition (RD) in all commodities is currently expressed as captan *per se* for both enforcement and dietary risk assessments. As a result of this re-evaluation, the RD in plant commodities is proposed to be defined as the sum of captan and the metabolite tetrahydrophthalimide (THPI) expressed as captan; the RD in animal commodities is proposed to be defined as the sum of captan and metabolites THPI, 3-OH THPI and 5-OH THPI expressed as captan, for enforcement and acute and chronic risk assessments.

The registrants submitted a position paper advocating for maintaining the residue definition for captan in plant commodities as captan *per se* for enforcement and risk assessment purposes. The registrant position is essentially based on their interpretation of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the European Union (EU) guidance documents on the definition of the residue with regard to captan. The PMRA noted that there is no objection concerning the proposed residue definition for captan in animal commodities. The PMRA had proposed and is maintaining the RD in plants as the sum of captan and THPI expressed as captan on the basis of the same principles put forth by the registrants and enumerated in JMPR, EU and the Organization for Economic Co-operation and Development (OECD) guidance documents on the definition of the residue.

9.1.1.4 Maximum Residue Limits for Captan in Food

A maximum residue limit (MRL) of 5 ppm has been specified for residues of captan (parent only) on apples, apricots, blueberries, cranberries, cherries, grapes, peaches/nectarines, pears, plums, raspberries, strawberries and tomatoes (see Appendix VII). This MRL was established on the basis of monitoring programs conducted in the early 1980s.

MRLs for pesticides in/on food are established by Health Canada's PMRA under the authority of the *Pest Control Products Act*. After the revocation of an MRL or where no specific MRL is specified for a pesticide under the *Pest Control Products Act*, Subsection B.15.002(1) of the Food and Drug Regulations applies. This requires that residues do not exceed 0.1 ppm, which is considered as a general MRL for enforcement purposes. Therefore, residues in/on all other crops appearing on the registered captan labels are regulated under the general MRL not to exceed 0.1 ppm for captan.

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to remove Canadian MRLs that are no longer supported. The registrants expressed their intent to support all current MRLs in a position paper submitted to the PMRA along with additional toxicology and residue data as well as a rationale for maintaining the current residue definition. The review of the additional toxicology did not change PMRA's position about the toxicology of the metabolites. Consequently, the PMRA is maintaining its position regarding the proposed change in RD and thus the Agency is proposing that the registrants file an *ad hoc* submission to amend the MRLs. Data requirements will be communicated as per the *ad hoc* submission.

A complete list of MRLs established in Canada can be found in the PMRA MRL database on the Pesticides and Pest Management section of the Health Canada website. The database is an online query application that allows users to search for established MRLs regulated under the *Pest Control Products Act*. For supplemental MRL information regarding the international situation and trade implications for captan, refer to Appendix VII.

9.1.2 Regulatory Action Related to Environment

Non-target aquatic organisms, small mammals, frogs and terrestrial plants, may be at risk from the use of captan. Mitigation in the form of label statements and buffer zones are required to protect terrestrial and aquatic systems (see Appendix XII).

9.2 Proposed Additional Data Requirements

9.2.1 Data Required for Continued Registration

9.2.1.1 Data requirements related to food residue chemistry

The following studies are required under Section 12 of the *Pest Control Products Act* for continued registration.

Given that the present dietary risk assessment was based on surveillance data, the following confirmatory data is required to determine the actual nature and magnitude of residues measured in these pesticide residue surveillance programs:

> Multiresidue analytical methodology evaluation: a laboratory study which quantifies the individual recovery efficiency for captan and its metabolites THPI, 3-OH THPI and 5-OH THPI by typical multiresidue methods used in food surveillance programs.

9.2.1.2 Data requirements related to occupational exposure assessment (seed treatment)

The following studies are required under Section 12 of the *Pest Control Products Act* to confirm assumptions for those uses proposed for continued registration:

Seed Treatment

There were no seed treatment exposure studies submitted for captan. As a result, surrogate exposure studies were used in the risk assessment.

There are limited data comparing the dust-off potential of the seed types registered for treatment with captan and the seeds treated in the surrogate exposure studies used to assess exposure. With seed treatment activities, there can be significant contact with seeds after they are treated and the amount of dust that comes off the seed can affect the degree to which a worker is exposed. Therefore, it is critical to determine whether the treated seeds in the exposure study have more or less dust-off potential than the captan treated seeds for which they are a surrogate.

If captan treated seeds produce less dust than the treated seeds in the study, then further data are not required. If captan treated seeds produce more dust than the treated seeds in the study, then further exposure studies may be required. If comparative dust-off data is not provided, exposure studies for treating each seed type with captan may be required.

- DACO 5.12 Laboratory dust-off data following seed cleaning and treating on the crops proposed for continued registration (alfalfa, beans, broccoli, Brussels sprouts, cabbage, cauliflower, clover, chickpea, corn, lentil, lupin, pea, soybean, sugar beet treated with captan), untreated canola, corn, and wheat, as well as the surrogate crops (wheat treated with Dividend (difenoconazole); wheat treated with Jockey (fluquinconazole and procloraz); wheat and corn treated with Gaucho (imidacloprid); wheat treated with Baytan (triadimenol); wheat treated with Austral Plus Net (fludioxonil, tefluthrin); corn and canola treated with Prosper (clothianidin, carbathiin, metalaxyl), Allegiance (metalaxyl) and Poncho (chlothianidin); and canola treated with Oftanol (isophenphos)).

- DACO 5.4 Mixer/Loader/Application - Passive dosimetry and/or monitoring data for workers treating seed in commercial and/or on-farm facilities may be required, depending on the results of the comparative dust-off study. Both captan and THPI residues should be considered.

Those crops for which estimates of amount of seed treated per day were not available (alfalfa, broccoli, Brussels sprouts, cabbage, cauliflower, clover, sugar beet), data are required to verify that the throughput values used in the exposure assessment do not underestimate the amount of seeds treated with captan in Canada.

- DACO 5.2 Use Description/Scenario. Information which fully describes the amount of seed treated per day in commercial facilities for alfalfa, broccoli, Brussels sprouts, cabbage, cauliflower, clover, sugar beet. The sources of information should be cited (for example, label, grower groups, surveys, custom applicators, agricultural experts and associations, databases).

There are currently no data available to assess exposure for workers treating small seed pelleted vegetable crops. Although this scenario was assessed using a commercial seed treatment study on wheat, it is unknown if it is representative of exposure as the treatment of small seed vegetable crops may be different from the process used to treat cereals. To support this use, detailed use description information and dust-off data are required. An exposure study may also be required.

- DACO 5.2 Use Description/Scenario. Information which fully describes the treatment of small seed vegetable crops with captan (broccoli, cabbage, cauliflower, Brussels sprouts, and sugar beet). Qualitative and quantitative information which will help characterize exposure should be included, these can be divided into the different activities in a commercial facility and should include estimates of amount of seed treated per day. The sources of information should also be included and cited (for example, label, grower groups, surveys, custom applicators, agricultural experts and associations, and databases).

- DACO 5.4 Mixer/Loader/Application - Passive dosimetry and/or monitoring data for workers treating and pelleting small seed vegetable crops may be required. Both captan and THPI residues should be considered.

  DACO 5.12 Laboratory dust-off data if the data submitted above under DACO 5.4 are conducted using a different seed type or formulation than the current label uses.

List of Abbreviations

a.i.	active ingredient
AAFC	Agriculture and Agri-Food Canada
AChE	acetylcholinesterase
ADI	acceptable daily intake
ARD	acute reference dose
ARfD	acute reference dose
atm	atmosphere
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BChE	brain acetylcholinesterase
BCPC	British Crop Protection Council
BUN	blood urea nitrogen
bw	body weight
Cal DPR	California Department of Pesticide Registration
CAS	chemical abstracts service
CFIA	Canadian Food Inspection Agency
ChE	cholinesterase
CI	confidence interval
cm	centimetre(s)
COHA	Canadian Ornamental Horticulture Alliance
CT	crop treated
DEEM®	Dietary Exposure Evaluation Model
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
DMI	demethylation inhibitors
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
DT_{75}	dissipation time 75% (the time required to observe a 75% decline in concentration)
DT_{90}	dissipation time 90% (the time required to observe a 90% decline in concentration)
DU	dust or powder
dw	dry weight
DWLOC	drinking water level of comparison
EBDC	ethylene bis(dithiocarbamate)
EC_{05}	effective concentration on 5% of the population
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
EChE	erythrocyte cholinesterase
EDE	estimated daily exposure
EEC	expected environmental concentration
EP	end-use Product
ER_{25}	effective rate on 25% of the population
ER_{50}	effective rate on 50% of the population
ETU	ethylene thiourea

EXAMS	Exposure Analysis Modeling System
F_0	parental generation
F_1	first filial generation
F_2	second filial generation
FC	food consumption
FIR	food ingestion rate
FOB	functional observational battery
FRAC	Fungicide Resistance Action Committee
g	gram(s)
GAP	good agricultural practice
GC-FPD	Gas Chromatography-Flame Photometric Detector
GC-MSD	Gas Chromatography-Mass Selective detector
GC-NPD	Gas Chromatography-Nitrogen Phosphorous Detector
ha	hectare(s)
Hct	hematocrit
HDT	highest dose tested
Hg	mercury
Hgb	hemoglobin
HPLC	high performance liquid chromatography
IPM	Integrated Pest Management
IRED	Interim Reregistration Eligibility Decision (USEPA Document)
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
JMPR	Joint WHO/FAO Meeting on Pesticide Residues
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
kg	kilogram(s)
K_{oc}	organic-carbon partition coefficient
K_{ow}	octanol–water partition coefficient
L	litre(s)
LADD	lifetime average daily dose
LC_{50}	lethal concentration to 50% (a concentration causing 50% mortality in the test population
LD_{50}	lethal dose to 50% (a dose causing 50% mortality in the test population)
LDT	lowest dose tested
LMA	locomotor activity
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOEC	lowest observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m	metre(s)
m^2	meter squared
m^3	metre(s) cubed
MA	motor activity
MBS	market basket survey
mg	milligram(s)
mL	millilitre(s)

mm	millimetre(s)
MMAD	mass median aerodynamic diameter
MoA	Mode of Action
MOE	margin of exposure
MRID	USEPA's Master Record Identifier number
MRL	Maximum residue limit
MS	mass spectrometry
MTD	maximum tolerated dose
N/A	not applicable
N/R	not required
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NRA	Australian National Registration Authority for Agricultural and Veterinary Chemicals
NTE	neuropathy target esterase
NTP	National Toxicology Program
OC	organic carbon content
OM	organic matter content
OP	organophosphate
OR	Odds Ratio
PCP	Pest Control Product
PChE	plasma cholinesterase
PDP	Pesticide Data Program (United States data)
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRZM	Pesticide Root Zone Model
PSI	pre-slaughter interval
Q_1^*	cancer potency factor
RBC	red blood cells
RED	Reregistration Eligibility Decision (USEPA Document)
REI	restricted-entry interval
RfD	reference dose
RSD	relative standard deviation
S9	mammalian metabolic activation system
$t_{1/2}$	half-life
T3	triiodothyronine
T4	thyroxine
TC	transfer coefficient
TGAI	Technical Grade Active Ingredient
TOCP	tri-*ortho*-cresylphosphate
TPM	triophanate-methyl
TRR	total radioactive residue

TSH	thyroid stimulating hormone
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
USC	Use-site Category
UV	ultraviolet
µg	micrograms
µm	micrometer
µg	micrograms
v/v	volume per volume dilution
↓ -	decreased
↑ -	increased
♂ -	males
♀ -	females
1/n	exponent for the Freundlich isotherm

Appendix I Captan Products Registered in Canada as of 24 March 2014 Excluding Discontinued Products or Products with a Submission for Discontinuation Based on PMRA's Electronic Pesticide Regulatory System (e-PRS) Database

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
4559	Commercial	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	CAPTAN 50-WP WETTABLE POWDER AGRICULTURAL FUNGICIDE	WETTABLE POWDER	Captan 50%
9582	Commercial	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	CAPTAN 80-WP WETTABLE POWDER FUNGICIDE	WETTABLE POWDER	Captan 80%
9922	Commercial	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	CAPTAN 4 FLOWABLE AGRICULTURAL FUNGICIDE	SUSPENSION	Captan 480 g / L
9986	Domestic	KING HOME & GARDEN INC.	KING FRUIT TREE & GARDEN SPRAY	DUST OR POWDER	Captan 10%; Carbaryl 10%; Malathion 5%
12028	Commercial	NORAC CONCEPTS INC.	AGROX FL	*SUSPENSION*	Captan 30%
14823	Commercial	MAKHTESHIM AGAN OF NORTH AMERICA INC.	CAPTAN 50W WETTABLE POWDER FUNGICIDE	WETTABLE POWDER	Captan 50%
14851	Domestic	KING HOME & GARDEN INC.	GARDAL ROSE, FLOWER, & EVERGREEN DUST	DUST OR POWDER	Captan 5%; Carbaryl 5%; Malathion 4%; Thiophanate-methyl 3%
14852	Domestic	SURE-GRO IP INC.	WILSON BULB & SOIL DUST	DUST OR POWDER	Captan 5%; Carbaryl 5%
18221	Technical	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	CAPTAN TECHNICAL FUNGICIDE	SOLID	Captan 88%
21107	Technical	MAKHTESHIM AGAN OF NORTH AMERICA INC.	CAPTAN TECHNICAL	DUST OR POWDER	Captan 95%
22819	Commercial	BAYER CROPSCIENCE INC.	CAPTAN 400 LIQUID SEED TREATMENT FUNGICIDE	SOLUTION	Captan 39.1%
23691	Commercial	MAKHTESHIM AGAN OF NORTH AMERICA INC.	CAPTAN 80 WDG WATER DISPERSIBLE GRANULE	WETTABLE GRANULES	Captan 80%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24613	Commercial	UNITED AGRI PRODUCTS CANADA INC.	SUPRA CAPTAN 80 WDG	WETTABLE GRANULES	Captan 80%
24684	Commercial	NORAC CONCEPTS INC.	AGROX FL (NON-DYED)	SUSPENSION	Captan 30%
26408	Commercial	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	MAESTRO 80 DF FUNGICIDE	WETTABLE GRANULES	Captan 80%
26987	Commercial	NORAC CONCEPTS INC.	CAPTION CT	WETTABLE POWDER	Captan 18%; Thiophanate-methyl 14%
27904	Technical	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	CAPTAN TECHNICAL 1	SOLID	Captan 95%
29963	Technical	SHARDA CROPCHEM LIMITED	SHARDA CAPTAN TECHNICAL	SOLID	Captan 95.2

Appendix IIa Commercial Class Uses of Captan Registered in Canada, Excluding Uses of Discontinued Products or Products with a Submission for Discontinuation as of 24 March 2014

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
Use-site Category 5: Greenhouse Food Crops								
Bean, celery, crucifer, eggplant, pea, pepper, tomato	Damping–off, fungus root rot	Wettable granules	Ground - soil treatment	85.0 g / 100 m^2 (8.5 kg / ha)	(8.5 kg / ha)	1	Not applicable	
		Wettable powder		106.25 g / 100 m^2 (10.6 kg / ha)	(10.6 kg / ha)			
Rhubarb - in forcing sheds	Gray-mold rot	Wettable powder	Ground -foliar	1.625 kg / 1000 L [50 - 100 L / ha] (0.1625 kg / ha)	(975.0 g / ha)	Not stated [6]	7	
		Wettable granules		1.6 kg / 1000 L of water [50 - 100 L / ha] (0.16 kg / ha)	(960.0 g / ha)			
	Leaf rot	Wettable granules		1.6 kg / 1000 L of water [1000 L / ha] (1.6 kg / ha)	[3.2 kg / ha]	Not stated [2]		
		Wettable powder		1.625 kg /1000 L of water [1000 L / ha] (1.625 kg / ha)	[3.25 kg / ha]			
Tobacco -seedling	*Pythium* damping-off	Wettable granules		124.8 g / 100 m^2 (12.48 kg / ha)	(24.96 kg / ha)	2	10	
		Wettable powder		125.0 g / 100 m^2 (12.5 kg / ha)	(25.0 kg / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
Use-site Category 6: Greenhouse Non-Food Crops[2] and Use-site Category 27: Ornamentals Outdoors								
Aster	Flower blight *Botrytis*	Wettable powder	Ground - foliar	1.0 kg / 1000 L of water (1.0 kg / ha)	(5.0 kg / ha)	Not stated [5 Typical]	7	24 March 2014 registrant provided revised supported use pattern for these crops[3].
		Wettable granules						
Camellia	Petal blight	Wettable powder		1.0 kg / 1000 L of water (1.0 kg / ha)	(5.0 kg / ha)			
		Wettable granules						
Carnation	Blight, leaf spot	Wettable powder		1.25 kg / 1000 L of water (1.25 kg / ha)	(6.25 kg / ha)			
		Wettable granules		1.2 kg / 1000 L of water (1.2 kg / ha)	(6.0 kg / ha)			
Chrysanthemum	Flower blight (*Botrytis*), *Septoria* leaf spot	Wettable powder		1.25 kg / 1000 L of water (1.25 kg / ha)	(6.25 kg / ha)			
		Wettable granules		1.2 kg / 1000 L of water (1.2 kg / ha)	(6.0 kg / ha)			
Dahlia, lilac, tulip	Flower blight (*Botrytis*)	Wettable powder		1.0 kg / 1000 L of water (1.0 kg / ha)	(5.0 kg / ha)			
		Wettable granules						
Ornamentals	Damping-off, root rot	Wettable powder	Ground - soil treatment	112.5 g / 100 m^2 (11.25 kg / ha)	(11.25 kg / ha)	1	Not applicable	
		Wettable granules		112.8 g / 100 m^2 (11.28 kg / ha)	(11.28 kg / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
Rose	Black spot	Wettable granules	Ground - foliar	1.2 kg / 1000 L of water (1.2 kg / ha)	(6.0 kg / ha)	Not stated [5 Typical]	7	24 March 2014 registrant provided revised supported use pattern for this crop[4].
		Wettable powder		1.25 kg / 1000 L of water (1.25 kg / ha)	(6.25 kg / ha)			
	Flower blight (*Botrytis)*	Wettable granules		1.0 kg / 1000 L of water (1.0 kg / ha)	(5.0 kg / ha)			
		Wettable powder						
	Damping-off, root rot	Wettable powder	Ground - soil treatment	112.5 g / 100 m^2 (11.25 kg / ha)	(11.25 kg / ha)	1	Not applicable	
		Wettable granules		112.8 g / 100 m^2 (11.28 kg / ha)	(11.28 kg / ha)			
Roses and other flowers, shrubs, trees - seedlings or transplants	Damping–off, fungus root rot	Wettable granules		85.0 g / 100 m^2 (8.5 kg / ha)	(8.5 kg / ha)			
		Wettable powder		106.25 g / 100 m^2 (10.6 kg / ha)	(10.6 kg / ha)			
Use-site Category 10: Seed Treatment Food and Feed								
Alfalfa	Storage rot, seed borne, and soil borne fungal seed decay, damping-off, seedling blights	Solution	Slurry treater equipment	260.0 g / 100 kg (33.8 g / ha)	(33.8 g / ha)	1	Not applicable	

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
Bean				99.705 g /100 kg seed (100.0 g / ha)	(100.0 g / ha)			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum snap bean seeding rate is 100 kg / ha. Maximum dry bean seeding rate is 83 kg / ha).
Beans - dry common *Phaseolus vulgaris*	Seedling blight, root rot, seed-borne *Anthracnose*	Wettable powder	Hand mixing. Mix with a paddle or stick.	23.4 g / 25 kg (77.69 g / ha)	(77.69 g / ha)			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum dry bean seeding rate is 83.0 kg/ha)
			Slurry treater equipment	93.6 g / 100 kg seed (77.69 g / ha)				

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
Beans - field, snap, dry, lima, runner, wax, kidney, teparary, adzuki, moth, mung, rice, urd, guar, yardlong, faba, jackbean, hyacinth, sword, asparagus bean, catjang, Chinese longbean, blackeyed bean, cowpea, crowder pea, southern pea	Storage rot, seed decay, root rot, damping-off, seedling blights after planting	Suspension		25.2 g / 25 kg (100.8 g /ha)	100.8 g/ha			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum dry bean seeding rate is 83.0 kg/ha)
Broccoli, Brussels sprouts, cabbage, cauliflower		Solution		52.785 g / 100 kg seed) (0.185 g / ha)	(0.185 g / ha)			
Chickpea		Suspension		23.52 g / 25 kg of seed (145.82 g / ha)	(145.82 g / ha)			
Clover		Solution		260.0 g / 100 kg of seed (28.6 g / ha)	(28.6 g / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
Corn	Storage rot, seed decay, root rot, damping-off, seedling blights after planting	Solution		119.255 g / 100 kg seed (34.46 g /ha)	(34.46 g/ha)			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum seeding rate for field corn 28.9 kg/ha and sweet corn 17.0 kg/ha)
Corn - field	Storage rot, seed decay, root rot, damping-off, seedling blights after planting	Suspension		18 g / 25 kg of seed (maximum seeding rate 28.9 kg / ha) (20.81 g / ha)	20.81 g / ha			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum seeding rate for field corn 28.9 kg/ha)
Corn - sweet				30.6 g / 25 kg of seed (maximum seeding rate 17.0 kg / ha) (20.81 g / ha)	20.81 g/ha			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum seeding rate for sweet corn 17.0 kg/ha)
	Seedling blight, root rot, seed-borne *Penicillium oxalicum, Penicillium spp.*	Wettable powder	Seed box treatment	22.5 g / 25 kg seed (15.3 g / ha)	15.3 g / ha			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum seeding rate for sweet corn 17.0 kg/ha)
Lentils	Storage rot, seed decay, root rot, damping-off, seedling blights after planting	Suspension	Slurry treater equipment	23.52 g / 25 kg of seed) (84.67 g / ha)	(84.67 g / ha)			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum seeding rate 90.0 kg/ha).
Lupin - grain, sweet, white, white sweet				23.52 g / 25 kg of seed (158.45 g / ha)	(158.45 g / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
Oat seed -destined for export only; planting in Canada prohibited				18.0 g / 25 kg of seed	(18.0 g / 25 kg of seed)			Use not supported by registrant.
Pea		Solution	Slurry treater equipment	74.29 - 99.705 / 100 kg seed (299.12 g / ha)	(299.12 g / ha)			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum seeding rate is 300.0 kg/ha)
		Suspension	Slurry treater equipment	25.2 g / 25 kg of seed (302.4 g / ha)	302.4 g / ha			
Peas - dwarf, edible, pod, English, field, garden, green, snow, sugar snap, pigeon				23.52 g / 25 kg of seed (282.24 g / ha)	282.24 g / ha			
Soybean	Storage rot, seed, soil borne fungal seed decay, seed rot, damping-off, seedling blights	Solution	Slurry treater equipment	99.705 g / 100 kg seed (108.7 g/ha)	108.7 g/ha			24 March 2014 registrant provided revised supported use pattern for this crop (Maximum seeding rate of 109.0 kg/ha).
		Suspension	Slurry treater equipment	25.2 g / 25 kg of seed (110.1 g/ha)	110.1 g/ha			
Sugar beets		Solution		220.915 g / 100 kg seed (4.95 g / ha)	(4.95 g / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
		Suspension		55.8 g / 25 kg of seed (5.0 g / ha)	(5.0 g / ha)			
Use-site Category 11: Seed Treatment Non-Food								
Azalea, carnation, chrysanthemum	Damping-off, rot	Wettable powder	Dip	4.8 g / L of water	4.8 g / L of water	1	Not applicable	
		Wettable granules						
	Stem rot of cuttings	Wettable powder		7.5 g / 10 L of water	7.5 g / 10 L of water			
		Wettable granules						
Begonia (tuberous), daffodil, dahlia, gladiolus, iris (bulbous), narcissus, tulip	Damping-off, bulb rots	Wettable granules		7.6 kg / 1000 L of water	7.6 kg / 1000 L of water			24 March 2014 registrant provided revised supported use pattern for these crops[5].
		Wettable powder						
Use-site Category 13 and 14: Terrestrial Feed Crops and Terrestrial Food Crops								
Apple	Bitter rot, black rot, Brooks spot, flyspeck, sooty blotch	Wettable granules	Aircraft or conventional ground equipment	3.0 kg / ha	(18.0 kg / ha)	Not stated [6]	Not stated [7]	24 March 2014 registrant provided revised supported use pattern for this crop[6].
		Wettable powder	Ground - foliar					
		Suspension		1.2 kg / 1000 L of water (3.6 kg / ha)	(21.6 kg / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
	Bulls-eye rot *Gloeosporium perennans*							
		Wettable granules	Aircraft or conventional ground equipment	3.0 kg / ha	(18.0 kg / ha)			
		Wettable powder	Ground - foliar					
	Primary scab infection							
		Wettable granules	Aircraft or conventional ground equipment					
		Suspension	Ground - foliar	1.2 kg / 1000 L of water (3.6 kg / ha)	(21.6 kg / ha)			
	Scab	Wettable powder		1.0 kg / 1000 L of water (3.0 kg / ha)	(18.0 kg / ha)			
		Wettable granules		0.96 kg / 1000 L of water (2.88 kg / ha)	(17.28 kg/ha)			
	Scab (low level in the orchard)	Wettable granules		0.48 kg / 1000 L of water (1.44 kg / ha)	(8.64 kg / ha)			
	Secondary scab infection	Suspension		0.6 kg / 1000 L of water (1.8 kg / ha)	(10.8 kg / ha)			
		Wettable granules	Aircraft or conventional ground equipment	1.52 kg / ha	(9.12 kg / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
		Wettable powder	Ground - foliar	1.5 kg/ha	(9.0 kg / ha)			
Pea	Damping–off, fungus root rot	Wettable granules	Ground - soil treatment	112.8 g / 100 m^2 (11.28 kg / ha)	(11.28 kg / ha)	1	Not applicable	
		Wettable powder		112.5 g / 100 m^2 (11.25 kg / ha)	(11.25 kg / ha)			
Potato	Early blight, late blight	Wettable granules	Aircraft or conventional ground equipment	3.0 kg / ha	21. 0 kg / ha [16.8 kg / ha][2]	7	Not stated [7]	
Turnip	Damping-off, root rot	Wettable powder	Ground -foliar	112.5 g / 100 m^2 or (11.25 kg / ha)	(11.25 kg / ha)	1	Not applicable	
		Wettable granules		112.8 g / 100 m^2 (11.28 kg / ha)	(11.28 kg / ha)			
Use-site Category 14: Terrestrial Food Crops								
Apricot	Brown rot -twig blight	Suspension	Ground - foliar	1.2 kg / 1000 L of water (3.6 kg / ha)	(10.8 kg / ha)	3	Not stated [7]	24 March 2014 registrant provided revised supported use pattern for this crop[7].
		Wettable granules	Aircraft or conventional ground equipment	3.6 kg / ha	(18.0 kg / ha)	Not stated [5]		
		Wettable powder	Ground - foliar	1.25 kg / 1000 L of water (3.75 kg / ha)	(18.75 kg / ha)			
Bean	Damping–off, fungus root rot	Wettable granules	Ground - soil treatment	85.0 g / 100 m^2 (8.5 kg / ha)	(8.5 kg / ha)	1	Not applicable	

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
		Wettable powder		106.25 g / 100 m^2 (10.6 kg / ha)	(10.6 kg / ha)			
Blackberry	Fruit rot	Wettable granules	Ground - foliar	1.8 kg / ha	(10.8 kg / ha)	Not stated [6]	7	24 March 2014 registrant provided revised supported use pattern for this crop[8].
		Wettable powder						
Blueberry	Fruit rot, mummy berry	Wettable powder						24 March 2014 registrant provided revised supported use pattern for this crop[9].
		Wettable granules	Aircraft or conventional ground equipment					
Broccoli, Brussels sprouts, cabbage, cauliflower	Damping-off, root rot	Wettable granules	Ground - soil treatment	112.8 g / 100 m^2 (11.28 kg / ha)	(11.28 kg / ha)	1	Not applicable	
		Wettable powder		112.5 g / 100 m^2 (11.25 kg / ha)	(11.25 kg / ha)			
Celery	Damping–off, fungus root rot	Wettable granules		85.0 g / 100 m^2 (8.5 kg / ha)	(8.5 kg / ha)			
		Wettable powder		106.25 g / 100 m^2 (10.6 kg / ha)	(10.6 kg / ha)			
Cherry – sour, sweet	Brown rot, leaf spot - shot hole	Wettable powder	Ground - foliar	1.25 kg / 1000 L of water (3.75 kg / ha)	(18.75 kg / ha)	Not stated [5]	Not stated [7]	24 March 2014 registrant provided revised supported use

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
		Suspension		2.4 kg / 1000 L of water (7.2 kg / ha)	(36.0 kg / ha)			pattern for this crop[10].
		Wettable granules	Aircraft or conventional ground equipment	3.6 kg / ha	(18.0 kg / ha)			
			Ground - foliar	1.2 kg /1000 L of water (3.6 kg / ha)				
Crucifers	Damping–off, fungus root rot	Wettable granules	Ground - soil treatment	85.0 g/ 100 m^2 (8.5 kg / ha)	(8.5 kg / ha)	1	Not applicable	
		Wettable powder		106.25 g / 100 m^2 (10.6 kg / ha)	(10.6 kg / ha)			
Cucumber	Anthracnose, scab	Wettable granules	Aircraft or conventional ground equipment	Mature plants = 3.4 kg / ha	(20.4 kg / ha)	Not stated [6]	5 [7]	24 March 2014 registrant provided revised supported use pattern for this crop[11].
		Wettable powder	Ground - foliar					
Eggplant, kale, rutabaga	Damping-off, fungus root rot	Wettable powder	Ground - soil treatment	112.5 g / 100 m^2 or (11.25 kg / ha)	(11.25 kg / ha)	1	Not applicable	
		Wettable granules		112.8 g / 100 m^2 (11.28 kg / ha)	(11.28 kg / ha)			
Grape	Black rot	Suspension	Ground - foliar	1.2 kg / 1000 L of water (1.2 kg / ha)	(6.0 kg / ha)	5	Not stated [7]	24 March 2014 registrant provided revised supported use

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
		Wettable granules	Aircraft or conventional ground equipment	2.8 kg / ha	(14.0 kg / ha)	Not stated [5]		pattern for this crop[12].
		Wettable powder	Ground - foliar					
	Dead arm -current season's infections	Wettable powder		1.625 kg / ha	(3.25 kg / ha)	2		
		Wettable granules	Aircraft or conventional ground equipment	1.6 kg / ha	(3.2 kg / ha)			
	Downy mildew	Wettable powder	Ground - foliar	2.8 kg / ha	(14. 0 kg / ha)	Not stated [5]		
		Wettable granules	Aircraft or conventional ground equipment					
Loganberry	Cane spot, fruit rot, leaf spot, spur blight	Wettable granules	Ground - foliar	1.8 kg / ha	(10.8 kg / ha)	Not stated [6]	7	24 March 2014 registrant provided revised supported use pattern for this crop[13].
		Wettable powder						
Nectarine	Brown rot, scab	Wettable granules	Aircraft or conventional ground equipment	3.6 kg / ha		Not stated [3 Typical]	Not stated [7]	24 March 2014 registrant provided revised supported use pattern for this crop[14].
Peach	Brown rot, scab	Wettable granules	Aircraft or conventional ground equipment	3.6 kg / ha	(18.0 kg / ha)	Not stated [5]	Not stated [7]	24 March 2014 registrant provided revised supported use pattern for this crop[15].

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
		Wettable powder	Ground - foliar	1.25 kg / 1000 L of water (3.75 kg / ha)	(18.75 kg / ha)			
		Suspension		1.2 kg / 1000 L (3.6 kg / ha)	(18.0 kg / ha)			
Pear	Scab	Wettable powder		3.0 kg/ha		Not stated [6]		24 March 2014 registrant provided revised supported use pattern for this crop[16.]
		Wettable granules	Aircraft or conventional ground equipment					
	Sooty blotch	Wettable granules					14 [7]	
		Wettable powder	Ground - foliar					
Pepper	Damping-off, fungus root rot	Wettable granules	Ground - soil treatment	112.8 g / 100 m^2 (11.28 kg / ha)	(11.28 kg / ha)	1	Not applicable	
		Wettable powder		112.5 g / 100 m^2 (11.25 kg / ha)	(11.25 kg / ha)			
Plum, prune	Black knot	Wettable granules	Aircraft or conventional ground equipment	1.2 kg / 1000 L of water (3.6 kg / ha)	(21.6 kg / ha)	Not stated [6]	Not stated [7]	24 March 2014 registrant provided revised supported use pattern for this crop[17.]
		Wettable powder	Ground - foliar	1.25 kg / 1000 L of water (3.75 kg / ha)	(22.5 kg / ha)			
	Brown rot	Wettable granules	Aircraft or conventional ground equipment	1.2 kg / 1000 L of water (3.6 kg / ha)	(21.6 kg / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
		Wettable powder	Ground - foliar	1.25 kg / 1000 L of water (3.75 kg / ha)	(22.5 kg / ha)			
		Suspension		1.2 kg / 1000 L of water (3.6 kg / ha)	(21.6 kg / ha)			
	Scab	Wettable granules		1.2 kg / 1000 L of water (3.6 kg / ha)				
Pumpkin	Anthracnose, scab	Wettable powder	Ground - foliar	Mature plant = 3.375 kg / ha	(Cannot calculate due to missing number of applications)	Not stated [Not provided]	5	
Raspberry	Fruit rot, spur blight	Wettable granules	Ground - foliar	2.0 kg / ha	(12.0 kg / ha)	Not stated [6]	Not stated [7]	24 March 2014 registrant provided revised supported use pattern for this crop[18.]
		Wettable powder						
Squash	Anthracnose, scab	Wettable powder	Ground - foliar	Mature plant = 3.375 kg / ha	(Cannot calculate due to missing number of applications)	Not stated [Not provided]	5	
Strawberry	*Botrytis* fruit rot	Suspension		3.6 kg/ha	(21.6 kg / ha)	Not stated [6]	7	24 March 2014 registrant provided revised supported use pattern for this crop[19.]
	Gray mold rot, leaf spot	Wettable granules	Aircraft or conventional ground equipment	3.4 kg / ha	(20.4 kg / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
		Wettable powder	Ground - foliar					
Tomato	Early blight, gray leaf spot, late blight	Wettable powder	Ground - foliar	2.0 kg / 1000 L of water (0.90 kg / ha)	(5.4 kg / ha)	Not stated [6]	7	24 March 2014 registrant provided revised supported use pattern for this crop[20].
		Wettable granules						
	Anthracnose, *Septoria* leaf rot	Wettable powder		3.4 kg / ha	(20.4 kg / ha)		5 [7]	
	Septoria leaf spot	Wettable powder						
		Wettable granules	Aircraft or conventional ground equipment					
	Damping-off, fungus root rot	Wettable granules	Ground - soil treatment	112.8 g / 100 m^2 (11.28 kg / ha)	(11.28 kg / ha)	1	Not applicable	
		Wettable powder		112.5 g / 100 m^2 or (11.25 kg / ha)	(11.25 kg / ha)			

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate (a.i. / ha)[1]		Maximum Number of Application per year [max. supported by the registrant][1]	Minimum Number of Days Between Applications [min. supported by registrant][1]	Comments
				Maximum Single	Maximum Cumulative			
Use-site Category 30: Turf								
Golf courses and sod farms only	Brown patch, damping-off, leaf spot, melting-out, root rot	Wettable powder	Ground - foliar	4.75 kg / ha	9.52 kg / ha	Not stated [2]	7 [10]	24 March 2014 registrant provided revised supported use pattern for this crop[21].
		Wettable granules		4.8 kg / ha	9.6 kg / ha			
Lawn seedbeds	Damping-off, fungus root rot	Wettable powder	Ground – soil treatment	106.25 g / 100 m^2	10.6 kg / ha	1	Not applicable	Not supported by the registrant.
		Wettable granules		85.0 g / 100 m^2	8.5 kg / ha			
Turf - ornamental, sports		Wettable powder		112.5 g / 100 m^2	11.25 kg / ha			Not supported by the registrant.

1. All information is derived from registered product labels, except for information provided by registrants which is indicated by [], and/or data calculated by PMRA which is indicated by ().
2. For ornamental uses that are silent with respect to greenhouse use, this use has been assumed to occur, and USC 6 has been included for these uses.
3. On ornamentals, the proposed typical active ingredient rate of 1.0 kg/ha is within the currently registered rate range of 0.96 - 1.2 kg a.i./1000L applied to foliage and the soil around the plants (assuming a spray volume of 1000L/ha). The Technical registrant supported 1 application.
4. On roses, the proposed typical active ingredient rate of 1.0 kg/ha is within the currently registered rate range of 0.96 - 1.2 kg a.i./1000L for foliar application (assuming a spray volume of 1000L/ha). The Technical registrant supported 1 application per year.
5. On begonia (tuberous), daffodil, dahlia, gladiolus, iris (bulbous), narcissus, tulip (before storage treatment), the proposed typical application rate of 4.8 g a.i./L is within the currently registered rate of 3.0-7.5 g a.i./L applied once before storage as a dip to control damping off and bulb rots. Since the proposed typical application rate of 4.8 g a.i. /L is significantly lower than the maximum application rate of 7.5 g a.i/L then efficacy of this proposed typical application rate is of concern as bulb rot can be caused by a number of pathogens and disease control at high pressure.
6. On apples, the proposed typical active ingredient rate of 2.4 kg/ha is lower than the currently registered foliar application rate range of 3.0 to 3.6 kg/ha. A tank mix rate range of 0.75 - 1.5 kg a.i. /ha is also registered. Since the proposed typical application rate of 2.4 kg a.i./ha is lower than the registered rate range, the efficacy of this rate is of concern. The Technical registrants support 4 applications per year.
7. On apricot, the proposed typical active ingredient rate of 3.2 kg/ha is within the registered foliar application rate range of 2.9 to 3.6 kg/ha to control brown rot. The Technical registrants support 2 applications per year.
8. On blackberries, the proposed typical active ingredient rate of 1.8 kg/ha is within the Canadian registered foliar application rate range 1.6-1.8 kg/ha. The Technical registrants support 2 applications per year.
9. On blueberries, the proposed typical active ingredient rate of 1.8 kg/ha is within the Canadian registered rate 1.6-1.8 kg/ha.
The Technical registrants support 2 applications per year.
10. On cherries, the proposed typical active ingredient rate of 3.2 kg/ha is within the registered foliar application rate range of 2.9 to 3.75 kg/ha to control brown rot and leaf spot. There is one product (a suspension) that had a rate range of 3.6 - 7.2 kg a.i./ha which was calculated by using a maximum water volume of 3000 L/ha. This spray volume is no longer considered suitable for today denser, size controlled plantings. The Technical registrants support 2 applications per year.

11. On cucumber, the proposed typical active ingredient rate of 2.8 kg/ha for foliar applications is higher than the rate range of 1.6 - 2.6 kg /ha for young plants and within the rate range for 2.5 - 3.4 kg /ha for mature plants. The proposed typical application rate will provide control for young plants. However, based on current labels, the maximum rate (3.4 kg a.i. /ha) is required to control severe infestations (under high disease pressure) on mature plants therefore the efficacy of the proposed rate is of concern.
12. On grapes, the proposed typical active ingredient rate is 2.4 kg/ha is within the currently registered foliar application rate range of 0.96 to 2.8 kg/ha to control downy mildew. The Technical registrants support 2 applications.
13. On loganberries, the proposed typical active ingredient rate of 1.8 kg/ha is within the Canadian registered rate foliar application rate range 1.1-1.8 kg/ha. The Technical registrants support 2 applications per year.
14. On nectarines, the proposed active ingredient rate of 3.2 kg/ha is within the currently registered foliar application rate range of 2.9 to 3.6 kg/ha to control brown rot, black knot and scab. The Technical registrants support 2 applications.
15. On peaches, the proposed typical active ingredient rate of 3.2 kg/ha is within the currently registered foliar application rate range of 2.9 to 3.75 kg/ha to control scab and brown rot. The Technical registrants support 2 applications per year.
16. On pears, the proposed typical active ingredient rate of 2.4 kg /ha is lower than the currently registered foliar application rate range of 2.88 to 3.0 kg /ha. Since the proposed typical application rate of 2.4 kg a.i./ha is lower than the registered rate range, the efficacy of this rate is of concern. The Technical registrants support 2 applications per year.
17. On plum the proposed typical active ingredient rate of 3.2 kg/ha is within the currently registered foliar application rate range of 2.9 to 3.75 kg/ha to control brown rot, black knot and scab. The Technical registrants support 2 applications per year. On prune, the proposed typical active ingredient rate of 3.2 kg/ha is within the currently registered foliar application rate range of 3.0 to 3.6 kg/ha to control brown rot, black knot and scab. The Technical registrants support 2 applications per year.
18. On raspberries, the proposed typical active ingredient rate of 2.0 kg/ha is the Canadian registered foliar application rate. The Technical registrants support 2 applications per year.
19. On strawberries, the proposed typical active ingredient rate of 2.8 kg. /ha is within the currently registered foliar application rate range (1.44 - 3.6 kg /ha). However, based on current labels, the maximum rate 3.6 kg a.i. /ha is required to control Botrytis fruit rot, gray mold rot and leaf spot under high disease pressure. Since the proposed typical application rate of 2.8 kg a.i. /ha is lower than the registered rate range, the efficacy of this rate is of concern under high pest pressure. The Technical registrants supported 2 applications per year.
20. On tomatoes, the proposed typical active ingredient rate of 2.4 kg /ha for foliar applications is within the currently registered rate range of 0.43 to 3.4 kg /ha. However, based on current labels, the maximum rate of 3.4 kg a.i./ha is required to control severe infestations (under high disease pressure) on mature plants therefore the efficacy of the proposed rate is of concern. The technical registrants supported 1 application per year.
21. On turf, the typical active ingredient rate of 4.72 kg/ha for BC and ON is within the currently registered application rate range of 4.25 to 4.8 kg/ha. The Technical registrants provided the typical number of applications/year (1 application).

Appendix IIb Domestic Class Uses of Captan Registered in Canada Excluding Discontinued Products as of 24 March 2014 with a Submission for Discontinuation – All Products Are Dusts or Powders and Contain Multiple Active Ingredients (Insecticide and Fungicide)

Sites	Pests	Application Methods and Equipment	Application rate (a.i. rate)		Maximum Number of Applications per Year	Typical Number of Days Between Applications	Registrant Supported Use?
			Maximum single	Maximum cumulative			
Use-site Category 6 and 27: Greenhouse Non-Food Crops and Outdoor Ornamentals							
Junipers	Blight	Dusting	Cannot calculate	Cannot calculate[1]	Not stated	7	Yes
Roses, flowers, ornamentals	Blackspot, powdery mildew						
Roses, evergreens, conifers, other ornamental flowers, shrubs	Aphids, mites, rose chafer, leafhoppers, sawfly, spruce budworm, tent caterpillars, leaf miners, other chewing insects						
Use-site Category 11: Seed Treatments Non-Food							
Iris, tulip, daffodil, narcissus, crocus bulbs, hyacinth bulbs, dahlia, begonia tubers, gladiolus corms	Damping-off, bulb rot, thrips (exposed)	Paper bag	0.75 g / kg bulbs	0.75 g / kg bulbs	1	Not applicable	Yes
Use-site Category 13: Terrestrial Feed Crops							
Apple	Most diseases and insects	Green Cross Dial-a-Sprayer	1.998 g / L of water	Cannot calculate[1]	Not stated	10	Yes
		Compressed air sprayer	1.0 g / L of water				
		Dusting	Cannot calculate				
Use-site Category 14: Terrestrial Food Crops							
Apples, apricots, blackberries, cherries, strawberries, cucumbers, peppers, tomatoes	Most diseases and insects	Green Cross Dial-a-Sprayer	1.998 g / L of water	Cannot calculate[1]	Not stated	10	Yes
		Compressed air sprayer	1.0 g / L of water				
		Dusting	Cannot calculate				

Sites	Pests	Application Methods and Equipment	Application rate (a.i. rate)		Maximum Number of Applications per Year	Typical Number of Days Between Applications	Registrant Supported Use?
			Maximum single	Maximum cumulative			
Use-site Category 27: Ornamentals Outdoor							
Ornamentals	Most diseases and insects	Green Cross Dial-a-Sprayer	1.998 g / L of water	Cannot calculate[1]	Not stated	10	Yes
		Compressed air sprayer	1.0 g / L of water				
		Dusting	Cannot calculate				
Iris, tulip, daffodil, narcissus, crocus bulbs, hyacinth bulbs, dahlia, begonia tubers, gladiolus corms	Damping-off, root rot, thrips (exposed)	Broadcast and work into the soil	5.0 g / 2 m^2 or 2.5 g / 8 m of row	5.0 g / 2 m^2 or 2.5 g / 8 m of row	1	Not applicable	Yes

[1] The maximum number of applications per year is not listed on any labels for this use; therefore the cumulative application rate per year could not be calculated.

Appendix III Toxicology Endpoints for Use in Health Risk Assessment for Captan

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary – general population	Not required		
Acute dietary – females 13-49 yrs	Developmental toxicity - rabbit	NOAEL = 20 mg/kg bw/day Malformations and early resorptions	300
	ARfD = 0.07 mg/kg bw		
Repeated dietary – general population	Reproductive toxicity - rat	NOAEL = 12.5 mg/kg bw/day ↓ pup body weight and body weight gain	100
	ADI = 0.13 mg/kg bw/day		
Repeated dietary – females 13-49 yrs	Developmental toxicity - rabbit	NOAEL = 20 mg/kg bw/day Malformations, variations and post-implantation loss	300
	ADI = 0.07 mg/kg bw/day		
Dermal, all durations – adult[2]	Developmental toxicity - rabbit	NOAEL = 20 mg/kg bw/day Malformations, variations and post-implantation loss	300
Short-term dermal – children[2]	Reproductive toxicity - rat	NOAEL = 12.5 mg/kg bw/day ↓ pup body weight and body weight gain	100
Short-term inhalation – all populations	21-day inhalation toxicity - rat	NOAEC = 5.3 µg/L (1.4 mg/kg bw/day) Degenerative changes to respiratory tract	100
Intermediate- and long-term inhalation – all populations	90-day inhalation toxicity - rat	LOAEC = 0.13 µg/L (0.04 mg/kg bw/day) Degenerative changes to respiratory tract	300 (intermediate-term) 1000 (long-term)
Non-dietary incidental oral	Reproductive toxicity - rat	NOAEL = 12.5 mg/kg bw/day ↓ pup body weight and body weight gain	100
Aggregate, all durations, all routes – females 13-49 yrs	Developmental toxicity - rabbit	NOAEL = 20 mg/kg bw Malformations, variations and post-implantation loss	300
Aggregate, all durations, all routes – general pop.[2]	Reproductive toxicity - rat	NOAEL = 12.5 mg/kg bw/day ↓ pup body weight and body weight gain	100
Cancer	Cancer risk (threshold) was addressed through the selected toxicology endpoints		

[1]CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary risk assessments; MOE refers to a target MOE for occupational and residential risk assessments

[2]Since an oral NOAEL was selected, a dermal absorption factor was used in a route-to-route extrapolation

Appendix IV Toxicological Information For Health Risk Assessment

Table 1 Toxicity Profile for Captan

NOTE: Effects noted below are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Effects on organ weights are known or assumed to reflect changes in absolute weight and relative (to bodyweight) weight unless otherwise noted.

Study Type/ Animal/ PMRA #	Study Results
Toxicokinetic Studies	
Rats (oral unless otherwise specified) PMRA # 1142421, 1142422, 1142423, 1163235, 1181462, 1217492, 1237376, 2066406	**Absorption:** Captan is readily absorbed by rats following acute or repeat gavage with comparable results following both regimes at doses of 10 mg/kg bw/day. At this dose, 77-84% of the administered compound was excreted within 24 hours suggesting a rapid rate of absorption. However, absorption appears to decrease at higher doses as manifested an increased reliance upon fecal excretion and a higher level of unchanged captan in the feces. This decrease in absorption of captan may be the result of the saturation of processes leading to gastrointestinal hydrolysis. ^{14}C-TMT radiolabel in feces ^{14}C-cyclohexene radiolabel in feces 14-22% @ 10 mg/kg bw (@96h) 8-9% @ 10 mg/kg bw (@48h) 22% @ 250 mg/kg bw (@96h) 12% @ 77-92 mg/kg bw (@96h) 33-40% @ 500 mg/kg bw (@96h) 23-25% @ 500 mg/kg bw (@96h) **Distribution:** Retention in the tissues and organs appears to be minimal with <2% detected in the tissues of dosed animals following 96 hours at both 10 and 500 mg/kg bw, regardless of the location of the radiolabel (TMT/cyclohexene). Tissues with the greatest accumulation of radiolabelled TMT moiety were the liver, kidneys and small intestine. Similarly, tissues with the greatest accumulation of radiolabelled THPI moiety (from the ^{14}C-cyclohexene label) were the kidney, intestines, gonads and blood. Tissue distribution of single and multiple intraperitoneal doses of ^{35}S- captan were similar in normal and hepatectomized ♂ rats. **Metabolism:** Studies suggest that captan is stable until reaching the alkaline regions of the duodenum at which point hydrolysis of the N-S bond occurs, yielding THPI and thiophosgene which follow separate metabolic pathways. The first pathway includes the phthalimide-based structures, beginning with THPI which undergoes hydroxylation and epoxide formation. The second pathway begins with the removal of a thiol group from thiocarbonyl chloride to yield thiophosgene. Thiophosgene either hydrolyzes to form carbon dioxide or is conjugated by thiols to form thiazolidine-2-thione-4-carboxylic acid (TTC) as well as diothiobis(methanesulfonic acid) (DMS) and its epoxide (DMS-O). A comparison of metabolites following oral or i.p dosing suggests that the formation of the latter two (DMS/DMS-O) metabolites occurs within the gastrointestinal tract. Another study also suggests that ♂ rats may present a lower DMS/DMS-O ratio in urine, compared to ♀ rats. With the exception of THPI-epoxide, the fecal metabolic profile is similar in composition to that of urine suggesting biliary excretion in rats. Captan may not undergo complete degradation at higher doses. Following acute administration of 250 mg/kg bw [14C-TMT] captan to male rats, 96% of the fecal radiolabel was present as the parent compound (fecal excretion accounting for 16% of total administered dose). In a separate study in which rats were exposed acutely to 500 mg/kg bw [14C-TMT] captan, 2% and 24% of fecal radioactivity was recovered in the feces as unchanged parent in ♂ and ♀ rats, respectively (fecal excretion accounting for 33% ♂/40% ♀ of total dose). The same study also

Study Type/ Animal/ PMRA #	Study Results
	investigated effects following acute administration of a 10 mg/kg bw dose, finding that the majority of metabolites at this dose were incorporated into an unresolved fecal fraction. In a third set of studies in which rats of both sexes were acutely exposed to 10 mg/kg bw or 500 mg/kg bw of [14C]-cyclohexene labelled captan, 7% and 42.5% of fecal radioactivity respectively, were identified as unknown metabolites, likely the parent compound. Fecal extraction in this last set of studies accounted for 8-9% (of 90% recovered @48h) at 10 mg/kg bw and 12% (of 97% recovered @96h) at 500 mg/kg bw. **Excretion:** At lower doses (10 mg/kg bw), captan is excreted rapidly, with >96% of radiolabel (^{14}C-cyclohexene radiolabel) recovered within 24 hours. Excretion is predominantly through the urine (88-90%) with peak excretion between 6 and 24 hours post-dosing. Fecal excretion accounted for 7-9% of the dose. When the radiolabel is located on the side-chain carbon (TMT), urinary excretion only accounted for 40-50% of the total with the balance being identified in CO_2 (22-26%) and the feces (14-22%). Organic volatiles in expired air accounted for 0.1-0.5% of the total radiolabel. Excretion was slower at 500 mg/kg bw when compared to 10 mg/kg bw with the majority of excretion occurring between 36-72 hours and 6-24 hours, respectively. Following administration of an acute dose of 500 mg/kg bw, urinary excretion (23-27% ^{14}C-TMT @96h, 69-73% ^{14}C-cyclohexene @96h) was decreased and fecal excretion (33-40% ^{14}C-TMT @120h, 23-25% ^{14}C-cyclohexene@96h) increased relative to the acute 10 mg/kg bw dose group, regardless of the location of the radiolabel. When compared to the 10 mg/kg bw dose groups, radiolabel (TMT) isolated in CO_2 (14-15%) was decreased and in organic volatiles (3.6-6.7%) was increased. Excretion patterns of single and multiple intraperitoneal doses of ^{35}S- captan were similar in normal and hepatectomized ♂ rats.
Mice/rats (oral) (comparative) PMRA # 1163889, 1217493	**Absorption:** Excretion data suggests that absorption occurs more rapidly in mice than rats with similar total quantity absorbed over time (96h). **Distribution:** Gastro- and intestinal- mobility appear to be more rapid in the mouse compared to the rat when administered TMT-labelled captan based on acute- and repeat-dosing scenarios. At 4h after acute dosing, radiolabel in duodenum was 1.5-8% in mouse versus 0-2% in rats. In a mouse dietary study, accumulation of radiolabel (THPI moiety) only occurred in the stomach (corresponding to feeding activity) and in the caecum. **Metabolism:** In both species, captan remains predominantly in its unchanged form in the stomach until reaching the duodenum, at which point it undergoes hydrolysis. Administration of 250 mg/kg bw radiolabelled (^{14}C-TMT) captan suggests that rats may metabolize an increased amount of thiophosgene to DMS and DMS-O than TTC when compared to mice. There were no studies identified regarding the metabolism of captan's ring-based metabolites. **Excretion:** Excretion is also more rapid in mice than rats with 31% of the dose excreted in urine and 10% in feces in 12 hours, compared to 12% and 0%, respectively in rats. In animals terminated 2 hours following intubation with captan (5 and 250 mg/kg bw), mice excreted a greater amount in urine and exhaled air than rats. By 96 hours, recovery was similar in mice (42% urine, 16%

Study Type/ Animal/ PMRA #	Study Results
	feces, 24% expired air) and rats (44% urine, 22% feces, 19% expired air). There does not appear to be any significant differences attributable to sex or repeat dosing regimens in either species.
Toxicokinetics – human (oral) PMRA # 2408546, 2408570	At 1 mg/kg bw, plasma levels of THPI ↑ progressively with peak levels observed at 10 hr post-dosing; monophasic elimination from plasma with elimination $t_{½}$ of 15.7 hr. THPI had a relatively small volume of distribution (3.4 L). Peak levels of THPI were seen in urine at 9 hr post-dosing with elimination $t_{½}$ of 11.7 hr. Cumulative excretion of THPI in urine over 96 hrs was 3.5% of ingested dose
Toxicokinetics – human (dermal) PMRA # 2408554, 2408570	At 10 mg/kg bw, plasma levels of THPI ↑ progressively with peak levels observed at 24 hr post-dosing; monophasic elimination from plasma with elimination $t_{½}$ of 24.7 hr. THPI had a relatively small volume of distribution (7.4 L). Peak levels of THPI were seen in urine at 12 hr post-dosing with elimination $t_{½}$ of 18.7 hr. Cumulative excretion of THPI in urine over 96 hrs was 0.02% of dermally-applied dose
Acute Toxicity Studies	
Acute Oral Toxicity - CF-1 mice PMRA # 1169888	LD50: 2110 mg/kg bw **Low toxicity**
Acute Oral Toxicity – Sprague Dawley rats PMRA # 1237387	LD50 > 2000 mg/kg bw Clinical signs included: alopecia, mild to moderate depression, ptosis, diarrhea, salivation, lacrimation, stained fur, piloerection, red stained muzzles, anogenital stains and easy agitation, bloody urine, ↓food consumption, ↓motor activity, weakness **Low toxicity**
Acute Dermal Toxicity - Sprague Dawley rats PMRA # 1180821	LD50 >2000 mg/kg bw **Low toxicity**
Acute Inhalation Toxicity – Sprague Dawley rats PMRA # 1170007, 1180822	LC50: 0.67-0.9 mg/L Clinical signs included: laboured breathing, facial stains, chromodacryorrhea and congestion **Slight toxicity**
Eye Irritation – NZW rabbits PMRA # 1217092, 1217093, 1170009, 1180826, 1181395	**Severely irritating; irreversible corneal opacity**
Dermal Irritation – Rabbits PMRA # 1217088, 1180827	**Minimally irritating**
Dermal Sensitization - Guinea Pigs PMRA # 1180828, 1180829, 1170010	**Sensitizing (Maximization assays)**

Study Type/ Animal/ PMRA #	Study Results
Dermal Sensitization – Humans PMRA # 2080093	**Sensitizing**
Short-Term Toxicity Studies	
28-Day Dietary Toxicity - Wistar rats PMRA # 1180830	≥ 100 mg/kg bw/day: ↓bwg, ↓fc, ↓water intake, ↓ food conversion efficiency in week 1, ↑relative kidney wt ≥ 200 mg/kg bw/day: ↑relative liver wt (♀) 600 mg/kg bw/day: ↑relative liver wt (♂) Supplemental - Limited parameters assessed.
28-Day Oral (capsule) Toxicity - Beagle dogs PMRA # 1180832	≥ 30 mg/kg bw/day: emesis, ↓fc; ↓bwg (♂) ≥ 300 mg/kg bw/day: ↓appetite; ↓bwg, ↓total protein(♀) ≥ 600 mg/kg bw/day: ↓albumin; ↓total protein ↑relative liver wt (♂) 1000 mg/kg bw/day: ↑LDH, ↑cholesterol; fatty changes in liver and kidneys (♂); ↑potassium,↑relative kidney wt (♀) **Supplemental - Range-finding study, low animal numbers**
1-Year Oral (capsule) Toxicity - Beagle dogs PMRA # 1237368	NOAEL = 300 mg/kg bw/day 300 mg/kg bw/day: emesis, soft stool, ↓protein, ↓albumin; slight ↑relative liver wt (♂) (*considered non- adverse)*
21-Day Dermal Dermal Toxicity - NZW rabbits PMRA # 1217089	NOAEL = 110 mg/kg bw/day (systemic) 1000 mg/kg bw/day: diarrhea or no stool, dermal irritation, ↓bwg, ↓fc
21-Day Inhalation Toxicity - Wistar rats PMRA # 1180835	NOAEC = 5.3 µg/L (1.4 mg/kg bw/day) ≥ 0.8 µg/L (0.2 mg/kg bw/day): respiratory noises, ↓albumin, ↓total protein, ↓triglycerides (*considered non-adverse)* ≥ 5.3 µg/L (1.4 mg/kg bw/day): ↓creatinine, mucosal nasal discharge;↑Hb (♀) (*considered non-adverse)* 24.8 µg/L (6.7 mg/kg bw/day): ↑alkaline phosphatase, ↑phosphorous, ↓ calcium, ulceration of the squamous epithelium of the nasal cavity; bronchiole necrosis, alveolar macrophage infiltration (♂); ulceration and necrosis of the epithelium in the larynx and nasal cavity, rhinitis, hyperplasia of the goblet cells in the nasal septum;↓hematocrit, larynx histopathology (ulceration of the larynx, loss of epithelium), nasal cavity histopathology (rhinitis, goblet cell hyperplasia, ulceration of the squamous epithelium, mucopurolent exudate, degeneration/atrophy/necrosis of olfactory epithelium (♀)
28-Day Inhalation Toxicity - Sprague Dawley rats PMRA # 1180842	≥ 47.3/26.9 µg/L: red nasal discharge, eyes closed, decreased activity, ano-genital staining, soft stool, ↓bw, ↑rel. thyroid wt; ↓glucose, ↓triglycerides, ↑rel. kidney wt, ↑rel. testes wt (♂) ≥ 143 µg/L: lacrimation, hunched posture, alopecia, dry rales; ↑kidney wt (♂); mortality, discolored nasal turbinates, reddened lungs (♀)

Study Type/ Animal/ PMRA #	Study Results
	345/348 µg/L: chromodacryorrhea, gasping/labored breathing, poor condition; mortality, reddened lungs (♂) **Supplemental** due to poor reporting, high MMAD (top two doses) and a lack of histopathological examination.
90-Day Inhalation Toxicity - Wistar rats PMRA # 1171286	LOAEC = 0.13 µg/L (0.04 mg/kg bw/day) ≥ 0.13 µg/L: histopathology of the larynx (squamous hyperplasia) (♀) ≥ 5.06 µg/L: histological changes in the epithelium of lungs and larynx (including loss of cilia, foci of necrotic cells, squamous metaplasia, etc.) 12.98 µg/L: histopathology of the nasal cavity, necrosis of respiratory tract epithelium, death (♂)(attributed to necrosis of bronchi/bronchioles) Recovery : Effects observed in the lungs and nasal passages (but not larynx) resolved during 4-week recovery period.
Chronic Toxicity/Oncogenicity Studies	
80-Week Dietary - B6C3F1 mice PMRA # 2435819	900 mg/kg bw/day: rough coats, alopecia, abdominal distention 2400 mg/kg bw/day: ↓bw, ↑duodenal tumours (adenomatous polyps plus adenocarcinomas) **Supplemental due to study design**
80-Week Dietary Carcinogenicity - CD-1 ♂ mice PMRA # 1237393	6000 ppm (660-714 mg/kg bw/day):↓bwg, ↓fc, intestinal dilation, intestinal mucosal thickening, invagination of the gut wall and a prominence of intestinal serosal vasculature, focal epithelial hyperplasia, duodenal adenomas and carcinomas, slight ↑mortality Hyperplasia, adenomas and carcinomas were localized to the proximal (7cm) small intestine. There was a decrease in incidence of hyperplasia following removal of captan from the diet, however, this pattern did not hold for the duodenal adenomas and carcinomas.

	Control	Group 2					Group 3		Group 4
Duodenal Histopathology (%)		**12wk**	**24wk**	**36wk**	**48wk**	**72wk**	**A**	**B**	**A&B**
Focal Epithelial Hyperplasia	15@48W 19@72W	70	95	85	94	100	10	13	25
Diffuse Epithelial Hyperplasia	0	35	40	15	17	14	0	0	0
Adenomas	0	0	10	25	17	18	20	6	21
Adenocarcinomas	4	0	0	0	0	27	0	13	29
Adenomas + Adenocarcinomas	4	0	10	25	17	36	20	19	42

3A: 24 wk treatment, 24 wk recovery; 3B: 24 wk treatment, 48 wk recovery; 4A: 48 wk treatment, 24-wk recovery; 4B: 48 wk treatment, 32 wk recovery

Supplemental due to study design; evidence of carcinogenicity

<table>
<tr><th>Study Type/
Animal/ PMRA #</th><th>Study Results</th></tr>
<tr><td>96-Week Dietary Carcinogenicity - CD-1 mice

PMRA # 1217484-87, 1217499, 1217504-7</td><td>NOAEL = 400 ppm (60 mg/kg bw/day)

≥ 800 ppm (120 mg/kg bw/day): lymphoid proliferation, duodenal hyperplasia, duodenal adenomas (♀)

6000 ppm (900 mg/kg bw/day): ↓bwg, ↓survival, duodenal focal mucosal hyperplasia, duodenal carcinoma; duodenal adenoma, lymphoid proliferation (♂)

<table>
<tr><th></th><th colspan="5">Dose (mg/kg bw/day)</th></tr>
<tr><td></td><td>0</td><td>15</td><td>60</td><td>120</td><td>900</td></tr>
<tr><td>Duodenal ♂
Hyperplasia ♀</td><td>4/91
11/85</td><td>2/83
9/82</td><td>7/93
8/83</td><td>6/87
13/81</td><td>12/84
28/91</td></tr>
<tr><td>Duodenal ♂
Tumours ♀</td><td>2/91
3/85</td><td>3/83
1/82</td><td>0/93
1/83</td><td>1/87
7/81</td><td>6/84
7/91</td></tr>
</table>

Evidence of carcinogenicity</td></tr>
<tr><td>113- Week Dietary Chronic Toxicity/ Carcinogenicity - CD-1 mice

PMRA # 1217467-72, 1217481-83</td><td>LOAEL = 6000 ppm (900 mg/kg bw/day)

≥ 6000 ppm (900 mg/kg bw/day): ↓bwg, ↓bw, ↓fc, mucosal hyperplasia (stomach, duodenum & jujenum), duodenal adenomas/polyps and carcinomas; distended abdomen (♂)

≥ 10000 ppm (1500 mg/kg bw/day): jejunal adenomas and carcinomas

16000 ppm (2400 mg/kg bw/day): thin, emaciated, small, weak, ↓survival (d-r), duodenal mucosal thickening/masses, mucosal hyperplasia; distended abdomens, alopecia, ungroomed appearance (♀)

<table>
<tr><td></td><td>0</td><td>Low</td><td>Mid</td><td>High</td></tr>
<tr><td>Duodenal ♂
Hyperplasia ♀</td><td>4.1%
8.3%</td><td>53.4%
42.3%</td><td>50.0%
48.7%</td><td>32.0%
44.7%</td></tr>
<tr><td>Combined ♂
Duodenal ♀
Adenoma & Carcinoma</td><td>2.6%
2.8%</td><td>27.4%
30.8%</td><td>29.2%
25.0%</td><td>52.0%
38.2%</td></tr>
</table>

Evidence of carcinogenicity</td></tr>
<tr><td>80-Week Dietary Carcinogenicity
- Osborne-Mendel rats

PMRA # 2435819</td><td>≥ 4000 ppm (200 mg/kg bw/day) for 21 wks, 2000 ppm (100 mg/kg bw/day) for 33 wks: rough coats, alopecia, pale mucous membranes, dermatitis, tachypnea, hematuria, ↓bw

16000 ppm (800 mg/kg bw/day): terminated early due to excessive toxicity.

Supplemental due to study design</td></tr>
</table>

Study Type/ Animal/ PMRA #	Study Results
2-Year Dietary Chronic Toxicity/ Carcinogenicity – rats PMRA # 1217097	NOAEL = 500 ppm (25 mg/kg bw/day) ≥ 2000 ppm (100 mg/kg bw/day): ↓bw, ↑ liver and kidney wt (@18 months), ↑relative thyroid/parathyroid wt (sex uncertain);↑relative heart wt, ↑relative brain wt, hepatocellular hypertrophy (♂) 5000 ppm (250 mg/kg bw/day): slight ↑relative liver and kidney wt (@ 2-yrs); hepatocellular hypertrophy (♀) **No evidence of carcinogenicity**
130-Week Dietary Chronic Toxicity/ Carcinogenicity - Wistar rats PMRA # 1169890-4, 1169896, 1245106	NOAEL = 500 ppm (24 mg/kg bw/day) 2000 ppm (98 mg/kg bw/day): ↓bw, ↓bwg, ↓fc, ↓food efficiency during week 1, pelvic mineralization; ↑relative liver wt, enlarged kidneys (♂) **No evidence of carcinogenicity**
Developmental/Reproductive Toxicity Studies	
Reproductive Toxicity - rats (1 generation) PMRA # 1217463	**Parental**: NOAEL = 25 mg/kg bw/day 25 mg/kg bw/day: slight ↓bw (*not considered adverse*) **Reproductive:** NOAEL ≥ 25 mg/kg bw/day No treatment-related effects **Offspring:** NOAEL = 12.5 mg/kg bw/day 25 mg/kg bw/day: ↓bw
Reproductive Toxicity - rats (3 generations) PMRA # 1217473	**Parental:** NOAEL = 25 mg/kg bw/day ≥100 mg/kg bw/day: ↓bw, ↓bwg ≥250 mg/kg bw/day: ↓fc **Reproductive:** NOAEL = 100 mg/kg bw/day 250 mg/kg bw/day: 2 dams with total resorptions (in nested developmental toxicity study below) **Offspring:** LOAEL = 25 mg/kg bw/day ≥ 25 mg/kg bw/day:↓bw, ↓bwg ≥ 250 mg/kg bw/day: ↓pup survival (PND0-4)
Developmental Toxicity (gavage) - Golden Syrian hamsters PMRA # 1217476	**Maternal:** NOAEL = 50 mg/kg bw/day ≥ 200 mg/kg bw/day: ↓bwg, mortality (1/30) 400 mg/kg bw/day: mortality (4/30), ↑early and late resorptions, ↑post-implantation loss **Developmental:**

Study Type/ Animal/ PMRA #	Study Results
	NOAEL = 200 mg/kg bw/day 400 mg/kg bw/day: ↓fetal bw, ↓viable fetuses, ↓♂/♀ sex ratio, ↑early and late resorptions, ↑post-implantation loss, delayed ossification, limb anomalies (3 fetuses, 1 litter), cleft palate (1 fetus, 1 litter), tail anomalies (3 fetuses, 3 litters), left hindleg shorter than right (1 fetus, 1 litter) and fetal anasarca (2 fetuses, 2 litters). Two fetuses (same litter) exhibited multiple malformations; both had exencephaly (one incidence seen in controls) and facial anomalies and one also showed spina bifida.
Developmental Toxicity (Dietary) - rats Conducted on 3rd mating of F1 ♀ within 3-generation study PMRA # 1217473	**Maternal:** NOAEL = 25 mg/kg bw/day ≥100 mg/kg bw/day: ↓bw, ↓bwg 250 mg/kg bw/day: 2 dams with total resorptions **Developmental:** NOAEL = 25 mg/kg bw/day 100 mg/kg bw/day: cleft palate (1) 250 mg/kg bw/day: 2 dams with total resorptions, cleft palate (1) 500 mg/kg bw/day: ↓fetal bw
Developmental Toxicity (gavage) CD rats PMRA # 1180862	**Maternal:** NOAEL = 18 mg/kg bw/day ≥ 90 mg/kg bw/day: ↓bw (GD7-8), ↓fc (GD7-9) 450 mg/kg bw/day: ↑hair loss, ↑lack of grooming, ↓bw, ↓bwg, ↓fc **Developmental:** NOAEL = 90 mg/kg bw/day 450 mg/kg bw/day: ↑small fetuses, ↓fetal weight, ↑fetal incidence of 14th rib, ↑litter incidence of incomplete fusion of vertebral hemicentra and reduced ossification of pubis **No evidence of malformations**
Developmental Toxicity (gavage) - NZW rabbits PMRA # 1217475	**Maternal:** NOAEL = 25 mg/kg bw/day 60 mg/kg bw/day: clinical signs (including anorexia, reduced faecal output and water intake), ↓bw (GD 6-10), ↓gravid uterine wt **Developmental:** NOAEL = 25 mg/kg bw/day 6 mg/kg bw/day: 1 pup with multiple malformations including digit-like projection of right forepaw 12 mg/kg bw/day: 1 pup with multiple malformations including malrotated right hind limb

Study Type/ Animal/ PMRA #	Study Results
	60 mg/kg bw/day: ↓bw (fetal & litter), ↓crown/rump length **Note: Inadequate number of pregnant dams at HDT (9/15)**
Developmental Toxicity (gavage) - NZW rabbits PMRA # 1142419	**Maternal:** NOAEL = 10 mg/kg bw/day ≥ 30 mg/kg bw/day: anorexia, ↓feces, ↓fc, ↓bwg, ↓bw 100 mg/kg bw/day: abortion (1) **Developmental:** 10 mg/kg bw/day: forepaw slightly flexed (1) *(not considered adverse due to the low severity; effect is known to reverse with growth)* ≥30 mg/kg bw/day: ↓bw (fetus, litter), ↑variants (↑odontoid partially ossified, ↑pre-sacral vertebrae, ↑normal length extra 13th ribs, ↓ossification vertebrae), microphthalmia (1), mandibles fused/lower jaws shortened (1), forepaw extremely flexed (1), total resorptions (1) 100 mg/kg bw/day: ↓gravid uterine wt, ↓bw(fetus & litter), slight ↑late resorptions, delayed ossification (focussed on lower lumbar vertebrae and in forepaw phalanges), fetuses with multiple malformations (2 fetuses/2 litters) (#1 encephalocoele, open eyes, gross malformation of the skull, pollex absent, forepaw extremely flexed), (#2 midbrain ventricles extremely dilated, cebocephaly, maxillae fused, nasals fused), one additional fetus with maxillae fused (same litter) , one additional fetus with forepaw extremely flexed (different litter), one additional fetus with forepaw slightly flexed (different litter), ↑post-implantation loss, abortion (1)
Developmental Toxicity (gavage) - NZW rabbits PMRA # 1181400	**Maternal:** NOAEL = 40 mg/kg bw/day 160 mg/kg bw/day: ↓bw (*including during exposure*), ↓bwg, ↓fc, ↓fecal output, post-implantation loss **Developmental**: NOAEL = 40 mg/kg bw/day 160 mg/kg bw/day: ↓gravid uterine weight, post-implantation loss, total fetal death (1 dam), abortion (2 dams), ↑minor skeletal variations (supernumerary ribs, etc.), delayed ossification (hyoid bone)
Developmental Toxicity (gavage) NZW rabbits PMRA # 2359929	**Maternal:** NOAEL = not established LOAEL = 10 mg/kg bw/day ≥ 10 mg/kg bw/day: thin build, few/small feces, ↓water intake, ↓fc, ↓bwg (48%) ≥ 20 mg/kg bw/day: hair loss, weight loss during GD 6-8 45 mg/kg bw/day: underactivity, weight loss during GD 6-12, eosinophilic infiltration and focal erosion of the duodenum, ↑early and late resorptions, ↑post-implantation loss **Developmental:** NOAEL = 20 mg/kg bw/day

Study Type/ Animal/ PMRA #	Study Results
	45 mg/kg bw/day: ↑early and late resorptions, ↑post-implantation loss, ↓fetal weight, ↑absent kidney and ureter (4 fetuses/2 litters), ↑lung atelectasia, slight ↑appendicular elongated acromion process and additional centre of the sternebrae, ↑skeletal variations (offset alignment of the pelvic girdle, supernumerary ribs, 20 thoracolumbar vertebrae), ossification delay (epiphyses, metacarpals, phalanges) **Evidence of malformations at a maternally toxic dose**
Developmental Toxicity (gavage) - Macaca Monkeys PMRA #2533063	**Maternal:** ≤ 25 mg/kg bw/day: no effects on bw or hematological parameters **Developmental:** 25 mg/kg bw/day: ↓crown/rump length, 2 abortions, 1 resorption There were wide variations in maternal bw, as well as fetal organ and bw. **Considered supplemental due to limited study design and reporting**
Genotoxicity Studies	
Reversion assay, *S. typhimurium* TA98, TA100, TA 102, TA 104, TA1535, TA1536, TA1537, TA1538 PMRA # 1181468, 2078595, 2078596, 2080213, 2472897, 2473325, 2473332, 2473329, 2473319, 2473334	A multitude of studies of varying quality were conducted. Typically, studies conducted in the **absence of activation were mixed** and studies conducted **in the presence of activation were typically negative**. There were no differences in this pattern when studies were categorized as investigating point or frameshift mutations. Studies investigating cross-linking (TA102) and oxidation (TA102/104) mechanisms of genotoxicity were positive without activation and negative with activation. One study demonstrated ↑ activity with ↓ pH. Another study suggested that mutagenicity is highly attenuated by whole blood compared to plasma.
Reversion assay, *S. typhimurium* TA100, TA1535, TA538 *E. coli* B/r WP2, WP2 *hcr* PMRA # 2080214, 1181442	In vitro mutagenicity was greatly ↓ or eliminated in the presence of activation, cysteine, glutathione and blood.
Reversion assay, *E. coli* PMRA # 2080211, 2078597, 1180875, 2472897, 2473325, 2473329, 2473327	Various forward and reverse mutation assays of varying quality (with details often limited) indicated **mixed results in the presence of activation** and **positive** results **in the absence of activation**. One study indicated ↑ mutagenicity with ↑ pH.
Reversion assay, B.subtilis TKJ5211, TKJ6321 PMRA # 2473334	**Positive** with activation
Gene mutation, V79 Chinese Hamster cells,	**Positive** without activation **Negative** with activation

Study Type/ Animal/ PMRA #	Study Results
HGPRT locus PMRA # 2080210	
Gene mutation, CHO cells, HGPRT locus PMRA # 1181501	**Positive** without activation at ≥ 0.25 µg/mL (cytotoxicity at ≥ 1.0 µg/mL)
Gene mutation, L5178Y mouse lymphoma, TK locus PMRA # 2080216	**Positive** without activation Size of colonies was not indicated.
Gene mutation, L5178Y mouse lymphoma, TK locus PMRA # 1180886	**Positive** in the absence of activation **Positive** in 1/3 assays with activation (at a cytotoxic level)
Chromosomal aberrations, Chinese Hamster V79 cells PMRA # 2078600	**Positive** without activation
Chromosomal aberrations, human fibroblasts PMRA # 1181523	**Negative** without activation up to 4 µg/mL
SCE, Chinese Hamster V79 cells PMRA # 2078600	**Positive** without activation
Cell transformation assay - BALB/3T3 cells PMRA # 2078604	**Positive** without activation **Negative** without activation Note - study also detects non-genotoxic carcinogens
UDS - human lung fibroblasts PMRA # 1181490	**Equivocal** in one assay (no dose-response) with activation at 3.7 – 300 µM; **Negative** in second assay with activation up to 1000 µM **Negative** without activation up to 6.3 µM, cytotoxic at ≥ 12.5 µM
UDS – human lung fibroblasts PMRA # 2080208	**Positive** at ≥ 1 µM (with and without activation)
DNA damage/repair, *S.typhimurium* TA1538, TA1978, *E.coli* PQ35, PQ37 PMRA # 2078595	**Positive** without activation in TA1538 **Negative** with activation in TA1538 and TA1978 and without activation in TA1538 **Positive** without activation in PQ37 (no excision repair system) **Negative** in PQ35 (excision repair system intact) with or without activation and in PQ37 with activation
DNA damage *E.coli*	**Positive**

Study Type/ Animal/ PMRA #	Study Results
PMRA # 2078596	
DNA damage, DNA alkaline elution technique - Chinese hamster V79 cells PMRA # 2434255	**Positive** without S9 **Negative** with S9
DNA damage, human fibroblasts PMRA # 2434252	**Positive** for single-strand breaks, inhibition of DNA synthesis, DNA adducts (at very high doses) More damage at low pH and in closed system.
Micronucleus – mouse, bone marrow (gavage) PMRA # 1180937	**Negative** up to 1000 mg/kg bw
Micronucleus/ Cytogenetics assay - mice, bone marrow and testis (gavage) PMRA # 1181547	**Positive** for micronuclei in bone marrow ≥ 100 mg/kg bw/day for 2 days **Positive** for chromosomal aberrations in bone marrow ≥ 400 mg/kg bw/day for 5 days and in spermatogonia at 800 mg/kg bw/day for 5 days **Positive** for aberrations in spermatocytes ≥ 50 mg/kg bw/day for 5 days
Chromosome aberrations – rat, bone marrow (intraperitoneal) PMRA # 1181443)	**Positive** at ≥ 50 mg/kg bw; slight ↓mitotic index at 500 mg/kg bw 6 hours post-dosing
Chromosome aberration – rats, bone marrow (gavage) PMRA # 1249733	**Negative** up to 800 mg/kg bw/day for 5 days
Chromosomal aberrations – Wistar rats, bone marrow (gavage) PMRA # 1181523	**Negative** up to 2000 mg/kg bw (single dose) or 500 mg/kg bw/day (5 consecutive daily doses)
Mouse spot test - C57b1/6J mouse PMRA # 1217478, 1217479	**Negative at 5000 ppm for 5 days**
Heritable translocation - ICR/SIM ♂mice (dietary) PMRA # 1237391, 2472897	**Equivocal at 5000 ppm for 8 weeks**
Dominant lethal assay – mice, Osborne-Mendel rats (i.p., gavage)	**Mice** **Negative** (acute i.p. up to 30 mg/kg bw, acute oral up to 800 mg/kg bw and repeated oral up to 600 mg/kg bw/day for 5 successive days) **Positive** (repeated i.p. at 10 mg/kg bw/day and oral at ≥ 100 mg/kg bw/day, both for 5 successive days)

Study Type/ Animal/ PMRA #	Study Results
PMRA # 1181523, 1181461, 2080102	**Rats** **Positive** (i.p. study at 10 mg/kg bw/day and oral study at ≥ 100 mg/kg bw/day, both for 5 successive days)
UDS - rat hepatocytes Gavage PMRA # 2533060	**Negative**
Sperm morphology assay - mouse PMRA # 2078599	**Positive** for morphologically abnormal sperm ≥200 mg/kg bw/day orally for 5 days
Nuclear aberration assay – CD-1 mice, proximal small intestine PMRA # 1180919, 2080339	**Negative** up to 16000 ppm for 1 week or 1000 mg/kg bw for 5 consecutive days. Captan had no effect on induction of nuclear aberrations by the GI carcinogen 1,2-dimethylhydrazine. Negative results were also obtained with captan following pre-treatment with L-buthionine-S,R-sulfoximine (glutathione-depleting agent). Negative results were obtained with the metabolite THPI (up to 1500 mg/kg bw); mortality was observed at 3000 mg/kg bw. Negative results were obtained with the impurity bis-(trichloromethyl)disulfide (up to 100 mg/kg bw) **Supplemental due to novel design (clastogenicity to villi crypts)**
Endocrine Studies	
Hershberger assay – Sprague-Dawley rats (gavage) PMRA # 2162312	**Androgen agonist assay** 200 mg/kg bw/day: abnormal breathing (2), mortality (1), ↓bw, ↓bwg 400 mg/kg bw/day: all animals sacrificed by day 8 due to abnormal breathing and/or weight loss **Androgen antagonist assay** 100 mg/kg bw/day + testosterone propionate: clinical signs (1), mortality (1), ↓bw, ↓bwg ≥200 mg/kg bw/day + testosterone propionate: all animals sacrificed by day 5 due to abnormal breathing and/or weight loss No effect on weight of androgen-dependent tissues in either assay
Special Studies (non-guideline and supplemental)	
28-Day Time Course Study (dietary) - CD-1 ♂ mice (Focus on duodenal histopathology) PMRA # 1164832	At 3000 ppm (450 mg/kg bw/day): ≥Day1: ↓fc, ↓bw, distention of the duodenal lumen *(bw effect not observed when compared to pair-fed animals)* ≥Day 3: crypt cell hyperplasia, villus shortening, disorganization of villus enterocytes ≥Day 7: immature villus enterocytes at tip of villi Severity of effects was maintained over time.

Study Type/ Animal/ PMRA #	Study Results
	No treatment related effects on the stomach, jejunum or ileum.
56-Day Toxicity (dietary) - CD-1 mice (Focus on formation of duodenal hyperplasia) PMRA # 1162895, 1184215	≥120 mg/kg bw/day: crypt cell hyperplasia (proximal 7cm of duodenum)(♀) ≥450 mg/kg bw/day: ↓bwg, ↓fc, ↑BRDU uptake by crypt cells, ↓villus height, ↓villus/crypt cell ratio, mononuclear inflammatory cells in the lamina propria, minor crypt cell hyperplasia (jejunum); mild hyperplasia of forestomach epithelium, hypertrophy of the gastric pits of the glandular portion of the stomach, crypt cell hyperplasia (proximal 7cm of duodenum)(♂) 900 mg/kg bw/day: mild hyperplasia of forestomach epithelium, hypertrophy of the gastric pits of the glandular portion of the stomach (♀)
91-Day Dietary Toxicity - CD-1 mice (Focus on duodenal hyperplasia) PMRA # 1184214	At 6000 ppm (900 mg/kg bw/day): In week 1: ↓bw, ↓fc ≥28 days: thickening of duodenal mucosa (diminished @91days), marked duodenal crypt cell hyperplasia (diffuse) and atrophy of villi (1st 7cm), inflammatory cell infiltrate present in expanded lamina propria,↑mitotic figures present within hyperplastic crypts, ↑# crypt cells (decreasing with time), ↓villus to crypt cell ratio, ↑PCNA labelling index in proximal duodenal crypt cells ≥56 days: effects similar to 28day findings but less pronounced, focal crypt cell hyperplasia (1st 7cm)
Promotion assay (dietary) - F344 rats PMRA # 2066418	Pre-treatment with 3 carcinogens (100 mg/kg diethylnitrosamine ip on day 0, 20 mg/kg N-methyl –N-nitrosourea on days 2,5,8,11 and 0.1% N-bis(2-hydrooxypropyl)nitrosamine in drinking water for 2 weeks) followed by 4000 ppm captan (~200 mg/kg bw/day) in diet for 16 weeks: ↓bw, ↑forestomach hyperplasia, ↑thyroid follicular cell hyperplasia, ↑altered renal tubules, ↑renal adenomas, ↑squamous cell papillomas in forestomach compared to animals with carcinogen pre-treatment only Area (but not number) of GST-P positive liver foci ↑ with captan and carcinogen pre-treatment, compared to carcinogen pre-treatment alone; no foci seen with captan without pre-treatment. The number of pepsinogen-isozyme-altered pyloric glands ↑ with captan with carcinogen pre-treatment and to a lesser extent without pre-treatment compared to carcinogen pre-treatment alone.
Initiation/ Promotion Study (Dermal) - Swiss albino mice PMRA # 2078593	Various testing regimens typically using 450 mg/kg bw(/day) captan acutely or repeatedly, along with the promoter 12-o-tetradecanoyl phobol-13-acetate (in the initiation assay) or the initiator dimethyl benzanthracene (in the promotion assay) or alone (in the complete carcinogenicity assay) <u>Initiation Assay</u> Single application of captan: benign squamous cell papillomas (3/14 animals @51weeks) Repeat application of captan: benign squamous cell papillomas (1st tumour @14 weeks, 12/18 animals) <u>Promotion Assay</u> No dermal tumors in captan groups

Study Type/ Animal/ PMRA #	Study Results
	Complete Assay No dermal tumours in captan groups Poor hair growth was noted in animals exposed to captan dermally (acute or repeat dose)
Other Toxicity (Dietary) - Sprague-Dawley rats PMRA # 2078594	Pregnant **Maternal:** ≥ 500 mg/kg bw/day: ↓bw, ↓uterine wt ≥ 2500 mg/kg bw/day:↓kidney wt, ↓spleen wt **Developmental**: ≥ 2500 mg/kg bw/day: abortion 5000 mg/kg bw/day: ↓live fetuses, ↓fetal survival DCR-pseudopregnant (induced by cervicovaginal stimulation during proestrus and estrus) **Maternal**: 5 mg/kg bw/day: ↑endometrial/myometrial wt, ↓myometrial glycogen ≥500 mg/kg bw/day: ↓uterine wt, ↓spleen wt ≥2500 mg/kg bw/day: ↓bw 5000 mg/kg bw/day: ↓kidney wt
DNA binding assay - mice & Osborne-Mendel rats PMRA # 2066400	There was no indication of a higher association of ^{14}C with the DNA of the duodenum than in other organs (in other words, stomach, kidneys, liver or testes). Further procedures suggested that the radioactivity was associated with the DNA (not the proteins) and was not covalently bound
DNA binding assay - CD-1 mice PMRA # 1136018, 1180930	The results suggest some association with DNA but do not prove covalent binding.^{35}S-radiolabels might not be covalently bound to DNA fractions. Radiolabel was shown to be associated with DNA extracts from all tissues sampled (stomach, duodenum, jejunum, liver, bone marrow)
DNA binding assay (*in vitro*) - calf thymus PMRA # 1149621	~0.3% of added radioactivity was associated with DNA. In the absence of glutathione, an association with DNA was observed, but there was no increase in association with time. In the presence of glutathione, an initial increase in association was observed, but rapidly reached a plateau. In both scenarios, radiolabel-DNA binding was concentration dependent and pH independent. It is unlikely that the radiolabel was covalently bound
DNA binding assay (*in vivo/in vitro*) - CD-1 mice hepatocytes PMRA # 1180908	Radioactivity detected in the DNA fraction was unlikely due to covalent bonding, but probably due to contamination of the DNA fractions with small amounts of protein molecules
Histone binding assay (in vitro) - rat liver PMRA # 2066406	Binding to histones was pH dependant with no binding at a pH of 7.5, while binding occurred at a pH of 9.0. Binding to the proteins was similar for both ^{35}S and ^{14}C radiolabels. The authors suggest that the binding of captan to the histones may destabilise the DNA structure and result in genotoxic effects

Study Type/ Animal/ PMRA #	Study Results
Tubulin formation (*in vitro)* - tubulin from porcine brain and mouse fibroblasts PMRA # 2434253	Inhibited microtubule formation at equimolar concentrations and promoted disassembly of preformed microtubules at lower concentrations.
Toxicity Studies with Metabolite THPI	
Reverse mutation: *S. typhimurium* TA98, TA 100, TA1535, TA1537, TA102 *E. coli* uvrA PMRA # 1180897, 2473319	**Negative**
Metabolism – rats (oral) PMRA # 1217492	Oral administration of 100 mg/kg bw ^{14}-C-THPI to 2 ♂ rats resulted in >95% recovery within 24 hours; 90% of excreted radiocarbon was present in the urine. The metabolites were qualitatively similar to those of captan.
Developmental Toxicity (gavage) NZW rabbits PMRA # 2359928	**Maternal:** NOAEL = 10 mg/kg bw/day 22.5 mg/kg bw/day: ↓bwg (83%) during GD 6-12 **Developmental:** NOAEL = 22.5 mg/kg bw/day No developmental toxicity observed **No evidence of malformations or fetal sensitivity**

Appendix V Dietary Exposure and Risk Estimates for Captan

Table 1 Dietary Exposure and Revised Risk Estimates for Captan

Population Subgroup	Revised Risk Estimates					
	Acute[1] (99.9 percentile)				Chronic[2]	
	Food Only		Food + Water		Food + Water	
	Exposure (mg/kg bw)	% ARfD	Exposure (mg/kg bw)	% ARfD	Exposure (mg/kg bw/day)	%ADI
General Population	N/A				--	--
All Infants <1 yr					0.009	7
Children 1-2 yrs					0.010	8
Children 3-5 yrs					0.008	6
Children 6-12 yrs					0.005	4
Males 13-19 yrs					0.003	3
Males 20+ yrs					0.003	2
Adults 50+ yrs					0.003	2
Females 13-49 yrs	0.015	21	0.025	36	0.003	4

[1]Acute Reference Dose (ARfD) of 0.07 mg/kg bw applies to females aged 13-49 years.
An acute dietary reference dose for all other population subgroups was not required.

[2]Acceptable Daily Intake (ADI) of 0.07 mg/kg bw/day applies to females aged 13-49 years.
ADI of 0.13 mg/kg bw/day applies to all other population subgroups.

Appendix VI Food Residue Chemistry Summary

Metabolism in livestock and plants – For all registered uses, the nature of the residue in animal and plant commodities is adequately understood based on metabolism studies in rats, lactating goats, laying hens, apple, orange, tomato, lettuce and soybean. Metabolism studies in plants indicate that parent captan was a major component of the residue in plants. The metabolite THPI was found at levels of radioactivity higher than 10% (trigger level) of the total radioactive residue (TRR) in apple peel and pulp and at approximately 10% TRR in lettuce leaves. In macerated plant commodities captan is converted to THPI sometimes at a rapid rate depending upon pH and temperature conditions. Parent captan was not detected in any animal tissue. The metabolite THPI along with its hydroxylated derivatives 3-OH THPI and 5-OH THPI were found to be the major residues in animal tissues and organs.

Magnitude of residues – A maximum residue limit (MRL) of 5 ppm has been specified for captan (parent only) on apples, apricots, blueberries, cranberries, cherries, grapes, peaches/nectarines, pears, plums, raspberries, strawberries and tomatoes and published on the Health Canada's Maximum Residue Limits for Pesticides webpage. This MRL was established on the basis of monitoring programs conducted in the early 1980s. Residues resulting from all other uses on captan labels but without a specified MRL are regulated under the general MRL, in other words, must not exceed 0.1 ppm. An amendment of the residue definition for both risk assessment and enforcement is being proposed to include the metabolites THPI for plants; THPI, 3-OH THPI and 5-OH THPI for animal commodities. Consequently, the PMRA is proposing that the registrants file an *ad hoc* submission for the establishment of new MRLs in accordance with the proposed residue definition and the supported use pattern.

Enforcement Analytical Methodology – Captan and the metabolite THPI are listed in the Canadian Food Inspection Agency (CFIA) Pesticide Multiresidue Analytical Methods Manual as compounds that can be analysed by the CFIA's multiresidue method. CFIA residue monitoring data for captan are reported as the combined residue of parent captan and metabolite THPI. The United States Department of Agriculture (USDA) 2009 Pesticide Data Program (PDP) residue monitoring data indicate that captan and THPI were measured separately, whereby captan was determined by using a modified QuEChERS (Quick, Easy, Cheap, Effective, Rugged, and Safe) extraction procedure with GC-EC detection for the pesticide class "halogenated", while THPI was measured by using a modified solid phase extraction method with GC-Ion Trap MS/MS detection. In addition, the 10/99 USFDA PESTDATA database (PAM Volume I, Appendix I) indicates that captan is completely recovered (>80%) using Multiresidue Method Sections 302 (E1-E3) and 304 (E1-E5 + C1-C4). THPI is completely recovered through Sections 302 (E1-E3) and 302 (E7+C6) but not through 304 (E1-E5 + C1-C4). Due to observed differences in the magnitude of residues reported in the different surveillance programs, a laboratory study which quantifies the individual recovery efficiency for captan and its metabolites by the multiresidue methods is required. Given that the present risk assessment was based on residue surveillance data, such a study will provide confidence as to the actual nature and magnitude of residues measured in these pesticide residue surveillance programs.

Residue Definition (RD) – The residue in all commodities (plants and animals) is currently expressed as captan per se. PMRA reevaluation and assessments from other regulatory agencies (in other words, EFSA Scientific Report 2009; JMPR 2007) indicate that available toxicology data cannot firmly rule out the toxic potential of the metabolite THPI and its hydroxylated

derivatives. Based on these toxicology concerns and metabolism studies outilined above, the PMRA is proposing the RD in raw and processed plant commodities to be defined as the sum of captan and THPI expressed as captan; the RD in animal commodities is defined as the sum of captan, THPI and the hydroxylated metabolites 3-OH THPI and 5-OH THPI, all expressed as captan. These RDs are proposed for both enforcement and acute and chronic dietary risk assessments. The RD in drinking water is the sum of captan and THPI.

Residue Definition (RD)	
ANIMAL	
RD for Enforcement Purposes (Monitoring and MRLs)	Captan + THPI + 3-OH THPI + 5-OH THPI expressed as captan
RD for Risk Assessment Purposes	
PLANT	
RD for Enforcement Purposes (Monitoring and MRLs)	Captan + THPI expressed as captan
RD for Risk Assessment Purposes	
WATER	
RD for Risk Assessment Purposes	Captan + THPI

The registrants submitted a position paper advocating for maintaining the residue definition for captan in plant commodities as captan *per se* for enforcement and risk assessment purposes. The registrant position is essentially based on their interpretation of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the European Union (EU) guidance documents on the definition of the residue with regard to captan. The PMRA noted that there is no objection concerning the proposed residue definition for captan in animal commodities. The PMRA had proposed and is maintaining the RD in plants as the sum of captan and THPI expressed as captan on the basis of the same principles put forth by the registrants and enumerated in JMPR, EU and the Organization for Economic Co-operation and Development (OECD) guidance documents on the definition of the residue.

DATA GAPS

Data required for continued registration (Section 12) – Given that the present dietary risk assessment was based on residue surveillance data, the following confirmatory data is required to determine the actual nature and magnitude of residues measured in pesticide residue surveillance programs:

> Multiresidue analytical methodology evaluation: a laboratory study which quantifies the individual recovery efficiency for captan and its metabolites THPI, 3-OH THPI and 5-OH THPI by multiresidue methods used by surveillance programs.

Other data gap (non Section 12) – Captan is currently registered for use on crops which are typically rotated with other crops. In the absence of a crop rotation study to determine the nature and the magnitude of residues in rotated crops, the following statement must be added to the captan label directions for use:

> "A minimum rotational crop plantback interval of 12 months must be observed for all crops other than those registered for use with captan."

Appendix VII Supplemental Maximum Residue Limit Information, International Situation and Trade Implications

Maximum residue limits (MRLs) may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

An MRL of 5 ppm has been specified for residues of captan (parent only) on domestic apples, apricots, blueberries, cranberries, cherries, grapes, peaches/nectarines, pears, plums, raspberries, strawberries and tomatoes. This MRL was established on the basis of monitoring programs conducted in the early 1980s. Residues in/on all other crops appearing on the registered captan labels are regulated under Section B.15.002(1) of the *Food and Drug Regulations* not to exceed 0.1 ppm (general MRL) for captan.

As a result of this re-evaluation, the current residue definition for risk assessment and enforcement (see Table 2) is proposed to be modified to include the metabolites tetrahydrophthalimide (THPI) for plants; THPI, 3-OH THPI and 5-OH THPI for animal commodities. Consequently, the PMRA is proposing that the registrants file an *ad hoc* submission for the establishment of new MRLs in accordance with the proposed residue definition.

Tolerances in the United States for residues of captan in/on the registered commodities have been established under 40 CFR §180.103(a). They are expressed in terms of captan *per se* for plant commodities and in terms of combined residues of captan and its metabolite 1,2,3,6-tetrahydrophthalimide (THPI) for livestock commodities as of 19 May 2015.

Most of the established American tolerances are harmonized with Codex MRLs. Canadian MRLs are not [Table 1]. This could potentially lead to trade irritations.

Table 1 Current Canadian MRLs and International Tolerances/MRLs

Crop/Commodity	Canadian MRL[1] (ppm)	United States Tolerance[2] (ppm) as of 19 May 2015	Codex MRL[3] (ppm)
Apples, Pears	5.0	25.0	15.0 (pomme fruits, accommodates post-harvest treatment)
Apricots	5.0	10.0	-
Blueberries	5.0	20.0	20.0
Cherries	5.0	50.0	25.0
Cranberries	5.0	-	-
Ginseng roots	1.5	-	-
Grapes	5.0	25.0	25.0
Nectarines	5.0	25.0	3.0
Peaches	5.0	15.0	20.0
Plums	5.0	10.0	10.0
Raspberries	5.0	25.0	20.0
Strawberries	5.0	20.0	15.0

Crop/Commodity	Canadian MRL[1] (ppm)	United States Tolerance[2] (ppm) as of 19 May 2015	Codex MRL[3] (ppm)
Tomatoes	5.0	0.05 (seed treatment)	5.0
Beans	*	0.05	-
Beets	*	0.05	-
Blackberry	*	25.0	-
Broccoli	*	0.05	-
Brussels sprouts	*	0.05	-
Cabbages	*	0.05	-
Cantaloupes	-	0.05	-
Cauliflower	*	0.05	-
Celery	*	0.05	-
Corn, sweet	*	0.05	-
Corn, field	*	0.05	-
Cucumbers	*	0.05	3.0
Dried grapes (= courrants, raisins & sultanas)	-	-	50.0
Eggplants	*	0.05	-
Kale	*	0.05	-
Loganberries	*	25.0	-
Melons, except watermelon	-	-	10.0
Oats, seed (export only)	*	0.05	-
Onions	-	0.05	-
Peas	*	0.05	-
Peppers	*	0.05	-
Pimentos	-	0.05	-
Pineapple	-	0.05	-
Prunes	*	10.0	10.0
Potatoes	*	0.05	0.05
Pumpkins	*	0.05	-
Rhubarb	*	0.05	-
Rutabagas	*	0.05	-
Soybeans	*	0.05	-
Spices, Roots and Rhizomes	-	-	0.05
Spinach	-	0.05	-
Squash (winter and summer)	*	0.05	-
Sugar beets	*	0.05	-
Swiss chard	-	0.05	-
Turnips	*	0.05	-
Watermelon	-	0.05	-
Almond	-	0.25	0.3
Almond, hulls	-	75.0	-
Animal feeds, nongrass, group 18	-	0.05	-
Caneberry, subgroup 13A	-	25.0	-
Cotton, undelinted seed	-	0.05	-
Dill, seed	-	0.05	-
Flax, seed	-	0.05	-
Grain, cereal, group 15	-	0.05	-
Grain, cereal, forage, fodder and straw, group 16	-	0.05	-
Grass, forage	-	0.05	-
Grass, hay	-	0.05	-
Okra	-	0.05	-
Peanut	-	0.05	-

Crop/Commodity	Canadian MRL[1] (ppm)	United States Tolerance[2] (ppm) as of 19 May 2015	Codex MRL[3] (ppm)
Peanut, hay	-	0.05	-
Rapeseed, seed	-	0.05	-
Rapeseed, forage	-	0.05	-
Safflower, seed	-	0.05	-
Sesame, seed	-	0.05	-
Sunflower, seed	-	0.05	-
Vegetable, brassica leafy, group 5	-	0.05	-
Vegetable, bulb, group 3	-	0.05	-
Vegetable, cucurbit, group 9	-	0.05	-
Vegetable, foliage of legume, group 7	-	0.05	-
Vegetable, fruiting, group 8	-	0.05	-
Vegetable, leafy, except brassica, group 4	-	0.05	-
Vegetable, leaves of root and tuber, group 2	-	0.05	-
Vegetable, legume, group 6	-	0.05	-
Vegetable, root and tuber, group 1	-	0.05	-
Cattle, fat	-	0.15	-
Cattle, meat	-	0.20	-
Cattle, meat byproducts	-	0.30	-
Goat, fat	-	0.15	-
Goat, meat	-	0.20	-
Goat, meat byproducts	-	0.30	-
Hog, fat	-	0.15	-
Hog, meat	-	0.20	-
Hog, meat byproducts	-	0.30	-
Horse, fat	-	0.15	-
Horse, meat	-	0.20	-
Horse, meat byproducts	-	0.30	-
Milk	-	0.10	-
Sheep, fat	-	0.15	-
Sheep, meat	-	0.20	-
Sheep, meat byproducts	-	0.30	-

* Covered under Part B, Division 15, subsection B.15.002(1) of the FDR as 0.1 ppm
[1] Maximum Residue Limits for Pesticides webpage as of 26 May 2015.
[2] Electronic Code of Federal Regulations.
[3] Codex Alimentarius webpage as of 2013.

Table 2 Current Enforcement Residue Definition in Canada and Other Jurisdictions

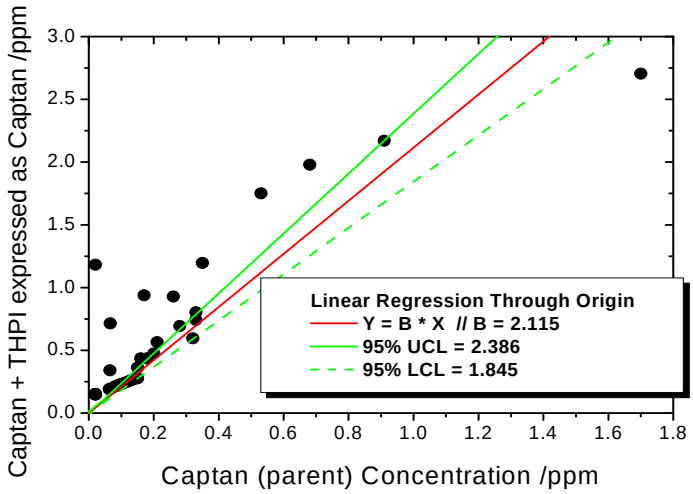
Jurisdiction	Enforcement Residue Definition	
	Plant	Animal
Canada	Captan	Captan
Codex	Captan	Captan
United States	Captan	Captan + THPI, measured at THPI
EFSA	Captan + THPI expressed as Captan	Captan + THPI + 3-OH THPI + 5-OH THPI expressed as Captan

Appendix VIII Residue Surveillance Data Used in Dietary Risk Assessments

The refined dietary risk assessments were performed by using available Canadian Food Inspection Agency (CFIA) and USDA Pesticide Data Program (PDP) residue surveillance data [Table 1 of this appendix], mostly for commodities identified as "critical" (in other words, commodities which contributed the most to the exposure) in the screening level assessment. The USEPA SOP 99.3 was used for crop translations when necessary.

Most of the commodities in the PDP monitoring programs were measured for both captan and THPI. For commodities which were not measured for THPI, the THPI contribution to the residue was estimated by using a statistical approach based on a data correlation procedure [see graph below]. First, for each THPI measured sample in PDP, the THPI residue was expressed as captan using the molecular weight (MW) ratio as a conversion factor, in other words, THPI residue expressed as captan was obtained by multiplying the THPI residue by the molecular weight ratio (captan MW÷THPI MW) whereby captan MW = 300.6 and THPI MW = 151.2. The obtained value was added to the captan residue measured in the same PDP sample. This procedure was repeated for all samples in which both captan and THPI were measured. Plotting the sums (captan residue + THPI residue expressed as captan) against captan residues and performing a linear regression through the origin yielded a correlation factor of 2.115 and a 95% confidence interval with a lower limit of 1.845 and an upper limit of 2.386. This implies that once captan residues are measured in a given sample population, the "total residue" in that sample can be predicted (in the 95% confidence limits) by multiplying the measured captan residue by a factor between 1.845 and 2.386. The more conservative upper bound value of 2.386 was chosen for the calculation of the PDP "total residue" in monitoring samples which were measured for captan but not for the metabolite THPI. When the measured captan value was "nondetect", captan ½ LOD was used in the calculation of the total residue, in other words, captan ½ LOD was multiplied by 2.386 to obtain the total (captan + THPI) residue. In cases where monitoring data were not available, Canadian/Codex MRLs or American Tolerances were used whereby the total residue was obtained by multiplying the MRL or the Tolerance by the factor 2.386. CFIA residue data for captan were already reported as the combined residue of captan and THPI; thus these data were used as reported.

Correlation between total residue (CAP+THPI) and CAP (only) residue from PDP monitoring data (samples measured for both CAP and THPI)



For comparison, the table below shows the ratios between the total (captan + THPI expressed as captan) residue and the captan (parent) residue obtained from different metabolism studies. The ratios span a broad range of values from 1.25 to 15.67 with a mean value of 3.811 (standard deviation = 5.28) and a median value of 1.565. The ratio of 2.386 obtained from PDP monitoring data (as described above) was deemed statistically more representative of the actual residues occurring on most consumed commodities.

Crop/commodity	Captan conc.	Total [captan + THPI expressed as captan]	Ratio total/captan conc.
Apple peel and pulp (acetone extract)	1.67 ppm	2.91 ppm	1.74
Apple juice and pomace	44% TRR	108% TRR	3.45
Tomato fruit	80% TRR	120% TRR	1.50
Tomato fruit (greenhouse)	82% TRR	118% TRR	1.44
Lettuce leaves	76% TRR	124% TRR	1.63
Lettuce leaves (greenhouse)	77% TRR	96% TRR	1.25
Orange peel and pulp	12% TRR	188 % TRR	15.67

TRR = Total Radioactive Residue

Total [captan + THPI expressed as captan] = captan conc. + [THPI conc. X $\frac{300.6}{151.2}$]

Table 1 Monitoring Residue Data Summary (Captan + THPI) for Acute[1] and Chronic[2] Exposure Assessments

Commodity	Proc. Factor Used[3]	Source of Data	Year Span	Number of Samples	Highest Residue Detected (ppm)	PCT[4] Chronic	PCT Acute	% Dom-Prod[5]	Chronic Average Residue (ppm)
Apple, fruit	1	*PDP Captan + THPI*	2004-2007	431	3.970	65	70	70	0.0949
Apple, juice	1	*PDP Captan + THPI*	2004-2007	106	0.341	75	78	49	0.0655
Apple, sauce	1	*PDP Captan + THPI*	2004-2007	216	0.301	75	78	49	0.0544
Apple, dried	8	*See Apple, fruit*				100	100	0	0.0949
Blueberry	1	*PDP Captan + THPI*	2004-2007	207	2.705	61	63	79	0.1259
Cantaloupe	1	*PDP Captan + THPI*	2004-2007	203	0.045	100	100	77	0.0256
Carrot, fresh	1	*PDP Captan + THPI*	2004-2007	341	0.282	30	30	70	0.0520
Carrot, juice	1	See Carrot, fresh				30	30	70	0.0520
Celery	1	*PDP Captan + THPI*	2004-2007	196	0.203	75	75	28	0.0683
Cherry, fruit	1	*PDP Captan + THPI*	2004-2007	122	0.938	47	58	48	0.0558
Cherry, juice	1.5	*See Cherry, fruit*				47	58	48	0.0558
Collard, greens	1	*PDP Captan + THPI*	2004-2007	117	0.058	61	61	39	0.0441
Grape, fruit	1	*PDP Captan + THPI*	2004-2007	1441	3.761	47	50	3	0.1146
Grape, juice	1.2	*See Grape, fruit*				47	50	3	0.1146
Grape, leaves	1	*See Grape, fruit*				47	50	3	0.1146
Grape, raisin	1	*PDP Captan + THPI*	2004-2007	216	0.119	53	56	0	0.0913
Grape, wine & sherry	1	*See Grape, fruit*				76	76	25	0.1146

Commodity	Proc. Factor Used[3]	Source of Data	Year Span	Number of Samples	Highest Residue Detected (ppm)	PCT[4] Chronic	PCT Acute	% Dom-Prod[5]	Chronic Average Residue (ppm)
Kale, greens	1	*PDP Captan + THPI*	2004-2007	133	ND	65	65	39	0.0441
Lettuce	1	*PDP Captan + THPI*	2004-2007	378	0.070	78	78	22	0.0481
Pear, fruit	1	*PDP Captan + THPI*	2004-2007	1296	5.743	59	68	15	0.1314
Pear, dried	6.25	*See Pear, fruit*				100	100	15	0.1314
Pear, juice	1	*See Pear, fruit*				59	68	15	0.1314
Squash, summer	1	*PDP Captan + THPI*	2004-2007	216	0.380	36	36	64	0.0593
Squash, winter	1	*PDP Captan + THPI*	2004-2007	245	0.138	36	36	64	0.0261
Watermelon, fruit	1	*PDP Captan + THPI*	2004-2007	269	0.078	98	98	2	0.0682
Watermelon, juice	1	*See Watermelon, fruit*				98	98	2	0.0682
Bean, fresh	1	*CFIA, Domestic*	2003-2010	144	ND	7.5	7.5	65	0.0004
		CFIA, Import	2004-2010	383	2.640	83	100		0.0239
Bean, seed	1	*CFIA, Domestic*	*See Bean, fresh*			100	100	91	0.0058
		CFIA, Import				100	100		0.0249
Broccoli, fresh	1	*CFIA, Domestic*	2003-2010	157	ND	16	16	33	0.0010
		CFIA, Import	2004-2010	428	0.031	100	100		0.0071
Cabbage, fresh	1	*CFIA, Domestic*	2003-2010	306	0.040	15.5	15.5	25	0.0012
		CFIA, Import	2004-2010	505	ND	100	100		0.0061
Cauliflower	1	*CFIA, Domestic*	2003-2010	146	ND	18	18	37	0.0012
		CFIA, Import	2004-2010	412	ND	100	100		0.0064
Corn, fresh sweet	1	*CFIA, Domestic*	2003-2010	159	ND	5	5	84	0.0003
		CFIA, Import	2004-2010	177	ND	81	100		0.0050

Commodity	Proc. Factor Used[3]	Source of Data	Year Span	Number of Samples	Highest Residue Detected (ppm)	PCT[4] Chronic	PCT Acute	% Dom-Prod[5]	Chronic Average Residue (ppm)
Corn, field, flour	1	*CFIA, Domestic*	See Corn, fresh sweet			100	100	0	0.0058
		CFIA, Import				100	100		0.0061
Corn, field, meal	1	*CFIA, Domestic*	See Corn, fresh sweet			100	100	0	0.0058
		CFIA, Import				100	100		0.0061
Corn, field, bran	1	*CFIA, Domestic*	See Corn, fresh sweet			100	100	0	0.0058
		CFIA, Import				100	100		0.0061
Corn, field, starch	1.5	*CFIA, Domestic*	See Corn, fresh sweet			100	100	0	0.0058
		CFIA, Import				100	100		0.0061
Corn, field, syrup	1.5	*CFIA, Domestic*	See Corn, fresh sweet			100	100	0	0.0058
		CFIA, Import				100	100		0.0061
Corn, field, oil	1	*CFIA, Domestic*	See Corn, fresh sweet			100	100	0	0.0058
		CFIA, Import				100	100		0.0061
Corn, field, pop	1	*CFIA, Domestic*	See Corn, fresh sweet			100	100	0	0.0058
		CFIA, Import				100	100		0.0061
Cucumber, fresh	1	*CFIA, Domestic*	2003-2010	246	ND	11	11	81	0.0010
		CFIA, Import	2004-2010	611	0.166	100	100		0.0072
Onion, fresh, green	1	*CFIA, Domestic*	2003-2010	142	0.110	100	100	52	0.0072
		CFIA, Import	2004-2010	214	ND	100	100		0.0059
Onion, dry bulb	9	*CFIA, Domestic*	See Onion, fresh, green			100	100	52	0.0072
		CFIA, Import				100	100		0.0059
Onion, dried	9	*CFIA, Domestic*	See Onion, fresh, green			100	100	52	0.0072
		CFIA, Import				100	100		0.0059
Peach, fresh	1	*CFIA, Domestic*	2003-2010	233	9.420	57.5	57.5	47	0.0937
		CFIA, Import	2004-2010	357	0.720	51	63		0.0062

Commodity	Proc. Factor Used[3]	Source of Data	Year Span	Number of Samples	Highest Residue Detected (ppm)	PCT[4] Chronic	PCT Acute	% Dom-Prod[5]	Chronic Average Residue (ppm)
Peach, dried	7	*CFIA, Domestic*	See Peach, fresh			100	100	47	0.0965
		CFIA, Import				100	100		0.0092
Peach, juice	1	*CFIA, Domestic*	See Peach, fresh			57.5	57.5	47	0.0937
		CFIA, Import				51	63		0.0062
Pepper, fresh sweet	1	*CFIA, Domestic*	2003-2010	274	0.062	9	9	44	0.0011
		CFIA, Import	2004-2010	529	1.260	100	100		0.0083
Pepper, dried	1	*CFIA, Domestic*	See Pepper, fresh sweet			100	100	44	0.0078
		CFIA, Import				100	100		0.0083
Potato, tuber	1	*CFIA, Domestic*	2003-2010	1335	0.109	100	100	96	0.0058
		CFIA, Import	2004-2010	566	0.042	11	100		0.0006
Potato, chips	1	*CFIA, Domestic*	See Potato, tuber			100	100	96	0.0058
		CFIA, Import				100	100		0.0051
Potato, dry	6.5	*CFIA, Domestic*	See Potato, tuber			100	100	96	0.0058
		CFIA, Import				100	100		0.0051
Potato, flour	1	*CFIA, Domestic*	See Potato, tuber			100	100	96	0.0058
		CFIA, Import				100	100		0.0051
Raspberry, fruit	1	*CFIA, Domestic*	2003-2010	78	7.100	90	90	58	0.6107
		CFIA, Import	2004-2010	188	7.100	74	78		0.1114
Raspberry, juice	1	*CFIA, Domestic*	See Raspberry, fruit			90	90	58	0.6107
		CFIA, Import				74	78		0.1114
Spinach	1	*CFIA, Domestic*	2003-2010	129	ND	0	0	14	0
		CFIA, Import	2004-2010	211	ND	100	100		0.0052
Strawberry, fruit	1	*CFIA, Domestic*	2003-2010	165	3.500	50	50	26	0.2620
		CFIA, Import	2004-2010	469	25.500	64	89		1.1578

Commodity	Proc. Factor Used[3]	Source of Data	Year Span	Number of Samples	Highest Residue Detected (ppm)	PCT[4] Chronic	PCT Acute	% Dom-Prod[5]	Chronic Average Residue (ppm)
Strawberry, juice	1	*CFIA, Domestic*	See Strawberry, fruit			50	50	26	0.2620
		CFIA, Import				64	89		1.1578
Tomato, fresh	1	*CFIA, Domestic*	2003-2010	454	0.257	7	7	82	0.0028
		CFIA, Import	2004-2010	839	0.510	100	100		0.0080
Tomato, dried	14.3	*CFIA, Domestic*	See Tomato, fresh			100	100	82	0.0082
		CFIA, Import				100	100		0.0080
Tomato, juice	1.5	*CFIA, Domestic*	See Tomato, fresh			7	7	82	0.0028
		CFIA, Import				100	100		0.0080
Tomato, paste	5.4	*CFIA, Domestic*	See Tomato, fresh			100	100	82	0.0082
		CFIA, Import				100	100		0.0080
Tomato, puree	3.3	*CFIA, Domestic*	See Tomato, fresh			100	100	82	0.0082
		CFIA, Import				100	100		0.0080
Parsnip, fresh	1	*CFIA, Domestic*	2003-2010	190	0.070	100	100	94	0.0066
		CFIA, Import	2004-2010	N/A	N/A				
Radish, fresh	1	*CFIA, Domestic*	2003-2010	142	0.360	100	100	39	0.0089
		CFIA, Import	2004-2010	130	ND				
Rutabaga	1	*CFIA, Domestic*	2003-2010	133	ND	23	23	98	0.0013
		CFIA, Import	2004-2010	N/A	N/A				
Brussels sprouts	1	*CFIA, Domestic*	2003-2010	N/A	N/A	64	64	54	0.0061
		CFIA, Import	2004-2010	217	0.287				
Eggplant	1	*CFIA, Domestic*	2003-2010	N/A	N/A	64	64	39	0.0052
		CFIA, Import	2004-2010	306	0.118				
Garlic, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	97	97	3	0.0067
		CFIA, Import	2004-2010	373	ND				

Commodity	Proc. Factor Used[3]	Source of Data	Year Span	Number of Samples	Highest Residue Detected (ppm)	PCT[4] Chronic	PCT Acute	% Dom-Prod[5]	Chronic Average Residue (ppm)
Grapefruit, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	0	0.0062
		CFIA, Import	2004-2010	718	ND				
Guava	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	0	0.0139
		CFIA, Import	2004-2010	183	0.808				
Leek, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	40	0.0130
		CFIA, Import	2004-2010	178	1.200				
Lemon, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	0	0.0057
		CFIA, Import	2004-2010	523	ND				
Lemon, juice	2	*CFIA, Domestic*	See Lemon, fresh			100	100	0	0.0057
		CFIA, Import							
Lemon, peel	1	*CFIA, Domestic*	See Lemon, fresh			100	100	0	0.0057
		CFIA, Import							
Lime, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	0	0.0052
		CFIA, Import	2004-2010	352	ND				
Lime, juice	2	*CFIA, Domestic*	See Lime, fresh			100	100	0	0.0052
		CFIA, Import							
Mango, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	0	0.0061
		CFIA, Import	2004-2010	445	0.040				
Mango, juice or dried	1	*CFIA, Domestic*	See Mango, fresh			100	100	0	0.0061
		CFIA, Import							
Melon, honeydew	1	*CFIA, Domestic*	2003-2010	N/A	N/A	23	23	77	0.0020
		CFIA, Import	2004-2010	980	0.170				
Nectarine, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	32	45	11	0.0032
		CFIA, Import	2004-2010	342	0.227				

Commodity	Proc. Factor Used[3]	Source of Data	Year Span	Number of Samples	Highest Residue Detected (ppm)	PCT[4] Chronic	PCT Acute	% Dom-Prod[5]	Chronic Average Residue (ppm)
Orange, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	0	0.0059
		CFIA, Import	2004-2010	1857	0.011				
Orange, juice	1.8	*CFIA, Domestic*	See Orange, fresh			100	100	0	0.0059
		CFIA, Import							
Orange, peel	1	*CFIA, Domestic*	See Orange, fresh			100	100	0	0.0059
		CFIA, Import							
Papaya, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	58	58	0	0.0037
		CFIA, Import	2004-2010	408	0.016				
Papaya, dried	1.8	*CFIA, Domestic*	See Papaya, fresh			100	100	0	0.0064
		CFIA, Import							
Papaya, juice	1.5	*CFIA, Domestic*	See Papaya, fresh			58	58	0	0.0037
		CFIA, Import							
Pea, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	56	56	88	0.0073
		CFIA, Import	2004-2010	328	0.381				
Pea, dry or seed	1	*CFIA, Domestic*	See Pea, fresh			100	100	98	0.0096
		CFIA, Import							
Pineapple, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	0	0.0050
		CFIA, Import	2004-2010	286	ND				
Pineapple, dried	5	*CFIA, Domestic*	See Pineapple, fresh			100	100	0	0.0050
		CFIA, Import							
Pineapple, juice	1.7	*CFIA, Domestic*	See Pineapple, fresh			100	100	0	0.0050
		CFIA, Import							
Plum, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	38	46	11	0.0034
		CFIA, Import	2004-2010	248	0.350				

Commodity	Proc. Factor Used[3]	Source of Data	Year Span	Number of Samples	Highest Residue Detected (ppm)	PCT[4] Chronic	PCT Acute	% Dom-Prod[5]	Chronic Average Residue (ppm)
Plum, prune, fresh	1	*CFIA, Domestic*	See Plum, fresh			50	66	11	0.0040
		CFIA, Import							
Plum, prune, dried	5	*CFIA, Domestic*	See Plum, fresh			100	100	11	0.0067
		CFIA, Import							
Plum, prune, juice	1.4	*CFIA, Domestic*	See Plum, fresh			50	66	11	0.0040
		CFIA, Import							
Sweet potato	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	0	0.0039
		CFIA, Import	2004-2010	214	ND				
Apricot, fresh	1	*CFIA, Domestic*	2003-2010	120	2.280	70	70	22	0.0524
		CFIA, Import	2004-2010	164	0.870	29	50		0.0151
Apricot, dried	6	*CFIA, Domestic*	See Apricot, fresh			100	100	0	0.0540
		CFIA, Import							0.0197
Apricot, juice	1	*CFIA, Domestic*	See Apricot, fresh			70	70	22	0.0524
		CFIA, Import				29	50		0.0151
Cranberry, fresh	1	*CFIA, Domestic*	2003-2010	N/A	N/A	100	100	96	0.0055
		CFIA, Import	2004-2010	105	ND				
Cranberry, dried	1	*CFIA, Domestic*	See Cranberry, fresh			100	100	96	0.0055
		CFIA, Import							
Cranberry, juice	1.1	*CFIA, Domestic*	See Cranberry, fresh			100	100	96	0.0055
		CFIA, Import							

[1] For the acute exposure assessment, residue distributions were used.
[2] For the chronic exposure assessment, average residues were used.
[3] Proc. Factor Used = processing factor used. Note: a processing factor of 1.0 was used for processed commodities for which direct monitoring data were available.
[4] PCT = percent crop treated
[5] % Dom-Prod = percent domestic production
ND = Nondetect
N/A = Not available

Appendix IX Occupational and Residential Exposure Risk Estimates for Captan

Table 1 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Groundboom Application

Form	Crop	A	App Rate	ATPD[a]	MOE					Combined MOE[bf] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100		Inhal (IT)[de] Target = 300			
						No Resp	Resp[g]	No Resp	Resp[g]	No Resp	Resp[g]
Baseline PPE: Open M/L, Open Cab, wearing single layer, CR gloves (except for application)											
L	Strawberry	Farmer	3.6 kg a.i./ha	9 ha	2348	N/A	1350	N/A	N/A	N/A	2319
		Custom		26 ha	813		4674		134		803
WP	Raspberry	Farmer	2.0 kg a.i./ha	5 ha	1134		1959		N/A		807
	Strawberry	Farmer	3.4 kg a.i./ha	9 ha	371		640				356
	Cucumber	Farmer	3.4 kg a.i./ha	5 ha	667		1153				641
			2.6 kg a.i./ha		872		1507				838
	Pumpkin, squash	Farmer	3.375 kg a.i./ha	6 ha	560		968				761
			2.5 kg a.i./ha		756		1306				727
	Flowers	Farmer	1.0 kg a.i./ha	10 ha	1134		1959				1090
		Custom		26 ha	436		754		22		419
	Flowers	Farmer	1.2 kg a.i./ha	10 ha	945		1633		N/A		908
		Custom		26 ha	363		628		18		349
WG	Raspberries	Farmer	2.0 kg a.i./ha	5 ha	3253		56566		N/A		3240
		Custom		26 ha	626		10878		311		623
	Blackberry, loganberry, blueberry	Both	1.8 kg a.i./ha	26 ha	695		12087		345		692
	Strawberry	Farmer	3.4 kg a.i./ha	9 ha	1063		18486		N/A		1059
		Custom		26 ha	368		6399		183		367
	Cucumber	Farmer	3.4 kg a.i./ha	5 ha	1913		33274		N/A		1906
			2.6 kg a.i./ha		2502		43512				2492
		Custom	3.4 kg a.i./ha	26 ha	368		6399		183		367
			2.6 kg a.i./ha		481		2112		239		479
	Tomato	Farmer	3.4 kg a.i./ha	15 ha	638		11091		N/A		635
		Custom		26 ha	368		6399		183		367
WG	Soil treatment: other veggies	Farmer	8.5 kg a.i./ha	8 ha	478	N/A	8318	N/A	N/A	N/A	476
			11.3 kg a.i./ha		360		6268				359
	Flowers	Farmer	1.0 kg a.i./ha	10 ha	3253		56566		N/A		3240
		Custom		26 ha	1251		21756		622		1246

Table 1 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Groundboom Application

Form	Crop	A	App Rate	ATPD[a]	MOE					Combined MOE[bf] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100		Inhal (IT)[de] Target = 300			
						No Resp	Resp[g]	No Resp	Resp[g]	No Resp	Resp[g]
		Farmer	1.2 kg a.i./ha	10 ha	2710		47138		N/A		2670
		Custom		26 ha	1043		18130		518		1038
	Golf course	Farmer	4.8 kg a.i./ha	16 ha	423		7365		N/A		422
Mid PPE: Open M/L, Open Cab, wearing coveralls over single layer, CR gloves (except for application)											
WP	Raspberry	Custom	2.0 kg a.i./ha	26 ha	314	N/A	377	N/A	11	N/A	297
	Blackberry, loganberry, blueberry	Both	1.8 kg a.i./ha	26 ha	349		419		12		329
	Tomato	Farmer	3.4 kg a.i./ha	15 ha	320		384		N/A		302
WG	Soil treatment: ornamental, celery	Farmer	8.5 kg a.i./ha	20 ha	333		3327				331
	Soil treatment: cabbage, cauliflower	Farmer	11.3 kg a.i./ha	15 ha	335		3343				332
	Soil treatment: rutabaga, turnip	Farmer	11.3 kg a.i./ha	10 ha	502		5015				499
	Sod farm	Farmer	4.8 kg a.i./ha	30 ha	393		3928				391
Partial EC (M/L-BL): Closed M/L, Open Cab wearing single layer, CR gloves (except for application)											
WP	Strawberry, cucumber, tomato	Custom	3.4 kg a.i./ha	26 ha	1326	N/A	4590	N/A	131	N/A	1300
	Cucumber	Custom	2.6 kg a.i./ha	26 ha	1734		6003		172		1700
WP	Pumpkin, squash	Custom	3.375 kg a.i./ha	26 ha	1336	N/A	4624	N/A	132	N/A	1310
			2.5 kg a.i./ha		1804		6243		178		1768
	Soil treatment: Ornamentals, celery	Farmer	10.6 kg a.i./ha	20 ha	553		1914		N/A		542
	Soil treatment: bean	Farmer	10.6 kg a.i./ha	25 ha	442		1531				434
	Soil treatment: other veggies	Farmer	10.6 kg a.i./ha	8 ha	1383		4785				1355

Table 1 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Groundboom Application

Form	Crop	A	App Rate	ATPD[a]	MOE					Combined MOE[bf] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100		Inhal (IT)[de] Target = 300			
						No Resp	Resp[g]	No Resp	Resp[g]	No Resp	Resp[g]
	Soil treatment: Ornamentals	Farmer	11.3 kg a.i./ha	20 ha	521		1804				511
	Soil treatment: cabbage, cauliflower	Farmer	11.3 kg a.i./ha	15 ha	695		2405				681
	Soil treatment: rutabaga, turnip	Farmer	11.3 kg a.i./ha	10 ha	1042		3607				1021
	Soil treatment: other veggies	Farmer	11.3 kg a.i./ha	8 ha	1303		4509				1277
	Sod farm	Farmer	4.75 kg a.i./ha	30 ha	823		2848				806
	Golf course	Farmer		16 ha	1543		5339				1512
WG	Potato	Farmer	3.0 kg a.i./ha	85 hah	460		1591				451
	Soil treatment: lawn seedbed	Farmer	8.5 kg a.i./ha	50 ha	368		955				358
	Soil treatment: bean	Farmer	8.5 kg a.i./ha	25 ha	736		1910				717
	Soil treatment: ornamental	Farmer	11.3 kg a.i./ha	20 ha	694		1799				675
Partial EC (M/L-Mid): Closed M/L wearing coveralls and CR gloves; Open Cab wearing coveralls over single layer											
WP	Soil treatment: Lawn seedbed	Farmer	10.6 kg a.i./ha	50 ha	410	N/A	766	N/A	N/A	N/A	395
Partial EC (A): Open M/L, Closed Cab wearing single layer, CR gloves (except for application)											
WG	Flowers	Custom	1.0 kg a.i./ha	26 ha	1408	N/A	NR[h]	N/A	760	N/A	1403
			1.2 kg a.i./ha		1173				633		1169
Engineering Controls (BL): Closed M/L, Closed Cab wearing single layer, CR gloves (except for application)											
L	Strawberry	Custom	3.6 kg a.i./ha	26 ha	2279	NR[h]	N/A	201	N/A	2229	N/A
WP	Raspberry	Custom	2.0 kg a.i./ha	26 ha	6488			256		6175	
	Blackberry, loganberry, blueberry	Custom	1.8 kg a.i./ha	26 ha	4187			285		4068	
WP	Strawberry, tomato,	Custom	3.4 kg a.i./ha	26 ha	2217			151		2153	

Table 1 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Groundboom Application

Form	Crop	A	App Rate	ATPD[a]	MOE					Combined MOE[bf] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100		Inhal (IT)[de] Target = 300			
						No Resp	Resp[g]	No Resp	Resp[g]	No Resp	Resp[g]
	cucumber										
	Cucumber	Custom	2.6 kg a.i./ha	26 ha	2899			197		2816	
	Pumpkin, squash	Custom	3.375 kg a.i./ha	26 ha	2233			152		2169	
			2.5 kg a.i./ha		3015			205		2929	
	Flowers	Custom	1.0 kg a.i./ha	26 ha	7537			513		7322	
			1.2 kg a.i./ha		6281			427		6101	
WG	Strawberry, cucumber, tomato	Custom	3.4 kg a.i./ha	26 ha	2216			151		2153	
	Cucumber	Custom	2.6 kg a.i./ha	26 ha	2899			197		2816	
Engineering Controls (Mid): Closed M/L, Closed Cab wearing single layer, CR gloves (except for application)											
WG	Potato	Custom	3.0 kg a.i./ha	360 ha	480	432	N/A	12	N/A	445	N/A

Shaded cells indicate MOEs that are less than the target MOE.
Form = formulation; L = liquid; WP = wettable powder; WG = wettable granule; A = applicator; ATPD = area treated per day; App Rate= application rate; Inhal = inhalation; M/L = mixer/loader; ST = short-term; IT = intermediate-term; No resp = without respirator; Resp = with respirator**;** CR = chemical-resistant; PPE = personal protective equipment; Single layer = long sleeved shirt, long pants; BL= level of mitigation that includes single layer; Mid = level of mitigation that includes coveralls over single layer; EC = engineering controls includes closed mixing/loading and/or closed cab
[a] Area treated per day values are refined where possible.
[b] Oral NOAEL of 20 mg/kg bw/day from a rabbit development study and target MOE of 300.
[c] Inhalation NOAEL of 1.4 mg/kg bw/day from a rat inhalation study and target MOE of 100.
[d] Inhalation NOAEL of 0.04 mg/kg bw/day from a rat inhalation study and an intermediate-term target MOE of 300.
[e] Where more than 3 applications are possible according to current label directions, intermediate-term inhalation exposure was considered for custom applicators.
[f] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure), as both the dermal and inhalation exposure could contribute to the oral endpoint.
[g] Respirators were not included with closed cabs, as the protection factor is already accounted for in the closed scenario and would be a double counting of protection. Respirators were also not included with closed mixing/loading. For scenarios where engineering controls were only applied to either mixing/loading or application, the 'resp' column was used as a respirator was assumed for the activity that did not have an engineering control.
[h] NR = not required. MOE was met at a lower level of mitigation. Additional mitigation was investigated as the intermediate-term inhalation MOEs did not reach the target MOE at a lower level of mitigation.

Table 2 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Airblast Application

Formulation	Crop	App Rate	ATPD[a]	MOE			Combined MOE[bd] Target = 300	
				Dermal[b] Target = 300	Inhal (ST)[c] Target = 100			
					No Resp	Resp[e]	No Resp	Resp[e]
Headgear (HO-BL): Open M/L wearing coveralls, CR gloves; Open Cab, wearing single layer, CR headgear, CR gloves								
L	Apple	2.4 kg a.i./ha	20 ha	298	N/A	2185	N/A	295
		1.5 kg a.i./ha		477		3496		472
	Pear	2.4 kg a.i./ha	5 ha	1191		8739		1180
	Cherry, sour	3.2 kg a.i./ha	11 ha	406		2979		402
	Cherry, sweet	3.2 kg a.i./ha	4 ha	1117		8192		1106
	Plum, prune	3.2 kg a.i./ha	3 ha	1489		10924		1475
	Apricot	3.2 kg a.i./ha	2 ha	2234		16286		2212
	Grape	2.4 kg a.i./ha	20 ha	298		2185		295
WG	Raspberry	2.0 kg a.i./ha	5 ha	1263		11089		1253
	Blackberry, loganberry, blueberry	1.8 kg a.i./ha	20 ha	351		3080		348
	Apple	1.5 kg a.i./ha	20 ha	421		3696		418
	Pear	2.4 kg a.i./ha	5 ha	1052		9241		1044
	Cherry, sour	3.2 kg a.i./ha	11 ha	359		3150		356
	Cherry, sweet	3.2 kg a.i./ha	4 ha	987		8663		979
	Plum, prune	3.2 kg a.i./ha	3 ha	1315		11551		1305
	Apricot	3.2 kg a.i./ha	2 ha	1973		17327		1957
Headgear (HO-Mid): Open M/L wearing coveralls, CR gloves; Open Cab, wearing coveralls, CR headgear, CR gloves								
L	Peach, nectarine	3.2 kg a.i./ha	20 ha	524	N/A	1639	N/A	513
WG	Apple, grape	2.4 kg a.i./ha	20 ha	534		2310		525
Partial EC (A): Open M/L wearing coveralls, CR gloves; Closed Cab wearing single layer, CR gloves								
WP	Raspberry	2.0 kg a.i./ha	5 ha	1550	N/A	1806	N/A	1462
	Blackberry, loganberry, blueberry	1.8 kg a.i./ha	20 ha	431		502		406
WP	Apple	2.4 kg a.i./ha	20 ha	323	N/A	376	N/A	305
		1.5 kg a.i./ha		517		602		487
	Pear	2.4 kg a.i./ha	5 ha	1292		1505		1219
	Cherry, sour	3.2 kg a.i./ha	11 ha	440		513		415
	Cherry, sweet	3.2 kg a.i./ha	4 ha	1211		1411		1142

Table 2 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Airblast Application

Formulation	Crop	App Rate	ATPD[a]	MOE			Combined MOE[bd] Target = 300	
				Dermal[b] Target = 300	Inhal (ST)[c] Target = 100			
					No Resp	Resp[e]	No Resp	Resp[e]
	Plum, prune	3.2 kg a.i./ha	3 ha	1615		1882		1523
	Apricot	3.2 kg a.i./ha	2 ha	2422		2823		2285
	Grape	2.4 kg a.i./ha	20 ha	323		376		305
Partial EC (M/L) and Headgear: Closed M/L wearing single layer, CR gloves; Open Cab, wearing single layer, CR headgear, CR gloves								
WP	Raspberry	2.0 kg a.i./ha	5 ha	1466	N/A	10294	N/A	1452
	Blackberry, loganberry, blueberry	1.8 kg a.i./ha	20 ha	407		2859		403
	Apple	2.4 kg a.i./ha	20 ha	305		2145		302
		1.5 kg a.i./ha		489		3431		484
	Pear	2.4 kg a.i./ha	5 ha	1222		8578		1210
	Cherry, sour	3.2 kg a.i./ha	11 ha	417		2924		412
	Cherry, sweet	3.2 kg a.i./ha	4 ha	1146		8042		1134
	Plum, prune	3.2 kg a.i./ha	3 ha	1527		10723		1512
	Apricot	3.2 kg a.i./ha	2 ha	2291		16085		2268
	Grape	2.4 kg a.i./ha	20 ha	305		2145		302
WG	Apple, grape	2.4 kg a.i./ha	20 ha	305		1877		302
Partial EC (M/L) and Headgear: Closed M/L wearing single layer, CR gloves; Open Cab, wearing coveralls, CR headgear, CR gloves								
WP/WG	Peach, nectarine	3.2 kg a.i./ha	20 ha	557	N/A	1410	N/A	542

Shaded cells indicate MOEs that are less than the target MOE.

L = liquid; WP = wettable powder; WG = wettable granule; ATPD = area treated per day; App rate = application rate; Inhal = inhalation; M/L = mixer/loader; ST = short-term; No resp = without respirator; Resp = with respirator; CR = chemical-resistant; PPE = personal protective equipment; Single layer = long sleeved shirt, long pants; HO = level of mitigation that includes headgear for applicators; Headgear = chemical resistant hat that covers the neck; BL= level of mitigation that includes single layer; Mid = level of mitigation that includes coveralls over single layer; EC = engineering controls includes closed mixing/loading and/or closed cab

[a] Area treated per day values are refined where possible.

[b] Oral NOAEL of 20 mg/kg bw/day from a rabbit development study and target MOE of 300.

[c] Inhalation NOAEL of 1.4 mg/kg bw/day from a rat inhalation study and target MOE of 100.

[d] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure), as both the dermal and inhalation exposure could contribute to the oral endpoint.

[e] Respirators were not included with closed cabs as the protection factor is already accounted for in the closed scenario and would be a double counting of protection. Respirators were also not included with closed mixing/loading. For scenarios where engineering controls were only applied to either mixing/loading or application, the 'resp' column was used as a respirator was assumed for the activity that did not have an engineering control.

Table 3 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Aerial Application

Form	Crop	Activity	App Rate	ATPD[a]	MOE			Combined MOE[bd] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100			
						No Resp	Resp[e]	No Resp	Resp[e]
Engineering Controls-BL: Closed M/L, Closed Cab wearing single layer, CR gloves (except for applicators)									
L	Strawberry	A	3.6 kg a.i./ha	340 ha	541	1307	N/A	526	N/A
	Apple, Pear, grape	M/L	2.4 kg a.i./ha	280 ha	503	1515		491	
		A			986	2381		958	
	Apple	M/L	1.5 kg a.i./ha		804	2424		786	
		A			1577	3810		1533	
	Apricot, cherry, peach, plum, prune	M/L	3.2 kg a.i./ha	280 ha	377	1136		368	
		A			739	1786		719	
WG	Blueberry	M/L	1.8 kg a.i./ha	340 ha	484	1017		468	
		A			1083	2614		1052	
	Strawberry	A	3.4 kg a.i./ha	340 ha	573	1384		557	
	Cucumber, tomato	M/L	3.4 kg a.i./ha	200 ha	436	915		421	
		A			974	2353		947	
	Cucumber	M/L	2.6 kg a.i./ha	200 ha	570	1197		551	
		A			1274	3077		1238	
	Potato	A	3.0 kg a.i./ha	400 ha	552	1333		537	
	Apple, pear	M/L	2.4 kg a.i./ha	280 ha	441	926		427	
		A			986	2381		958	
	Apple	M/L	1.5 kg a.i./ha	280 ha	705	1481		682	
		A			1577	3810		1533	
	Apricot, cherry, peach, plum, prune	M/L	3.2 kg a.i./ha	280 ha	331	694		320	
		A			739	1786		719	
	Grape	M/L	2.4 kg a.i./ha	340 ha	363	763		351	
		A			812	1961		789	
Engineering Controls-Mid: Closed M/L, wearing coveralls over single layer, CR gloves									
L	Strawberry	M/L	3.6 kg a.i./ha	340 ha	544	832	N/A	520	N/A
WG	Strawberry	M/L	3.4 kg a.i./ha	340 h	699	538		640	
	Potato	M/L	3.0 kg a.i./ha	400 ha	673	519		617	

Shaded cells indicate MOEs that are less than the target MOE.

Form = formulation; L = liquid; WP = wettable powder; WG = wettable granule; A = applicator; ATPD = area treated per day; App rate = application rate; Inhal = inhalation; M/L = mixer/loader; ST = short-term; IT = intermediate-term; No resp = without respirator; Resp = with respirator CR = chemical-resistant; PPE = personal protective equipment; Single layer = long sleeved shirt, long pants; BL= level of mitigation that includes single layer; Mid = level of mitigation that includes coveralls over single layer;

[a] Area treater per day values are refined where possible.
[b] Oral NOAEL of 20 mg/kg bw/day from a rabbit development study and target MOE of 300.
[c] Inhalation NOAEL of 1.4 mg/kg bw/day from a rat inhalation study and target MOE of 100.
[d] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure), as both the dermal and inhalation exposure could contribute to the oral endpoint.
[e] Respirators were not included with closed cabs as the protection factor is already accounted for in the closed scenario and would be a double counting of protection. Respirators were also not included with closed mixing/loading.

Table 4 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Handheld Application

Form	Crop	App Equip	App Rate	ATPD[a]	MOE					Combined MOE[bf] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100		Inhal (IT)[d] Target = 300			
						No Resp	Resp[g]	No Resp	Resp[g]	No Resp	Resp[g]
Baseline PPE: Open M/L, wearing single layer, CR gloves											
L	Strawberry	Backpack	1.8 kg a.i./1000 L	150 L	4353	N/A	66798	N/A	N/A	N/A	4333
		Man PHW		150 L	25127		91773		N/A		24654
WP	Greenhouse soil treatment	Backpack	2.1 kg a.i./1000 L	150 L	3367		NR[e]		851		3333
			2.3 kg a.i./1000 L		3173				801		3141
	Greenhouse flowers	Backpack	1.0 kg a.i./1000 L	150 L	7138				1800		7067
			1.2 kg a.i./1000 L		5949				1503		5889
	Greenhouse rhubarb	Backpack	1.6 kg a.i./1000 L	150 L	4393				1110		34736
	Raspberries	Backpack	2.0 kg a.i./1000 L	150 L	3569		31558		NR[e]		3541
		Man PHW		150 L	1080		2624				1050
	Blackberry, loganberry, blueberry	Backpack	1.8 kg a.i./1000 L	150 L	3966		35065				3935
		Man PHW		150 L	1201		2915				1167
	Strawberry	Backpack	3.4 kg a.i./1000 L	150 L	2099		18564				2083
		Man PHW		150 L	636		1543				618
	Tomato	Backpack	7.6 kg a.i./1000 L	150 L	945		8354				937
	Field soil treatment	Backpack	2.1 kg a.i./1000 L	150 L	3367		29772				3341
		Man PHW		150 L	1019		2475				991
		Backpack	2.3 kg a.i./1000 L	150 L	3173		28052				3148
		Man PHW		150 L	960		2332				933
	Flowers	Backpack	1.0 kg a.i./1000 L	150 L	7138		63116				7082
		Man PHW		150 L	2161		5247				2100
	Flowers	Backpack	1.2 kg a.i./1000 L	150 L	5949		52597				5902

Table 4 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Handheld Application

Form	Crop	App Equip	App Rate	ATPD[a]	MOE					Combined MOE[bf] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100		Inhal (IT)[d] Target = 300			
						No Resp	Resp[g]	No Resp	Resp[g]	No Resp	Resp[g]
		Man PHW		150 L	1801		4373				1750
	Sod farm, golf courses	Backpack	4.75 kg a.i./ha	0.4 ha	564		4983				559
		Turf gun[h]		2.0 ha	542		771				517
WG	Greenhouse soil treatment	Backpack	1.7 kg a.i./1000 L	150 L	4474		N/A[e]		1988		4454
		Man PHW		150 L	22670				2715		22297
		Backpack	2.3 kg a.i./1000 L	150 L	3371				1498		3356
		Man PHW		150 L	17082				2046		16802
WG	Greenhouse tobacco seedlings	Backpack	2.5 kg a.i./1000 L	150 L	12189	N/A	NR[e]	N/A	5416	N/A	12134
		Man PHW		150 L	61759				7397		60745
	Greenhouse flowers	Backpack	1.0 kg a.i./1000 L	150 L	7605				3380		7572
		Man PHW		150 L	38538				4616		33023
		Backpack	1.2 kg a.i./1000 L	150 L	6338				2817		6310
		Man PHW		150 L	32115				3846		31587
	Greenhouse rhubarb	Backpack	1.6 kg a.i./1000 L	150 L	4695				2086		4674
		Man PHW		150 L	23789				2849		23398
	Raspberry	Backpack	2.0 kg a.i./1000 L	150 L	3802		59147		NR[e]		3786
		Man PHW		150 L	19269		80773				18952
	Blueberry, loganberry, blackberry	Backpack	1.8 kg a.i./1000 L	150 L	4226		65718				4207
		Man PHW		150 L	21410		89748				21058
	Strawberry	Backpack	3.4 kg a.i./1000 L	150 L	2237		34792				2227
		Man PHW		150 L	13302		48586				13052
	Tomato	Backpack	7.5 kg a.i./1000 L	150 L	1007		15656				1002
		Man PHW		150 L	5101		21381				5017
	Field soil Treatment	Backpack	1.7 kg a.i./1000 L	150 L	4474		69584				4454
		Man PHW		150 L	22669		95027				22297
		Backpack	2.3 kg a.i./1000 L	150 L	3371		52435				3356
		Man PHW		150 L	17082		71607				16802
	Field Flowers	Backpack	1.0 kg a.i./1000 L	150 L	7606		118293				7572
		Mec PHG		3800 L	293		1939				290
WG	Field Flowers	Man PHW		150 L	38538	N/A	161546	N/A	NR[e]	N/A	37905
		Backpack	1.2 kg a.i./1000 L	150 L	6338		98578				6310

Table 4 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Handheld Application

Form	Crop	App Equip	App Rate	ATPD[a]	MOE					Combined MOE[bf] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100		Inhal (IT)[d] Target = 300			
						No Resp	Resp[g]	No Resp	Resp[g]	No Resp	Resp[g]
		Man PHW		150 L	32115		134622				31587
	Golf course, sod farm	Backpack	4.8 kg a.i./ha	0.4 ha	594		9242				592
		Turf gun[h]		2.0 ha	517		2441				509
Mid PPE: Open M/L, wearing coveralls over single layer, CR gloves											
WG	Field Flowers	Mec PHG	1.2 kg a.i./1000 L	3800 L	551	N/A	1616	N/A	NR[e]	N/A	539
Partial EC (M/L): Closed M/L wearing single layer, CR gloves											
WP	Greenhouse soil treatment	Man PHW	2.1 kg a.i./1000L	150 L	21334	N/A	NR[e]	N/A	2226	N/A	20933
			2.3 kg a.i./1000L		20101				2098		19723
	Greenhouse Flowers	Man PHW	1.0 kg a.i./1000L	150 L	45228				4720		44377
			1.2 kg a.i./1000L		37690				3933		36981
	Greenhouse Rhubarb	Man PHW	1.6 kg a.i./1000L	150 L	27833				2904		27309
	Tomato	Backpack	7.6 kg a.i./1000 L	150 L	5986		21864		NR[e]		5873
	Flowers	Mec PHG	1.0 kg a.i./1000 L	3800 L	302		1952				298
Partial EC (M/L): Closed M/L wearing coveralls over single layer, CR gloves											
WP	Greenhouse soil treatment	Mec PHG	2.1 kg a.i./1000 L	3800 L	324	N/A	NR[e]	N/A	26	N/A	316
			2.3 kg a.i./1000 L		305				25		298
	Greenhouse Flowers	Mec PHG	1.0 kg a.i./1000 L	3800 L	686				56		670
			1.2 kg a.i./1000 L		572				46		558
	Field soil treatment	Mec PHG	2.1 kg a.i./1000 L	3800 L	324		921		NR[e]		316
	Field soil treatment	Mec PHG	2.3 kg a.i./1000 L	3800 L	305		868				298
	Flowers	Mec PHG	1.2 kg a.i./1000 L	3800 L	572	N/A	1627	N/A		N/A	558
WG	Greenhouse soil treatment	Mec PHG	1.7 kg a.i./1000 L	3800 L	404		NR[e]		33		394
		Mec PHG	2.3 kg a.i./1000 L	3800 L	304				25		297
	Greenhouse tobacco seedlings	Mec PHG	2.5 kg a.i./1000 L	3800 L	1100				89		1074

Table 4 M/L/A Short- to Intermediate-Term Exposure and Risk Assessment for Handheld Application

Form	Crop	App Equip	App Rate	ATPD[a]	MOE					Combined MOE[bf] Target = 300	
					Dermal[b] Target = 300	Inhal (ST)[c] Target = 100		Inhal (IT)[d] Target = 300			
						No Resp	Resp[g]	No Resp	Resp[g]	No Resp	Resp[g]
	Greenhouse flowers	Mec PHG	1.0 kg/1000 L	3800 L	686				56		670
			1.2 kg/1000 L		572				47		558
	Field soil treatment	Mec PHG	1.7 kg a.i./1000 L	3800 L	404		1148		NR[e]		394
			2.3 kg a.i./100 L	3800 L	304		865				297

Shaded cells indicate MOEs that are less than the target MOE.
Form = formulation; L = liquid; WP = wettable powder; WG = wettable granule; ATPD = area treated per day; App rate= application rate; Inhal = inhalation; M/L = mixer/loader; ST = short-term; IT = intermediate-term; No resp = without respirator; Resp = with respirator; CR = chemical-resistant; PPE = personal protective equipment; Single layer = long sleeved shirt, long pants; EC = engineering controls includes closed mixing/loading and/or closed cab; Man PHW = manually pressurized handwand; Mec PHG= mechanically pressurized handgun
[a] Area treated per day values are refined where possible.
[b] Oral NOAEL of 20 mg/kg bw/day from a rabbit development study and target MOE of 300.
[c] Inhalation NOAEL of 1.4 mg/kg bw/day from a rat inhalation study and target MOE of 100.
[d] Inhalation NOAEL of 0.04 mg/kg bw/day from a rat inhalation study and an intermediate-term target MOE of 300.
[e] Not required. For non-greenhouse scenarios, only short-term inhalation exposure was assumed. For greenhouse scenarios, only intermediate-term inhalation was assumed.
[f] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure), as both the dermal and inhalation exposure could contribute to the oral endpoint.
[g] Respirators were included with closed mixing/loading scenarios as there was only 1 unit exposure value for mixers/loaders and applicators.
[h] Unit exposure values from Outdoor Residential Exposure Task Force (ORETF)

Table 5 Summary of Amount Handled per Day

Application Equipment	Proposed PPE	Amount Handled per Day Threshold[a]	Crop where MOE<Target MOE at proposed PPE	Additions Mitigation to Reach Target MOE	Outcome	Additional Mitigation
Wettable Powder						
Groundboom	Open cab, wearing single layer, respirator	389 kg a.i./day	Soil Treatment: lawn seedbed	Requires coveralls	MOEs met with higher mitigation	
Mechanically-Pressurized Handgun	Closed M/L, wearing single layer, CR gloves, respirator	3.8 kg a.i./day	Outdoor crops	Requires coveralls	MOEs met with higher mitigation	
			Greenhouse crops		MOEs **not** met with higher	Do not handle more than 0.62 kg

					mitigation.	a.i./day
Wettable Granule						
Groundboom	Open cab, wearing single layer, respirator	389 kg a.i./day	Potato (Custom)	Required closed cab	MOEs met with higher mitigation	
Aerial	Closed M/L (WSP), wearing single layer, CR gloves	956 kg a.i./day	Strawberry Potato	Requires coveralls	MOEs met with higher mitigation	
Mechanically-Pressurized Handgun	Closed M/L (WSP), wearing single layer, CR gloves, respirator	3.8 kg a.i./day	Outdoor crops	Requires coveralls	MOEs met with higher mitigation	
			Greenhouse crops		MOEs **not** met with higher mitigation.	Do not handle more than 0.62 kg a.i./day

WSP = water soluble package; MOE = margin of exposure' single layer = long sleeved shirt, long pants; CR = chemical resistant

[a] PPE = personal protective equipment. PPE that will be proposed (Section 8) for this application equipment/scenario

[b] Amount handled per day at which the lower level of mitigation, being proposed on the label, will reach the target MOE. Above this amount, the additional PPE will be required.

Table 6 Commercial Seed Treatment Exposure and Risk Assessment

Crop	Form	Activity[a]	Application Rate (g a.i./100 kg seed)	Throughput[b] (kg seed/day)	MOE		
					Dermal[c] Target = 300	ST Inhalation[d] (Resp/DM) Target = 100	Combined[e] Target = 300
Dean 1993: Closed Mix/load, wearing single layer, CR gloves							
Alfalfa, clover	Liquid	Treater/bagger	260	20263[f]	340	179	300
		Stacker/tagger			1970	309[g]	1360
		Forklift operator			10,100	8790[g]	9350
Broccoli, Brussels sprouts, cabbage, cauliflower		Treater/bagger	52.785	99810[f]	340	179	300
		Stacker/tagger			1970	309[g]	1360
		Forklift operator			10,100	8790[g]	9350
Sugar beet		Treater/bagger	223.2	23604[f]	340	179	300
		Stacker/tagger			1970	309[g]	1360
		Forklift operator			10,100	8790[g]	9350
Krolski, 2006: Open Mix/load, wearing single layer, CR gloves							
Pea	Liquid	M/L/A	100.8	73,000	327	6160	616
Lentil, chickpea		M/L/A	94.08	73,000	351	6600	660
Lupin		M/L/A	94.08	55,000	466	8760	876
Wilson, 2009a: Closed Mix/load, wearing single layer, CR gloves and CR coveralls for cleaners							
Alfalfa, clover	Liquid	Treater	260	20,263[h]	138,000	1,330,000	137,000
		Cleaner			1330	6730	1320
		Treater+cleaner			1320	6700	1300
Broccoli, Brussels sprouts, cabbage, cauliflower		Treater	52.785	99,810[h]	138,000	1,330,000	137,000
		Cleaner			6570	33,200	6480
		Treater+cleaner			6270	32,350	6190
Sugar beet		Treater	223.2	23,604[h]	138,000	1,330,000	137,000
		Cleaner			1550	7840	1530
		Treater+cleaner			1540	7800	1520
Pea		Treater	100.8	73,000	98,800	951,000	98,100
		Cleaner			3440	17,400	3390
		Treater+cleaner			3320	17,000	3280
Lentil, chickpea	Liquid	Treater	94.08	73,000	106,000	1,020,000	105,000
		Cleaner			3690	18,600	3640
		Treater+cleaner			3560	18,300	3510

Table 6 Commercial Seed Treatment Exposure and Risk Assessment

Crop	Form	Activity[a]	Application Rate (g a.i./100 kg seed)	Throughput[b] (kg seed/day)	MOE		
					Dermal[c] Target = 300	ST Inhalation[d] (Resp/DM) Target = 100	Combined[e] Target = 300
Lupin		Treater	94.08	55,000	141,000	135,000	140,000
		Cleaner			3690	18600	3640
		Treater+cleaner			3590	18,300	3540
Krolski, 2010: Closed Mix/load, wearing single layer, CR gloves							
Corn	Liquid	Treater	119.255	60,000	349	5734	348
		Bagger, sewer, stacker			1060	879[g]	974
		Cleaner			423	470	398
Corn, field		Treater	72.0	60,000	579	9497	576
		Bagger, sewer, stacker			1750	1460[g]	1610
		Cleaner			700	778	658
Corn, sweet		Treater	122.4	60,000	340	5586	339
		Bagger, sewer, stacker			1030	857[g]	949
		Cleaner			412	458	387
Soybean		Treater	100.8	45,000	551	9044	549
		Bagger, sewer, stacker			1670	1390[g]	1540
		Cleaner			500	556	470
Bean		Treater	100.8	73,000	340	5575	338
		Bagger, sewer, stacker			1030	855[g]	947
		Cleaner			500	556	470
Bean	WP[i]	Treater	93.6	73,000	366	6000	364
		Bagger, sewer, stacker			1110	921[g]	1020
		Cleaner			538	598	506

Resp= respirator; DM= dust mask; WP=wettable powder; M/L/A= mixer/loader/applicator; Form= formulation; ST=short-term; CR = chemical resistant; Single layer = long sleeved shirt, long pants

[a] Activities are based on what was monitored in the exposure study.

[b] Throughput is dependent on seed type.

[c] Based on an oral NOAEL of 20 mg/kg bw/day from a rabbit development toxicity study and dermal absorption of 25%.

[d] Inhalation NOAEL of 1.4 mg/kg bw/day from a 21-day rat inhalation study.
[e] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure). As both the dermal and inhalation exposure could contribute to the oral endpoint
[f] There were no data available to estimate throughputs for alfalfa, clover, broccoli, Brussels sprouts, cabbage, cauliflower, sugar beet. The throughput at which the mixer/loader activity reached the target MOE was calculated. These throughputs were considered to be reasonable and likely agronomically feasible.
[g] For activities downstream of mixing/loading, where the exposure values were reported separately for these activities, a dust mask instead of a respirator was included in the risk assessment. The footnote "g" indicates that a protection factor of 80% for a N95 dust mask was used otherwise; a protection factor of 90% for a respirator was used
[h] Calculated throughput value, as determined using Dean (1993).
[i] For closed mix/load scenarios, the wettable powder was assumed to be in water soluble packets, and exposure was assumed to be equivalent to the liquid formulation.

Table 7 On-Farm Seed Treatment Exposure and Risk Assessment for Mixing/Loading and Planting

Crop	Form	Activity[a]	Application Rate (g a.i./100 kg seed)	Throughput[b] (kg seed/day)	MOE			
					Dermal[c] Target = 300	ST Inhalation[d] Target = 100		Combined[e] Target = 300
						No Resp	DM[f]	
Klonne, 2005[g]: Open loading, closed cab planter, single layer, CR gloves								
Corn, sweet	WP (dust)[h]	Mix/load, plant	90.0	425	1600	258	N/A	1120
Klonne, 2005 [g]: Open loading, closed cab planter, CR coveralls over single layer, CR gloves								
Beans, dry common	WP (dust) [h]	Mix/load, plant	93.6	8300	216	13	N/A	99
Purdy, 1999: Open loading, open cab planter, single layer, CR gloves								
Beans, dry common	Liquid	Mix/load, plant	94.08	8300	2010	N/A	322	1400
Soybeans			94.08	5232	3190		510	2220
Peas			94.08	9600	1740		278	1210
Sugar beet			208.32	72	105,000		16,800	73,200
Corn, field (custom)			67.2	2312	10,100		1620	7030
Corn, field (farmer)			67.2	1156	20,200		3230	14,100
Corn, sweet			114.2	425	32,400		5170	22,500
Lupin			94.08	5376	3110		496	2160
Chickpea			94.08	7440	2250		359	1560
Lentil			94.08	4320	3900		618	2690

Shaded cells indicate where the MOE is less than the target MOE.
Resp= respirator; DM= dust mask; WP=wettable powder; M/L/A= mixer/loader/applicator; Form= formulation; ST=short-term; CR = chemical resistant; Single layer = long sleeved shirt, long pants; N/A = not applicable
[a] Activities are based on what was monitored in the exposure study.
[b] Throughput is dependent on seed type, seeding rate and area planted. See Section 3.12 for more information
[c] Based on an oral NOAEL of 20 mg/kg bw/day from a rabbit development toxicity study and dermal absorption of 25%.
[d] Inhalation NOAEL of 1.4 mg/kg bw/day from a 21-day rat inhalation study.
[e] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure). As both the dermal and inhalation exposure could contribute to the oral endpoint
[f] A dust mask with a protection factor of 80% was used for a NIOSH approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested.
[g] The PPE in this study was open mix/load, closed cab, single layer and gloves. Protection factors were used to estimate exposure with higher levels of PPE. Respiratory protection was not considered feasible with a closed cab; as planting inhalation was not monitored separately from mixer/loader exposure, a respirator or dust mask could not be applied to the inhalation exposure.
[h] Wettable powder applied as a dust

Table 8 Planting Exposure and Risk Assessment for Commercially Treated Bagged Seed[a]

Crop	Form	Application Rate (g a.i./100 kg seed)	Planting Rate[b] (seed/ha)	Planted Area [c] (ha)	MOE				
					Dermal[c] Target = 300	ST Inhalation[e] Target = 100		Combined[f] Target = 300	
						No Resp	DM[f]	No Resp	DM[f]
Dean, 1990: Open loading, closed cab planting, single layer, CR gloves									
Beans, common	Liquid	100.8	83.0	100	1800	12,100	N/A	1790	N/A
	WP	93.6			1940	13,000		1920	
Soybeans	Liquid	100.8	109	48	2660	19,100		2830	
Zietz, 2007: Open loading, closed cab planting, single layer, CR gloves									
Corn (farmer)	Liquid	119.255	28.9	40	3060	981	N/A	2510	N/A
Corn (custom)				80	1530	490		1260	
Corn, field (field)		72		40	5080	1630		4170	
Corn, field (custom)				80	2540	812		2080	
Corn, sweet		122.4	17	25	8120	2600		6660	

Crop	Form	Application Rate (g a.i./100 kg seed)	Planting Rate[b] (seed/ha)	Planted Area [c] (ha)	MOE				
					Dermal[c] Target = 300	ST Inhalation[e] Target = 100		Combined[f] Target = 300	
						No Resp	DM[f]	No Resp	DM[f]
Krainz, 2013 (AH823): Open loading, closed planting, single layer, jacket, CR gloves									
Alfalfa (seed production)	Liquid	260	1.0	80	30,800	1740	N/A	13,740	N/A
Alfalfa (forage)			13		2370	134		1060	
Broccoli, Brussels sprouts, cabbage, cauliflower		52.785	0.35	6	5,940,000	336,000		2,660,000	
Clover (seed production)		260	2.2	32	35,000	1970		15,600	
Clover (forage)			11		7000	395		3120	
Sugarbeet		223.2	2.24		34,0000	1940		15,300	

Resp= respirator; DM= dust mask; WP=wettable powder; Form= formulation; ST=short-term; CR = chemical resistant; Single layer = long sleeved shirt, long pants

[a] Planting on-farm treated seed was addressed in the on-farm exposure studies. Planting commercial bulk seed is considered to be addressed by on-farm treating and planting of seed as there is no additional exposure from loading seed from bags. Planted seeds treated with liquid or wettable powder were considered to have the same exposure; this is an uncertainty in the assessment.

[b] Planting rate values were based on PMRA survey information.

[c] Planted area was based on Statistics Canada Census of Agriculture, EPA SOP#15 and PMRA survey information.

[d] Based on an oral NOAEL of 20 mg/kg bw/day from a rabbit development toxicity study and dermal absorption of 25%.

[e] Inhalation NOAEL of 1.4 mg/kg bw/day from a 21-day rat inhalation study.

[f] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure). As both the dermal and inhalation exposure could contribute to the oral endpoint

[g] Respiratory protection is not considered to be feasible for closed cabs. As loader and planter inhalation was not monitored separately, respiratory protection could not be applied only to one activity.

Table 9 Summary of Postapplication Exposure and Risk Assessment for Captan

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI (days)
USC 5/6: Greenhouse Crops					
Tobacco Seedings (1 application)					
Transplanting	230	12.48 kg a.i./ha	WG	111	ND[c]
Flowers (1 application)					
Cut flowers: hand harvesting, disbudding, hand pruning (tall height)	4000	1.2 kg a.i./ha	WG/WP	67	ND[c]
		1 kg a.i./ha		80	
Potted plants, all activities	230	1.2 kg a.i./ha		1159	12 hours
		1 kg a.i./ha		1391	
Irrigation (non-handset), mechanical weeding	No TC	REI not required [f]			
Flowers (4 applications, 7 days apart[e])					
Potted plants, all activities	230	1.2 kg a.i./ha	WG/WP	290	12 hours
		1 kg a.i./ha		348	
Rhubarb in Forcing Sheds (1 application)					
Transplanting	230	0.162 kg a.i./1000L (100 L/ha)	WG/WP	8588	12 hours
		0.162 kg a.i./1000L (1000L/ha)		859	12 hours
Rhubarb in Forcing Sheds (2 applications, 7 days apart[e])					
Transplanting	230	0.162 kg a.i./1000L (1000L/ha)	WG/WP	429	12 hours
Rhubarb in Forcing Sheds (6 applications, 7 days apart[e])					
Transplanting	230	0.162 kg a.i./1000L (100L/ha)	WG/WP	1431	12 hours

Table 9 Summary of Postapplication Exposure and Risk Assessment for Captan

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI (days)
USC 13/14: Food and feed Crops					
Fruit Trees (Apples, Peaches, Plums, Prunes, Pear, Nectarines, Apricots, Cherries) (1 application)					
Thinning	3000	3.2 kg a.i./ha[e]	All	33	38
		2.4 kg a.i./ha[e]	All	44	33
		1.5 kg a.i./ha (apple only)	All	71	25
Hand harvesting	1400	3.2 kg a.i./ha[e]	All	71	25
		2.4 kg a.i./ha[e]	All	95	20
		1.5 kg a.i./ha (apple only)	All	152	12
Hand pruning, scouting, training	580	3.2 kg a.i./ha[e]	All	172	10
		2.4 kg a.i./ha[e]	All	230	5
		1.5 kg a.i./ha (apple only)	All	368	12 hours
Transplanting	230	3.2 kg a.i./ha[e]	All	435	12 hours
		2.4 kg a.i./ha[e]	All	580	12 hours
		1.5 kg a.i./ha (apple only)	All	930	12 hours
Hand weeding, propping, bird control, orchard maintenance	100	3.2 kg a.i./ha[e]	All	1000	12 hours
		2.4 kg a.i./ha[e]	All	1333	12 hours
		1.5 kg a.i./ha (apple only)	All	2133	12 hours
Mechanical weeding, mechanical harvesting, irrigation (non-handset), frost control, spreading bins, fertilizing	No TC	REI not required [f]			

Table 9 Summary of Postapplication Exposure and Risk Assessment for Captan

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI (days)
Grapes (1 application)					
Turning, girdling (table grapes)	19300	2.4 kg a.i./ha[e]	All	11	94
		1.2 kg a.i./ha	Liquid	22	74
Hand harvesting, training, tying, leaf pulling	8500	2.4 kg a.i./ha[e]	All	25	70
		1.2 kg a.i./ha	Liquid	49	51
Scouting, hand weeding, hand pruning, propagating, bird control, trellis repair	640	2.4 kg a.i./ha[e]	All	326	12 hours
		1.2 kg a.i./ha	Liquid	651	12 hours
Transplanting	230	2.4 kg a.i./ha[e]	All	906	12 hours
		1.2 kg a.i./ha	Liquid	1182	12 hours
Irrigation (non-handset), mechanical harvesting, mechanical weeding, burn down, ditching, mechanical pruning	No TC	REI not required [f]			
Cucumber (1 application)					
Handset irrigation	1750	3.4 kg a.i./ha	WG/WP	57	11
		2.8 kg a.i./ha[e]		69	10
		2.6 kg a.i./ha[d]		74	10
Hand harvesting, training, mechanically-assisted harvesting	550	3.4 kg a.i./ha		180	4
		2.8 kg a.i./ha[e]		218	2
Training	550	2.6 kg a.i./ha[d]		235	2
Transplanting	230	3.4 kg a.i./ha		430	12 hours
		2.8 kg a.i./ha[e]		522	12 hours
		2.6 kg a.i./ha[d]		564	12 hours
Scouting, hand weeding	90	3.4 kg a.i./ha		1099	12 hours
		2.8 kg a.i./ha[e]		1335	12 hours
		2.6 kg a.i./ha[d]		1437	12 hours
Irrigation (non-hand set), mechanical weeding	No TC	REI not required [f]			

Table 9 Summary of Postapplication Exposure and Risk Assessment for Captan

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI (days)
Potato (1 application)					
Roguing	1000	3 kg a.i./ha	WG	112	7
Scouting	210			534	12 hours
Hand weeding	70			1602	12 hours
Irrigation (non-handset), mechanical weeding, mechanical harvesting	No TC	REI not required [f]			
Potato (2 applications, 7 days apart)					
Roguing	1000	3 kg a.i./ha	WG	83	9
Scouting	210			396	12 hours
Hand weeding	70			1187	12 hours
Pumpkin, squash (1 application)					
Handset irrigation	1750	3.375 kg a.i./ha	WP	57	11
		2.5 kg a.i./ha[d]		77	9
Hand harvesting, turning (pumpkin), training, mechanically assisted harvesting	550	3.375 kg a.i./ha		181	4
Turning (pumpkin), training	550	2.5 kg a.i./ha[d]		245	2
Transplanting	230	3.375 kg a.i./ha		433	12 hours
		2.5 kg a.i./ha[d]		584	12 hours
Scouting, thinning fruit, hand weeding	90	3.75 kg a.i./ha		1107	12 hours
		2.5 kg a.i./ha[d]		1495	12 hours
Mechanical weeding, irrigation (non-handset), fertilizing	No TC	REI not required [f]			
Tomato (1 application)					
Handset irrigation	1750	3.4 kg a.i./ha	WG/WP	57	11
		2.4 kg a.i./ha[e]		80	9
Hand harvesting, training, tying	1000	3.4 kg a.i./ha		90	8
		2.4 kg a.i./ha[e]		127	6
Transplanting	230	3.4 kg a.i./ha		430	12 hours
		2.4 kg a.i./ha[e]		609	12 hours

Table 9 Summary of Postapplication Exposure and Risk Assessment for Captan

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI (days)
Scouting	210	3.4 kg a.i./ha		471	12 hours
		2.4 kg a.i./ha[e]		667	12 hours
Hand pruning, hand weeding	70	3.4 kg a.i./ha		1413	12 hours
		2.4 kg a.i./ha[e]		2002	12 hours
Irrigation (non-handset), mechanical weeding, mechanical harvesting	No TC	REI not required [f]			
USC 14: Food Crops					
Strawberry (1 application)					
Hand harvesting	1100	3.6 kg a.i./ha	Liquid	85	9
		3.4 kg a.i./ha	WG/WP	90	8
		2.4 kg a.i./ha[e]	All	109	7
Transplanting	230	3.6 kg a.i./ha	Liquid	406	12 hours
		3.4 kg a.i./ha	WG/WP	430	12 hours
		2.4 kg a.i./ha[e]	All	522	12 hours
Scouting	210	3.6 kg a.i./ha	Liquid	445	12 hours
		3.4 kg a.i./ha	WG/WP	471	12 hours
		2.4 kg a.i./ha[e]	All	572	12 hours
Hand weeding, canopy management	70	3.6 kg a.i./ha	Liquid	1335	12 hours
		3.4 kg a.i./ha	WG/WP	1413	12 hours
		2.4 kg a.i./ha[e]	All	1716	12 hours
Irrigation (non-hand set), mechanical weeding	No TC	REI not required [f]			
Raspberry (1 application)					
Handset irrigation	1750	2 kg a.i./ha	WG/WP	96	8
Hand harvesting	1400			120	6
Scouting, hand pruning, hand weeding, tying/training	640			263	1
Transplanting	230			731	12 hours

Table 9 Summary of Postapplication Exposure and Risk Assessment for Captan

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI (days)
Irrigation (non-hand set), mechanical weeding, mechanical harvesting, burn down, frost control	No TC	REI not required [f]			
High Bush Blueberry, Blackberry, Loganberry (1 application)					
Handset irrigation	1750	1.8 kg a.i./ha	WG/WP	107	7
Hand harvesting, tying/training (blackberry, loganberry)	1400			133	6
Scouting, hand pruning, hand weeding, tying/training, frost control (blueberry), bird control (blueberry)	640			292	12 hours
Transplanting	230			812	12 hours
Irrigation (non-handset, mechanical harvesting, mechanical weeding, burn down, frost control	No TC	REI not required [f]			
Low Bush Blueberry (1 application)					
Handset irrigation	1750	1.8 kg a.i./ha	WG/WP	107	7
Hand harvesting, scouting	1100			170	4
Transplanting	230			812	12 hours
Hand weeding	70			2669	12 hours
Irrigation (non-hand set), mechanical weeding, mechanical harvesting	No TC	REI not required [f]			
USC 27: Outdoor Ornamentals					
Flowers (1 application)					
Cut flowers: hand harvesting, disbudding, hand pruning (tall height)	4000	1.2 kg a.i./ha	WG/WP	70	10
		1 kg a.i./ha		84	9
Handset irrigation	1750	1.2 kg a.i./ha		160	4
		1 kg a.i./ha		192	3
Potted plants, all activities (except handset irrigation)	230	1.2 kg a.i./ha		1218	12 hours
		1 kg a.i./ha		1462	12 hours
Irrigation (non-handset), mechanical weeding	No TC	REI not required [f]			

Table 9 Summary of Postapplication Exposure and Risk Assessment for Captan

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI (days)
Flowers (6 applications, 7 days apart)					
Handset irrigation	1750	1.2 kg a.i./ha	WG/WP	125	7
		1 kg a.i./ha		104	6
Potted plants, all activities (except handset irrigation)	230	1.2 kg a.i./ha		795	12 hours
		1 kg a.i./ha		953	12 hours
USC 30: Turf					
Golf course and sod farm (1 application)					
Transplanting/planting, harvesting (sod farm only)	6700	4.8 kg a.i./ha	WG	249	2
		4.75 kg a.i./ha	WP	251	2
		4.72 kg a.i./ha[e]	Both	253	2
Mowing, watering, irrigation (sod farm only), [cup changing, irrigation repair, miscellaneous grooming- golf course only]	3500	4.8 kg a.i./ha	WG	476	12 hours
		4.75 kg a.i./ha	WP	481	12 hours
		4.72 kg a.i./ha[e]	Both	484	12 hours
Aerating, fertilizing, hand pruning, scouting, mechanical weeding	1000	4.8 kg a.i./ha	WG	1667	12 hours
		4.75 kg a.i./ha	WP	1684	12 hours
		4.72 kg a.i./ha[e]	Both	1695	12 hours
Roll harvesting	No TC	REI not required [f]			

Shaded cells indicate where the MOE does not reach the target MOE or REIs are potentially not agronomically feasible

Form= formulation; USC = Use-site Category; WG = wettable granular; WP = wettable powder; REI = restricted-entry interval; MOE = margin of exposure.

[a] TC= transfer coefficient. Values from PMRA Agricultual TC memo.

[b] Based on an oral NOAEL of 20 mg/kg bw/day from a rabbit development toxicity study and dermal absorption of 25%.

[c] ND= not determined. As there were no chemical-specific studies submitted, the default assumption of 0% dissipation was used. Therefore risk only on the day of application can be calculated.

[d] Application rate for young plants

[e] Registrant proposed rate

[f] Dermal exposure is expected to be minimal due to limited contact with treated foliage, so an REI is not required.

[e] Interval is based on current use pattern, as no dissipation is assumed for greenhouse crops.

Table 10 Postapplication Dermal Exposure from Treated Soil

Max Appl Rate	Soil Concentration[a] (mg a.i./kg soil)	Adherence Factor[b] (mg soil/cm^2)	Surface Area[c] (cm^2)	Dermal Exposure[d] (ug/kg bw/day)	Dermal MOE[e] Target = 300
Commercial Worker in a Greenhouse					
11.28 kg a.i./ha	75.7	0.1	3300	0.0781	256,000

Appl = application
[a] Concentration of captan in soil. Based on assumptions from the USEPA Residential SOP and the application rate so includes any THPI that may have degraded from captan.
[b] From the USEPA Superfund guidance document (USEPA, 2004)
[c] Surface area of exposed skin (head, hands, forearms). Value from the USEPA Superfund guidance document (USEPA, 2004)
[d] Dermal exposure (ug/kg bw/day) = soil concentration × conversion factor (1×10^3 mg to ug) × adherence factor × conversion factor ($1x10^{-6}$ kg soil to mg soil) × surface area × 1 event/day × dermal absorption factor (0.25) /body weight (70kg).
[e] Oral NOAEL of 20 mg/kg bw/day from a rabbit development study and target MOE of 300.

Table 11 Residential Mixer/Loader/Applicator Exposure and Risk Assessment

Formulation	Application equipment	Application Rate	ATPD	Unit Exposure[a] (mg/kg ai)		MOE[c]		
				Dermal	Inhalation	Dermal[d] (Target = 300)	Inhalation[e] (Target = 100)	Combined[f] (Target = 300)
Fruit (apple, apricot, cherry, blackberry, strawberry), Gardens (cucumber, tomato, pepper), Ornamentals								
Dust (WP applied as a dust)	Plunger duster; Bulb duster	50 g a.i./can[b]	1 can	551.16	3.75	230	600	230
		15 g a.i./can[o]				770	2000	750
	Shaker can; Electric/power duster; Hand crank duster	50 g a.i./can[b]		9479.88	39.86	14	56	13
		15 g a.i./can[o]				45	190	44
Wettable powder (applied as a liquid)	ManPHW; backpack	2 g a.i./L	18.9 L	152.12	2.43	1100	1200	1000
		1 g a.i./L				2200	2400	2100
	Hose-end sprayer	2 g a.i./L	41.6 L	127.87	0.0031	600	430,000	600
		1 g a.i./L				1200	870,000	1200
	Sprinkler can	2 g a.i./L	18.9 L	127.87	0.0031	1300	960,000	1300
		1 g a.i./L				2600	1,900,000	2600
Bulbs and Soil								
Dust (WP applied as a dust)	Plunger duster; Bulb duster	0.75 g a.i./kg bulb	4 kg bulbs	551.16	3.75	3900	10000	3800
	Shaker can; Electric/power duster; Hand crank duster			9479.88	39.86	230	940	220
	Plunger duster	25 g a.i./can[b]	1 can	551.16	3.75	460	1200	450
	Shaker can; Electric/power duster; Hand crank duster			9479.88	39.86	27	110	27

Shaded cells indicate where the MOE is less than the target MOE
ATPD = area treated per day; MOE = margin of exposure; ManPHW= manually pressurized handwand.
[a] Values are from the USEPA Residential SOPs (2012).
[b] Based on a container size of 500 g and 5% or 10% ai = 25 - 50 g a.i./can
[o] Based on a container size of 300 g and 5% ai = 15 g a.i./can. This rate applies to ornamentals only
[c] Where MOE = NOAEL/((unit exposure × area treated × use rate)/80 kg bw).
[d] Oral NOAEL of 20 mg/kg bw/day from a rabbit development study and target MOE of 300.
[e] Short-term Inhalation NOAEL of 1.4 mg/kg bw/day from a rat inhalation study and target MOE of 100.
[f] Combined MOE = NOAEL/(dermal exposure + inhalation exposure). As both the dermal and inhalation exposure could contribute to the oral endpoint

Table 12 Postapplication Dermal Exposure from Treated Soil

Max Appl Rate	Soil Concentrationa (mg a.i./kg soil)	Adherence Factor[b] (mg soil/cm^2)	Surface Area[c] (cm^2)	Dermal Exposure[d] (ug/kg bw/day)	Dermal MOE[e] Target = 300
Residential Gardeners (Adult, 80 kg)					
2.5 g a.i./m^2	167.92	0.07	5700	0.2094	96,000
Residential Gardeners (Youth, 57 kg, Child (6<11 yrs), 32 kg)					
There were no youth or child-specific factors outlined in the USEPA RAGS document. Given the degree by which the adult gardening MOE exceeds the target MOE, the youth and child (6<11 years) exposure scenarios were not expected to have any risk concerns.					

Appl = application

[a] Concentration of captan in soil. Based on assumptions from the USEPA Residential SOP and the application rate so includes any THPI that may have degraded from captan.

[b] From the USEPA RAGS document (USEPA, 2004)

[c] Surface area of exposed skin (head, hands, lower legs, forearms). Value from the USEPA RAGS document (USEPA, 2004)

[d] Dermal exposure (ug/kg bw/day) = soil concentration × conversion factor (1×10^3 mg to ug) × adherence factor × conversion factor (1×10^{-6} kg soil to mg soil) × surface area × 1 event/day × dermal absorption factor (0.25) /body weight (80kg).

[e] Oral NOAEL of 10 mg/kg bw/day from a rabbit development study and target MOE of 300.

Table 13 Residential Postapplication Dermal Exposure and Risk Assessment

Form	Sub-pop	App Rate[a] (kg a.i./ha)	# Apps	DFR/TTR (µg/cm^2) [b]	TC[c] (cm^2/hr)	Exposure[d] (mg/kg bw/day)	Dermal MOE[e] (Target = 300)
Gardens (blackberry, strawberry, cucumber, tomato, pepper, ornamentals)							
Liquid	Adults	3.4	1	8.09	8400	0.467	43
		1.7		4.04		0.234	86
	Youth (11<16 yrs)	3.4		8.09	6900	0.269	74
		1.7		4.04		0.135	149
	Child (6<11 yrs)	3.4		8.09	4600	0.320	39
		1.7		4.04		0.160	78
Dust	Adults	5	1	12.5	8400	0.722	28
		1.5[f]		3.75		0.217	92
	Youth	5		12.5	6900	0.416	48
		1.5[f]		3.75		0.125	160
	Child	5		12.5	4600	0.494	40
		1.5[f]		3.75		0.148	135
Trees (apple, apricot, cherry, ornamental)							
Liquid	Adults	2.4[g]	1	6.00	1700	0.032	627
		1.5[g]		3.75		0.020	1004
		3.4	1	8.51		0.045	442
		1.7	1	4.26		0.023	884
			2	8.99		0.048	419
	Youth	2.4[g]	1	6.00	1400	0.018	1086
		1.5[g]		3.75		0.012	1737
		3.4	1	8.51		0.026	765
		1.7	1	4.26		0.013	1530
			2	8.99		0.028	725
	Child	2.4[g]	1	6.00	930	0.022	918
		1.5[g]		3.75		0.014	1468
		3.4	1	8.51		0.031	647
		1.7	1	4.26		0.015	1293
			2	8.99		0.033	613
Dust	Adults	5	1	12.5	1700	0.066	301
		1.5[f]		3.75		0.020	1004
	Youth	5		12.5	1400	0.038	521
		1.5[f]		3.75		0.012	1737
	Child	5		12.5	930	0.045	440
		1.5[f]		3.75		0.014	1468
Golf Courses							
Liquid	Adults	4.8[g]	1	0.480	5300	0.0318	630
		4.75[g]		0.475		0.0315	640
		4.72[g]		0.472		0.0313	640
	Youth	4.8[g]		0.480	4400	0.0371	540
		4.75[g]		0.475		0.0367	550
		4.72[g]		0.472		0.0364	550
	Child	4.8[g]		0.480	2900	0.0435	460
		4.75[g]		0.475		0.0430	460
		4.72[g]		0.472		0.0428	470

Shaded cells indicate where the MOE is less than the target MOE

Form = formulation; Sub-pop = sub-population or lifestage; App(s) = application(s); Exp = exposure; MOE = margin of exposure

[a] Application rate determine using the assumption of 18.9 L or one container of dust is applied to a 111 m^2 garden. These are based on the area treated per day assumptions used for residential applicators as well as the default garden

size from the USEPA residential SOP (2012). These rates were applied to both gardens and trees.
[b] DFR = dislodgeable foliar residue. TTR = turf transferrable residues. DFR values are determined on the day of application and were calculated using chemical-specific data for liquids and default peak value of 25% of the application rate for dusts. TTR peak values were based on the default value of 1% of the application rate.
[c] TC = transfer coefficient. TCs from the USEPA Residential SOP (2012) were used.
[d] Exposure = DFR (ug/cm^2) × DA (25%) × TC × duration/Body Weight. Durations were 2.2, 1, and 4 hr for gardens, trees, and golfing, respectively for adults and youth. For children, durations were 1.1, 0.5, and 4 hr for gardens, trees, and golfing, respectively. Body weights were 80, 57, and 32 kg for adults, youth, and children (6<11 years), respectively.
[e] Oral NOAEL of 20 mg/kg bw/day from a rabbit development study and target MOE of 300.
[f] Rate is for ornamentals only
[g] Application rate from commercial products

Table 14 Bystander Inhalation Exposure and Risk Assessment

Subpopulation	Air Concentration[a] (pg/m^3)	Inhalation Exposure[b] µg/kg bw/day	MOE[c] Target = 300
Adult (80 kg)	5074	0.0000609	656,944
Youth (11<16 years) (57 kg)		0.000112	356,627
Toddler (6<12 months) (9 kg)		0.000389	102,826

[a] Maximum value from literature studies.
[b] Inhalation exposure = air concentration × inhalation rate × exposure time × conversion factor (µg/1x 10^6 pg)/ body weight. Inhalation rate was 0.64 m^3/hr for adults, 0.63 m^3/hr for youth, and 0.23 m^3/hr for toddlers. Exposure time was 3, 2 and 1.5 hr/day for toddlers, youth, and adults, respectively
[c] Based on a rat inhalation study with a NOAEL of 0.04 mg/kg bw/day and target of 300 for intermediate-term inhalation exposure.

Table 15 Combined Residential Mixer/Loader/Applicator and Postapplication Exposure

Sub-population	Form	M/L/A Scenario	Homeowner M/L/A Exposure[a] (mg/kg bw/day)		Postapplication Scenario	Postapplication Exposure[b] (mg/kg bw/day)	Total Exposure[c]	Combined MOE[d] Target = 300 (100 for children)
			Dermal	Inhalation		Dermal		
Gardens (blackberry, strawberry, cucumber, tomato, pepper, ornamentals								
All	WP (liquid)[e]	Postapplication MOEs did not reach the target MOE						
All	WP (dust)[e]	Mixer/loader/applicator and postapplication MOEs did not reach the target MOE						
Trees (apple, apricot, cherry, ornamental)								
Adults (80 kg)	WP (liquid)[e] (2 kg a.i./L)	ManPHW; backpack	0.018	0.0012	All activities (1 app)	0.045	0.0644	311
		Hose-end sprayer	0.033	3.2×10^{-6}			0.0785	255
		Sprinkler can	0.012	1.5×10^{-6}			0.0603	331
	WP (liquid)[e] (1 kg a.i./L)	ManPHW; backpack	0.009	0.00057	All activities (2 apps)	0.048	0.0573	349
		Hose-end sprayer	0.017	1.6×10^{-6}			0.0644	311
		Sprinkler can	0.076	7.3×10^{-7}			0.0553	362
	Liquid (2.4 kg a.i./ha)	Commercial Applicator			All activities (1 app)	0.032	0.032	627
	Liquid (1.5 kg a.i./ha)					0.020	0.020	1004
Youth (57 kg)	WP (liquid)[e] (2 kg a.i./L)	N/A[f]			All activities (1 app)	0.026	0.026	765
	WP (liquid)[e] (1 kg a.i./L)				All activities (2 apps)	0.028	0.028	725
	Liquid (2.4 kg a.i./ha)				All activities (1 app)	0.018	0.018	1086
	Liquid (1.5 kg a.i./ha)					0.012	0.012	1737
Children (32 kg)	WP (liquid)[e] (2 kg a.i./L)	N/A[f]			All activities (1 app)	0.031	0.031	404
	WP (liquid)[e] (1 kg a.i./L)				All activities (2 apps)	0.033	0.033	383
	Liquid (2.4 kg a.i./ha)				All activities (1 app)	0.022	0.022	573
	Liquid (1.5 kg a.i./ha)					0.014	0.014	918
All	WP (dust)[e]	Mixer/loader/applicator MOEs did not reach the target MOE						
Soil Treatment								
Mixer/loader/applicator MOEs did not reach the target MOE								
Bulb Treatment								
Mixer/loader/applicator MOEs did not reach the target MOE								
Golfing								
Adults (80 kg)	WG (4.8 kg a.i./ha)	Commercial Applicator			Golfing	0.0318	0.0318	630
	WP (4.75 kg a.i./ha)					0.0315	0.0315	640

Sub-population	Form	M/L/A Scenario	Homeowner M/L/A Exposure[a] (mg/kg bw/day)		Postapplication Scenario	Postapplication Exposure[b] (mg/kg bw/day)	Total Exposure[c]	Combined MOE[d] Target = 300 (100 for children)
			Dermal	Inhalation		Dermal		
	Both (4.72 kg a.i./ha)					0.0313	0.0313	640
Youth (57 kg)	WG (4.8 kg a.i./ha)	N/A[f]			Golfing	0.0371	0.0371	540
	WP (4.75 kg a.i./ha)					0.0367	0.0367	550
	Both (4.72 kg a.i./ha)					0.0364	0.0364	550
Children (32 kg)	WG (4.8 kg a.i./ha)	N/A[f]			Golfing	0.0435	0.0435	290
	WP (4.75 kg a.i./ha)					0.0430	0.0430	290
	Both (4.72 kg a.i./ha)					0.0428	0.0428	290

Shaded cells indicate where the MOE is less than the target MOE

MOE = margin of exposure; ManPHW= manually pressurized handwand; M/L/A = mixer/loader/applicator; Form = formulation; WP = wettable powder; WG= wettable granular; N/A= not applicable

[a] Exposure estimates are from Table 11, Appendix IX.

[b] Exposure estimates are from Table 13, Appendix IX.

[c] Total exposure = M/L/A exposure (dermal and inhalation) + postapplication exposure (dermal)

[d] Based on an oral NOAEL of 20 mg/kg bw/day and target MOE of 300 for youth and adults. For children an oral NOAEL of 12.5 mg/kg bw/day and target MOE of 100 was used.

[e] Domestic products are wettable powders that can be applied as a dust or a liquid. '(dust)' indicates when the product is applied as a dust. '(liquid)' indicates when the product is applied as a liquid.

[f] Youth and children are assumed not to apply pesticides (USEPA Residential SOPs, 2012).

Table 16 Residential Aggregate Exposure and Risk Assessment

Sub-population	Form	Scenario[a]	Residential Exposure[b] (mg/kg bw/day)	Dietary Exposure[c] (mg/kg bw/day)	Total Exposure[d] (mg/kg bw/day)	Aggregate MOE[e] Target = 300 (100 for children)
Trees (apple, apricot, cherry, ornamental)						
Adults (80 kg)	WP (2 kg a.i./ha)	Hose-end Sprayer	MOEs did not meet the target MOE for all sub-populations and application equipment			
	WP (1 kg a.i./ha)		0.06644	0.003065	0.0675	297
	Liquid (2.4 kg a.i./ha)	Postapp activities	0.032		0.0350	572
	Liquid (1.5 kg a.i./ha)		0.020		0.0230	870
Youth (57 kg)	WP (2 kg a.i./ha)	Postapp activities	MOEs did not meet the target MOE for all sub-populations			
	WP (1 kg a.i./ha)		0.028	0.003256	0.0308	648
	Liquid (2.4 kg a.i./ha)		0.018		0.0217	923
	Liquid (1.5 kg a.i./ha)		0.012		0.015	1354
Children (32 kg)	WP (2 kg a.i./ha)	Postapp activities	MOEs did not meet the target MOE for all sub-populations			
	WP (1 kg a.i./ha)		0.033	0.005404	0.0381	328
	Liquid (2.4 kg a.i./ha)		0.022		0.0272	460
	Liquid (1.5 kg a.i./ha)		0.014		0.0190	657
Golfing						
Adults (80 kg)	WG (4.8 kg a.i./ha)	Postapp activities	0.0318	0.003065	0.0349	574
	WP (4.75 kg a.i./ha)		0.0315		0.0345	579
	Both (4.72 kg a.i./ha)		0.0313		0.0343	582
Youth (57 kg)	WG (4.8 kg a.i./ha)		0.0371	0.003256	0.0403	496
	WP (4.75 kg a.i./ha)		0.0367		0.0399	501
	Both (4.72 kg a.i./ha)		0.0364		0.0397	504
Children (32 kg)	WG (4.8 kg a.i./ha)		0.0435	0.005404	0.0489	256
	WP (4.75 kg a.i./ha)		0.0430		0.0485	258
	Both (4.72 kg a.i./ha)		0.0428		0.0482	259

Form = formulation, WG = wettable granular, WP = wettable powder; Postapp = postapplication

[a] Scenario or application equipment with the highest exposure from Table 15

[b] Total exposure from mixer/loader/applicator + postapplication activities for adults. Only postapplication exposure was included for youths and children.

[c] Chronic (background) dietary exposure

[d] Total exposure from dermal/inhalation and dietary exposure

[e] MOE = NOAEL/Exposure. Based on an oral NOAEL of 20 mg/kg bw/day with a target MOE of 300 for youth and adults. For children an oral NOAEL of 12.5 mg/kg bw/day and target MOE of 100 was used. .

Table 17 Bystander Aggregate Exposure and Risk Assessment

Subpopulation	Inhalation Exposure [a] (µg/kg bw/day)	Dietary Exposure [b] (µg/kg bw/day)	Total Exposure [c] (µg/kg bw/day)	Aggregate MOE[d] (Target = 300) (Toddler Target = 100)
Adult (80 kg)	0.0000609	3.07	3.07	6525
Youth (57 kg)	0.000112	3.26	3.26	6142
Toddler (9 kg)	0.000389	10.2	10.2	1965

[a] Values are from Table 14.
[b] Chronic (background) dietary exposure
[c] Total exposure from inhalation and dietary exposure
[d] MOE = NOAEL/Exposure. For adults and youth: NOAEL of 10 mg/kg bw/day and target of 300, based on the oral rabbit developmental study. For toddlers: NOAEL of 12.5 mg/kg bw/day and target of 100, based on the rat reproductive toxicity assay.

Table 18 Summary of Mitigation and Data Requirements for Captan

Scenario		Mixer/Loader/Applicator	Postapplication
USC[a]	Crop	Mitigation	Mitigation[b]
5/6	Rhubarb (forcing shed)	Increased PPE, engineering controls	REI potentially agronomically feasible at 2-6 applications depending on the dilution
	Soil Treatment (pre-plant)	Increased PPE, engineering controls	REI potentially agronomically feasible
	Potted Flowers	Increased PPE, engineering controls	REI potentially agronomically feasible at 4 applications
	All other greenhouse uses	Increased PPE, engineering controls	MOE did not reach the target MOE even with all possible mitigation considered. Uses are proposed for cancellation.
6/27	Flower Bulb Dip	Data not available. Use proposed for cancellation.	Data available. Use proposed for cancellation
	Ornamental Stem Dip	Data not available. Use proposed for cancellation.	Data available. Use proposed for cancellation
13/14	Fruit Trees, grapes	Increased PPE, engineering controls	REIs not considered to be agronomically feasible even with all possible mitigation considered. Use proposed for cancellation.
	Blueberry, blackberry, loganberry, raspberry, strawberry	Increased PPE, engineering controls	REIs not agronomically feasible at current use pattern. Uses proposed for cancellation..
	Cucumber (mature, young), pumpkin/squash (young), potato	Increased PPE, engineering controls	REI potentially agronomically feasible at 1 application.
	Pumpkin/squash (mature), tomato	Increased PPE, engineering controls	REIs not agronomically feasible at current use pattern. Use proposed for cancellation.
13/14	Soil Treatment (pre-plant)	Increased PPE, engineering control	REI potentially agronomically feasible
27	Flowers (potted)	Increased PPE, engineering controls, limits on amount of active handled per day	REI potentially agronomically feasible at 6 application.
	Flowers (cut)	Increased PPE, engineering controls, limits on amount of active handled per day	REIs not agronomically feasible at current use pattern. Use proposed for cancellation.

Table 18 Summary of Mitigation and Data Requirements for Captan

Scenario		Mixer/Loader/Applicator	Postapplication
USC[a]	**Crop**	**Mitigation**	**Mitigation[b]**
30	Sod Farm, Golf Course	Increased PPE, engineering controls	REI potentially agronomically feasible at 1 application
10	Commercial Seed Treatment	Increased PPE. Require comparative dust-off data (DACO 5.12) and access to worker exposure studies. Need DACO 5.2 information about small vegetable seed treatment.	
	On-Farm Seed Treatment (liquid)	Require comparative dust-off data (DACO 5.12) and access to worker exposure studies	
	On-Farm Seed Treatment for sweet corn (WP applied as a dust)	Increased PPE, engineering controls. Require comparative dust-off data (DACO 5.12) and access to worker exposure studies	
	On-Farm Seed Treatment for beans (WP applied as a dust)	MOEs did not reach the target MOE. Use proposed for cancellation.	
	Planting Commercially Treated/Bagged Seed	Increased PPE, engineering controls. Require comparative dust-off data (DACO 5.12) and access to worker exposure studies	
Dom	Trees (WP applied as a liquid at low rate (1.0 kg a.i./L))	Aggregate MOEs reached the target MOE for all sub-populations	
	Trees (WP applied as a liquid at high rate (2.0 kg a.i./L))	Aggregate MOEs did not reach the target MOE for all sub-populations. Propose removing the high rate from the domestic class label.	
Dom	Gardens (WP applied as a liquid)	MOEs reached the target MOE	MOEs did not reach the target MOE on Day 0. Proposed removing these uses from the domestic class label.
	Domestic products applied as a dust to gardens and trees	Most MOEs did not reach the target MOE. Propose removing these dust uses from the domestic class label.	MOEs did not reach the target MOE on Day 0. Propose removing these dust uses from the domestic class label.
	Dust application to flower beds	MOEs did not reach the target MOE for all application equipment. Propose removing these dust uses from the domestic class label.	MOEs reached the target MOE on Day 0

Table 18 Summary of Mitigation and Data Requirements for Captan

Scenario		Mixer/Loader/Applicator	Postapplication
USC[a]	Crop	Mitigation	Mitigation[b]
	Dust application to bulbs	MOEs did not reach the target MOE for all application equipment. Propose removing these dust uses from the domestic class label.	Assessed qualitatively.
	Bystander inhalation	Not Applicable	Aggregate MOEs reached the target MOE

USC = use-site category, DFR = dislodgeable foliar residues; WP = wettable powder,
[a] 5/6 = greenhouse food and feed crops; 13/14 = outdoor food and feed crops; 27 = outdoor ornamentals; 30 = turf; 10 = seed treatment; Dom = domestic
[b] Agronomically feasible = REI is considered to be feasible for most postapplication activities in a crop.

Table 19 Seed Treatment Exposure Studies Used in the Risk Assessment

Study Summary	PPE/Engineering Controls[a]	Tasks	Unit Exposure (µg/kg ai)	
			Dermal	Inhalation
Commercial Slurry Application (alfalfa, broccoli, Brussels sprouts, cabbage, cauliflower, clover, sugar beet)				
Dean, 1993. Exposure of Workers to Triadimenol During Treatment of Grain Seeds with Baytan 312FS. Sponsored by Miles Inc. Unpublished. The study measured exposure of workers during commercial seed treatment of winter wheat with BAYTAN 312 FS, a liquid formulation of triadimenol, at three treatment facilities (large, medium and small) in Ontario, Canada. Workers were monitored for 3 - 3.5 hours at each facility for a total of 55 half-day replicates. The maximum amount of active ingredient handled per replicate was 21.9 kg. Dermal exposure was estimated using patch dosimeters and hand washes. Inhalation exposure was measured using personal air sampling pumps.	Closed mix/load, single layer and gloves	Treater/bagger	357.42	118.76
		Stacker/tagger	61.68	34.36
		Forklift operator	12.02	1.21
Wilson, 2009. Fluquinconazole and Prochloraz: Determination of Operator Exposure During Cereal Seed Treatment with Jockey Fingicide in Germany, United Kingdom and France. Sponsored by Seed Tropex Task Force. Unpublished. AHETF AH817. Workers were monitored for exposure during the treatment of wheat with a liquid formulation of Jockey (fluquinconazole, prochloraz) in commercial facilities. Three different job activities were monitored: mixer/loader/calibrator (n=9), bagging (n=22), and cleaning (n=8). Workers were monitored for 0.03-7.72 hours. Dermal exposure was estimated using whole body dosimeters, face/neck wipes, and hand washes. Inhalation exposure was measured using personal air sampling pumps.	Closed M/L, single layer, CR gloves, chemical-resistant coveralls for cleaners	Treater	0.88	0.016
		Cleaner	18.46 µg/ g a.i./100 kg seed	0.64 µg/ g a.i./100 kg seed
Commercial Slurry Application (chickpea, lentil, lupin, pea)				
Krolski, M.E. 20 November 2006, Gaucho 480 SC – Worker Exposure During On-farm and Commercial Seed Treatment of Cereals. Sponsored by Bayer CropScience. Unpublished. AHETF AH803. The study measured exposure of workers during commercial and on-farm treating of wheat seed. Twelve trials were conducted with on-farm/planters and four were conducted with commercial applicators. Only the commercial applicators were considered for this scenario. Wheat seed was treated with Gaucho 480 SC. Dermal exposure was measured using a whole body inner dosimeter, hand rinses, and face/neck wipes. Inhalation exposure was measured using a personal air sampling pumps. The 90th percentile was used for this study due to the small sample size (n=4).	Closed ML, single layer, gloves	Mixer/loader, applicator (no bagging)	265.70	2.47
Wilson, 2009. Fluquinconazole and Prochloraz: Determination of Operator Exposure During Cereal Seed Treatment with Jockey Fingicide in Germany, United Kingdom and France. Sponsored by Seed Tropex Task Force. Unpublished. AHETF AH817.	Closed M/L, single layer, CR gloves, chemical-resistant coveralls	Treater	0.88	0.016
		Cleaner	18.46 µg/ g a.i./100 kg seed	0.64 µg/ g a.i./100 kg seed

Study Summary	PPE/Engineering Controls[a]	Tasks	Unit Exposure (µg/kg ai)	
			Dermal	Inhalation
See description above.	for cleaners			
Commercial Slurry Application (corn, bean, soybean)				
Kroliski, 2010. Observational Study to Determine Dermal and Inhalation Exposure to Workers in Commercial Seed Treatment Facilities: Mixing/Treating with a Liquid Pesticide Product and Equipment Clean-out. Sponsored by Bayer CropScience. Unpublished. AHETF AH806. Twenty-four workers were monitored for exposure during the treatment of canola or corn with liquid formulations of clothianidin, metalaxyl and/or carbathiin (Prosper, Allegiance, and/or Poncho) in commercial facilities. Three different job activities were monitored: treatment of seed (treater/applicator), packaging of treated seeds (bagger/sewer/stacker) and cleaning of seed equipment (cleaner).Workers were monitored for 31-681 minutes. Dermal exposure was estimated using whole body dosimeters, face/neck wipes, and hand washes. Inhalation exposure was measured using personal air sampling pumps.	Closed ML, single layer, gloves	Mixer/loader	256	2.73
		Bagging/sewer/ stacker	84.7	8.9
		Cleaning	127 µg/ g a.i./100 kg seed	20.0 µg/ g a.i./100 kg seed
On-Farm Dry Application and Planting (bean, corn)				
Klonne, 2005. Determination of Dermal and Inhalation Exposure of Workers During On-Farm Application of a Dry Hopper Box Pesticide Treatment to Seed, and Planting of Treated Seed. Sponsored by Agricultural Handlers Exposure Task Force. AHE10. Unpublished. Sixteen workers were monitored for exposure while treating cotton seed with a dry powder formulation of acephate (as Orthene 90S soluble powder) on-farm in open seed hopper boxes and planting the treated seed in a closed cab planter. The monitoring periods lasted approximately 4.5 to 10 hours. The total kg of a.i. handled across the replicates ranged from 5.2 kg – 15.8 kg. The amount of seed planted ranged from 308 kg – 671 kg over a total area planted of 25.9 – 86.2 ha. The dermal exposure was measured using whole body dosimeters, face/neck wipes, and hand washes. Inhalation exposure was measured by means of personal air sampling pumps.	Open mix/load, Single layer and gloves, closed cab planter	Mixer, coater, planter	10,468	1133
On-Farm Slurry Application and Planting (bean, chickpea, corn, lentil, lupin, pea, soybean, sugarbeet)				
Purdy, 1999. On-farm Operator Exposure Study with Dividend 36FS Seed Treatment on Wheat. Sponsored by Novartis Crop Protection Canada Inc. Unpublished. AHETF. AH804. Sixteen replicates of on-farm seed treatment procedures were monitored for potential exposure to workers treating seed and handling treated seed for planting (in other words, loading, calibration, planting, repair, cleanup). The study was conducted at 15 different farms in Manitoba using the Canadian liquid formulation of Dividend 36FS. Dermal exposure was monitored with whole body dosimeters, face/neck wipes and hand washes. Inhalation was monitored using personal air sampling pumps.	Open mix/load, single layer and gloves, open cab	Mixer, coater, planter	407.34	223.03

Study Summary	PPE/Engineering Controls[a]	Tasks	Unit Exposure (µg/kg ai)	
			Dermal	Inhalation
Planting Commercially Treated Seed (bean, soybean)				
Dean, V.C. 1990. Exposures of Workers to Isofenphos During Planting of Oftanol-Treated Canola Seeds. Sponsored by Mobay Corporation. Unpublished. Loading and planting exposure of canola seed treated with Oftanol (isofenphos) in Manitoba was monitored in this study. Workers loaded the treated seed from bags into seed hoppers and planted using tractor driven planters. Demal exposure was monitored using patches and hand washes. Inhalation exposure was monitored using personal air sampling pumps.	Manual loading. Single layer and gloves, closed cab	Loader, planter	424.17	1.11
Planting Commercially Treated Seed (corn)				
Zietz, 2007. Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds under Realistic Field Conditions in Germany and Italy. Sponsored by SeedTropex Task Force. Unpublished. AHETF. AH825 The study measured exposure of 16 workers loading (from bags) and planting corn seed treated with Gaucho in Germany and Italy. Workers were monitored for approximately 6 to 8 hours, handled an average of 1.20 kg of active ingredient and planted seed to 5.5 to 40.2 ha of land. Dermal exposure was measured using whole body dosimeters, face/neck wipes and hand wash samples. Inhalation exposure was measured with personal air sampling pumps.	Manual loading. Single layer and gloves, closed cab	Loader, planter, unloading of remaining seed, repair	1515	82.83
Planting Commercially Treated Seed (alfalfa, broccoli, Brussels sprout, cabbage, cauliflower, clover, sugarbeet)				
Krainz, 2013, Determination of Dermal and Inhalation Exposure to Operators During Loading and Sowing Seed Treated with Austral® Plus Net Using Conventional or Pneumatic Sowing Machines. Sponsored by Syngenta Crop Proection. AHETF, AH823. Unpublished. Loading and planting of wheat seeds treated with Austral plus net (tefluthrin) in France was monitored in this study. Thirteen workers were monitored while performing both loading and sowing of treated seeds. Monitoring time ranged from approximately 4 to 9 hours with the majority of the time associated with sowing activities. Demal exposure was monitored using whole body dsoimeters, face/neck wipes and hand washes. Inhalation exposure was monitored using personal air sampling pumps.	Manual loading. Single layer, jacket, and gloves, open cab	Loader, planter,	999.35	310.20

[a] For studies where there was only a single layer of PPE, protection factors could be used, where requied, to estimate exposure at higher levels of PPE (for example, coveralls).

Table 20 DFR and TTR Data Applied to Commercial and Domestic Canadian Crops

Surrogate Crop (app equipment)	Study (site)	Rate (kg a.i./ha)	Application Regime[a]	Equation[b]	Correlation Coefficient (r^2)	Peak DFR[c]	Daily Dissipation[d]	Extrapolated to Canadian Crops
Commercial Uses								
Apple (airblast)	Jones, 1988 (New York)	4.48	8 applications, 5-7 days apart	Y=-0.0579x+3.237	0.90	53%	5%	Apples, apricot, cherries (sweet, sour), peach, pear, plum, prune, nectarine, ornamental trees and shrubs
Apple (airblast)	Rashid, 1987 (PA)	4.49	1 application	N/A[i]		25%	N/A[i]	
Grape (airblast)	Winterlin, 1986 (California)	2.24	1 application	N/A[e] (r^2 below 0.85)	0.434	16%	3.5%	Grape
Strawberry (groundboom)	Blewett, 1992 (Calfornia)	2.24	1 application	Y=-0.1504x+1.67	0.96	24%	9.4%	Cucumber, tomato, pumpkin, squash, potato, raspberries, blackberry, loganberry, blueberry, strawberry, Camellia, carnation, chrysanthemum, rose, aster, dahlia, lilac, rose, tulip
Default DFR[f]	N/A					25%	-	Greenhouse: potted plants, tree seedlings, tobacco, rhubarb
Default TTR[g]	N/A					1%	10%	Golf course, sod farm
Residential Uses								
Apple (airblast)	Jones, 1988 (New York)	4.48	8 applications, 5-7 days apart	Y=-0.0579x+3.237	0.90	53%	5%	Liquid application: Apples, apricot, cherries, ornamental trees and shrubs
Apple (airblast)	Rashid, 1987 (PA)	4.49	1 application	N/A[i]		25%	N/A[i]	
Strawberry (groundboom)	Blewett, 1992 (Calfornia)	2.24	1 application	Y=-0.1504x+1.67	0.96	24%	9.4%	Liquid application: Cucumbers, peppers, tomatoes, blackberry, strawberry, ornamental flowers
Default DFR	N/A					25%	N/A[h]	Dust application

APP = application; DFR = dislodgeable foliar residues; TTR = turf transferrable residues; N/A = not applicable; PA = Pennsylvania

[a] For studies with multiple applications, Canadian crops were assessed based on the application regime in the available study. For studies with 1 application, the study data were extrapolated to the registered Canadian use pattern.

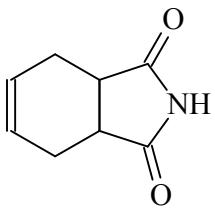
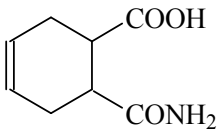
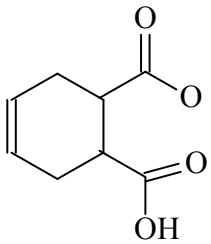
[b] The equation of the line was derived from linear regression of the study data (performed either by PMRA or the study authors), calculated by plotting the natural logarithms (ln) of DFR versus dissipation time (postapplication interval). The correlation coefficient (r^2) value must be greater than 0.85 for the equation to be used to predict DFR in risk assessment.

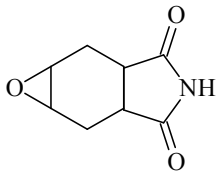
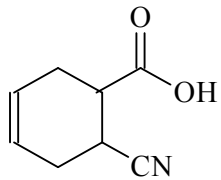
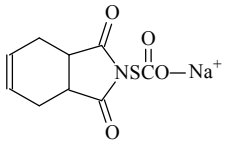
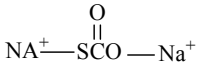
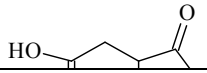
[c] Peak DFR is the highest mean DFR value, expressed as a percentage of the application rate (kilograms per hectare).

[d] Daily dissipation is the rate (expressed as a percentage per day) at which the dislodgeable foliar residue is lost to the environment; derived from the slope of the DFR curve (ln of transferable residue vs. time).
[e] Typically when the r^2 is below 0.85, the actual study data are used. Winterlin, 1986 only reported the linear regression equation derived from the study data (no daily residue data was reported), so the peak DFR and percent dissipation per day were used to estimate residues on grapes.
[f] There were no greenhouse DFR studies, so the default peak value of 20% of the application rate was used in the risk assessment. As dissipation rate in greenhouses is unknown, no dissipation was assumed.
[g] There were no turf transferable residue (TTR) studies available, so the default peak TTR of 5% of the application rate, with a default dissipation rate of 10% per day was assumed.
[h] Multiple application scenarios were not required as the single application scenario had risks of concern.
i The linear regression from Rachid, 1987 is based on DFR samples collected following 8 applications and has an unacceptably low r^2 (0.645). However, DFR samples were collected on the day of the first application and were used with the linear regression from Jones (1988) to estimate DFR following a single application.

Appendix X Tables and Figures Used in Environment Risk Assessment

Table 1 Information on major and minor transformation products of captan detected in environmental fate studies

Chemical name (IUPAC)	Code	Chemical Structure	Occurrence (max. amounts on average replicates and at termination)		
			System	Max %AR	% AR at end
Major transformation products					
Cyclohex-4—ene-1,2-dicarboximide O=C1NC(=O)C2CC=CCC12	THPI		24 h-Hydrolysis 25ºC	pH 5 = 62 at 18 h (end) pH 7 = 44.7 at 10.3 hr (end) pH 9 = 14.4 at 9 hr. (end)	pH 5 = 62 at 18 hr pH 7 = 44.7 at 10.3 hr pH 9 = 14.4 at 9 hr.
			5 days- Soil phototransf.	50 at 4 days	21.3 at day 5
			322 d-Aerobic soil biotransf.	66 at 7 days	0.18 at 244 days
			90 d- Aerobic aqua. biotransf.	81.2 at 0 day	< 0.1 at 59 days
			256 d-Anaerobic soil biotransf.	42.4 at 24 days	11.3%
Cyclohex-4-ene-2-amido-1-carboxilic acid [COOH]C1CC=CCC1[COOH2]	THPAm		24 h-Hydrolysis	ND	ND
			5 days- Soil phototransf.	3.3 at 3 days	2.1 at day 5
			322 d- Aerobic soil biotransf.	16.8 at 14 days	< 0.18 at 244 days (LOQ)
			90 d- Aerobic aqua. biotransf.	27 at 7 days	< 0.1 at 90 days; 24.6 at 90 days in sterile Old Basing system
			256 d-Anaerobic soil biotransf.	36.4 at 49 days	34.4 at 256 days
Cyclohex-4-ene-1,2-dicarboxilic acid O=C(O)C1CC=CCC1C(=O)[O]	THPAL		24 h-Hydrolysis	ND	ND
			5 days- Soil phototransf.	0.9 at 5 days	0.9 at 5 days
			322 d- Aerobic soil biotransf.	3.2 at 14 days	< 0.18 at 244 days (LOQ)
			90 d- Aerobic aqua. biotransf.	5 - 11.3 at 14 days	< 0.1 at 59 days
			256 d-Anaerobic soil biotransf.	21.6 at 256 days	21.6 at 256 days

Cyclohex-4,5-epoxy-1,2-dicarbomixide O=C2NC(=O)C3CC1OC1CC23	THPI epoxide		24 h-Hydrolysis	ND	ND
			5 days- Soil phototransf.	7.8 at 4 days	3 at 5 days
			322 d- Aerobic soil biotransf.	1.6 at 7 days	1.26 at 63 days
			90 d- Aerobic aqua. biotransf.	9.4-11 at 14 days	< 0.1 at 59 days
			256 d-Anaerobic soil biotransf.	ND	ND
Cyclohex-4-ene-2-cyano-1-carboxilic acid O=C(O)C1CC=CCC1[CN]	THCY		24 h-Hydrolysis	ND	ND
			5 days- Soil phototransf.	15.3 at 4 days	6 at 5 days
			322 d- Aerobic soil biotransf.	ND	ND
			90 d- Aerobic aqua. biotransf.	ND	ND
			256 d-Anaerob. soil biotransf.	20.8 at 117 days	16.1 at end
Sodium tetrahydrophthalimide thicarbonate C=C2C1CC=CCC1C(=O)[N]2[S][C](=O)[O][Na]	THPC		24 h-Hydrolysis	pH 5 = 4.6 at 0.11 hr pH 7 = 27 at 10.3 hr pH 9 = 43 at 9 hr	pH 5 = 2.2 at 18 hr pH 7 = 27 at 10.3 hr pH 9 = 43 at 9 hr
			5 days- Soil phototransf.	ND	ND
			322 d- Aerobic soil biotransf.	ND	ND
			90 d- Aerobic aqua. biotransf.	ND	ND
			256 d-Anaerobic soil biotransf.	ND	ND
Sodium thiocarbonate O=[S]([Na])[Na]			24 h-Hydrolysis	pH 5 = 1.1 at 15 hr pH 7 = 7.4 at 6.2 hr pH 9 = 12.2 at 10 hr	pH 5 = 0.9 at 25.3 hr pH 7 = 7.4 at 6.2 hr pH 9 = 12.2 at 10 hr
			5 days- Soil phototransf.	ND	ND
			322 d- Aerobic soil biotransf.	ND	ND
			90 d- Aerobic aqua. biotransf.	ND	ND
			256 d-Anaerobic soil biotransf.	ND	ND
Minor transformation products					
5,6-dihydroxyhexahydro-1H-isoindole-1,3(2H)-dione	Diol		24 h-Hydrolysis	ND	ND
			5 days- Soil phototransf.	ND	ND

O=C1NC(=O)C2CC(O)=C(O)CC12			322 d- Aerobic soil biotransf.	0.6 at 7 days	0 at 63 days
			90 d- Aerobic aqua. biotransf.	ND	ND
			256 d-Anaerobic soil biotransf.	ND	ND

ND = Not detected

Table 2 Fate and Behaviour of captan in the Terrestrial Environment

Process	Substance	Value	Maj transf. product (max % A.R.)	Comments	Reference
Abiotic transformation					
Hydrolysis	Captan	DT_{50} < 1 day	N/A	An important route of transformation in the environment	PMRA 1237447 PMRA 1217553 PMRA 1237446 PMRA 1217552
	THPI	N/A	62.0 at 18 hr - pH 5 44.7 at10.3 hr - pH 7 14.4 at 9.3 hr – pH 9		PMRA1237447 PMRA 1217553
	Sodium thiocarbonate	N/A	12.2 -19.8 at 1 – 10 hr – pH 9		PMRA 1237446
	THPC	N/A	26.7-29.0 at 6.2-17 hr – pH 7 38.4-66.0 at 1-10 hr pH 9		PMRA1237447 PMRA 1217553 PMRA 1237446
Phototransformation in soil	Captan	DT_{50} = 12 – 87.7 days	N/A	Not an important route of transformation in the environment	PMRA 1237397 PMRA 1237398 EPA RED, 1999
	THPI	N/A	50 at 4 days at ph 7.1	N/A	
	THCY	N/A	15.3 at 4 days at pH 7.1	N/A	
Phototransformation in air	Captan	Vapour pressure (2.1×10^{-5} Pa) Henry's Law constant (2.0×10^{-4} $Pa.m^3/mol$	N/A	Not an important route of transformation in the environment	PMRA 1237396, PMRA 1237400
Biotransformation					
Aerobic soil biotransformation	Captan	DT_{50} < 7days	N/A	Non-persistent according to Goring *et al*. (1975)	PMRA 1217568 PMRA 1237404 PMRA 1163898 EPA RED, 1999 EFSA, 2006
	THPI	DT_{50} = 5.8 - 20 days	N/A	Non-persistent to slightly persistent according to Goring *et al*. (1975)	PMRA 1163900 EPA RED, 1999 EFSA, 2006
	THPAm	DT_{50} = 4 - 7 days	N/A	Non-persistent to slightly persistent according to Goring *et al*. (1975)	PMRA 1163901 EFSA, 2006
Anaerobic soil biotransformation	Captan	DT_{90} < 7 days	N/A	Non-persistent according to Goring *et al*. (1975)	EFSA, 2006

	THCY	DT_{90} < 7 days	N/A	Non-persistent according to Goring *et al*. (1975)	EFSA, 2006
Mobility					
Adsorption /desorption	Captan	Koc = 97 mL/g	N/A	High mobility according to McCall *et al*.(1981)	EFSA, 2006
	THPI	Koc = 2.2-11.0 mL/g	N/A	Very high mobility according to McCall et al.(1981)	1163896 EPA RED, 1999 EFSA, 2006
	THPAm	Koc = 4.5 – 100 mL/g	N/A	High to very high mobility according to McCall *et al*.(1981)	
Aged soil column leaching	Captan	DT_{50} = 10 - 35 days	N/A	Non-persistent to slightly persistent according to Goring *et al*.. (1975)	PMRA 1163897 EFSA, 2006
	THPI	N/A	6 at 30 days in 0 - 5 cm 15 at 30 days in leachate	Very high mobility according to EFSA(2006)	
	THPAm	N/A	1 at 30 days in 0 – 5 cm 3 at 30 days in leachate	High mobility according to EFSA (2006)	
Thin Layer chromatography	Captan	Rf = 0.08 – 0.21 Kd = 3.0 – 8.0	N/A	Low mobility according to Helling and Horner (1968) Low to moderately mobile according to to McCall *et al*.(1981)	PMRA 1239401 PMRA 1217565 PMRA 1237499 EPA RED, 1999
Volatility	Captan		0.003 – 0.4 after 9 days	Not volatile	PMRA 1237400
			Vapour pressure = 1.0 – 1.3 × 10^{-5} Pa	Relatively non-volatile according to Kennedy and Talbert (1977)	
			Henry's law constant =2.0 × 10^{-4} (1/H = 1.2 × 10^{7})	Non-volatile from water surface or moist soil according to EPA (1975)	
Cohen criteria	Captan	3/8 criteria met	N/A	Low potential for leaching	Present PMRA review
GUS score	Captan	GUS = -15 – 1.7	N/A	Non-leacher	Present PMRA review
	THPI	GUS = 2.2 – 4.1	N/A	Borderline leacher to a leacher	
	THPAm	GUS = 1.2 – 2.9	N/A	Non-leacher to a leacher	
Dissipation and accumulation field studies					
United States field studies					
Oregon	Captan	DT_{50} = 3.4 d	N/A	Non-persistent to slightly persistent (Goring et al. 1975)	1237690, present PMRA review
	THPI	N/A	Maintained in the 0-7.6 cm	N/A	
New York	Captan	DT_{50} = 3.9 d	N/A	Non-persistent (Goring et al. 1975)	1237691, present PMRA review
	THPI	N/A	Maintained in the 0-7.6 cm	N/A	

N/A = Not applicable
[1] = Value in ( ) were recalculated by present reviewer

Table 3 Fate and behaviour in the aquatic environment

Process	Substance	Value	Maj transf. product (max % A.R.)	Comments	Reference
Abiotic transformation					
Hydrolysis	Captan	DT_{50} < 1 day	N/A	An important route of transformation in the environment	PMRA 1237447 PMRA 1217553 PMRA 1237446 PMRA 1217552
	THPI	N/A	62.0 at 18 hr - pH 5 44.7 at10.3 hr - pH 7 14.4 at 9.3 hr – pH 9		PMRA1237447 PMRA 1217553
	Sodium thiocarbonate	N/A	12.2 -19.8 at 1 – 10 hr – pH 9		PMRA 1237446
	THPC	N/A	26.7-29.0 at 6.2-17 hr – pH 7 38.4-66.0 at 1-10 hr pH 9		PMRA1237447 PMRA 1217553 PMRA 1237446
Phototransformation in water	Captan	DT_{50} = 10 hr, irradiated DT_{50} = 10 hr, dark	N/A	Not an important route of transformation in the environment	PMRA 1237448 EPA RED, 1999 EFSA, 2006
Aerobic aquatic biotransformation	Captan	DT_{50} = < 1 day	N/A	Non persistent (McEwen and Stephensen, 1979)	PMRA 1163905 EPA RED, 1999 EFAS, 2006
	THPI	DT_{50} = 7 days	N/A	Non-persistent (McEwen and Stephensen, 1979)	
	THPAm	DT_{50} = 17.8 day	N/A	Slightly persistent (McEwen and Stephensen, 1979)	
Anaerobic aquatic biotransformation	No study required				
Aquatic field dissipation studies	No study required				
Bioconcentration					

N/A = Not applicable
[1] = Value in ( ) were recalculated by present reviewer

Table 4 Effects on Aquatic Organisms

Organism	Exposure	Endpoint value	Degree of toxicity[a]
Freshwater species			
Daphnia magna	Acute: TGAI EUP	48 hr EC_{50} = 8.4 mg a.i./L 24 hr EC_{50}= 3.4 mg a.i./L	Moderately toxic
	Chronic	21 day NOEC = 0.56 mg a.i./L LOEC: 1.0 mg a.i./L, reduced offspring & wt.	-
Rainbow trout	Acute	96 hr LC_{50} = 0.186 mg ai./L *	Highly toxic
	Chronic (EUP)	28 day NOEC = 0.1992 mg ai./L	-
Bluegill sunfish	Acute	96 hr LC_{50} = 72-310 mg ai./L, GM= 0.1494 mg ai../L.*	Very highly toxic
Fathead minnow	Acute	96 hr LC_{50} = 0.065 mg ai./L*	Very highly toxic
	Chronic	Full life cycle NOEC = 0.0165 mg ai./L LOEC: 0.039 mg a.i./L (growth, wt, survival)	-
Brook trout	Acute	96 hr LC_{50} = 0.034 mg ai./L*	Very highly toxic
Coho salmon	Acute	96 hr LC_{50} =0.137 mg ai./L*	Highly toxic
Harlequin fish	Acute	96 hr LC_{50} =0.300 mg ai./L*	Highly toxic
Brown trout	Acute	96 hr LC_{50} =0.0262-0.098 mg ai./L GM= 0.0506 mg ai../L.*	Very highly toxic
Fish HC_5 from SSD[b]	Acute	HC_5 = 0.0268 mg ai./L (95% CI: 0.00729-0.0506 mg ai./L)	Very highly toxic
Freshwater alga	Acute (cell density) 1. Selenastrum 2 Anabaena 3 Pavlova 4. Isochrysis 5. Scenedesmus	EC_{50} (mg a.i./L) 1.77 1.2 0.55 0.21 0.32	-
Vascular plant	7 day (Dissolved) *Lemna gibba*	EC_{50} = 12.7 mg a.i./L (EPA)	-
	Over-spray	NA	-
Marine species			
Crustacean: Mysid shrimp	Acute	96hr EC50: 8.4 mg a.i./L	Moderately toxic
	Chronic	-	-
Mollusk: oyster	Acute	Shell deposition: 96hr EC50: 0.0033 mg a.i./L	Very highly toxic
	Chronic	-	-
Fish: Sheepshead minnow	Acute	96hr LC50: 1.9 mg a.i./L	Moderately toxic
	chronic	-	-
Marine alga	Acute (cell density) *Skeletonema costatum*	EC50: 0.18 mg a.i./L	-

* Indicates fish data used to generate HC_5 value, [a] USEPA classification, where applicable; [b] SSD HC_5 is the 5th percentile concentration derived from a Log-logistic equation (Model: ETX 2) based on LC_{50} data sets, GM: geometric mean.

Table 5 Summary of endpoints used in the risk assessment with appropriate conversions

Organism	Exposure	Endpoint	Value	Uncertainty factor applied[1]
Earthworm	Acute chronic	14d-LC_{50} NOEC (reproduction)	419.5 mg ai./kg soil 0.8 mg ai./kg soil	2
Bee	contact	48h-LD_{50}	>215 ug/bee > 16 kg/ha	1
Beneficial Insects		EC_{50}	26 kg/ha	1
Birds (Bobwhite quail)	Acute	14d LD_{50}	>215 mg/kg bw	10
	Acute Dietary	5d-LD_{50} (LC_{50} converted to dose)	>25.5 mg/kg bw	10
	Reproduction	Xd-NOEL (NOEC converted to dose)	106 mg/kg bw	-
Mallard duck	Acute	14d LD_{50}	>200 mg/kg bw	10
	Acute Dietary	5d-LD_{50} (LC_{50} converted to dose)	>28.3 mg/kg bw	
	Reproduction	Xd-NOEL (NOEC converted to dose)	56.6 mg/kg bw	-
Mammals (Rat)	Acute	LD_{50}	>200 mg/kg bw	10
	Acute Dietary	Xd-LD_{50} (LC_{50} converted to dose)	NA	10
	Reproduction	NOEC (pup wt.)	100 mg/kg/bw/d	1
Terrestrial vascular plants	Seedling emergence	7d-EC_{50}	No effects at 9kg a.i./ha	1
	Vegetative vigour	7d-EC_{50}	No effects at 9kg a.i./ha	1
Freshwater invertebrates	Acute	96h-LC_{50}	4.2 mg a.i./L	2
	Chronic	21 day NOEC	0.56 mg a.i./L	1
Freshwater fish (HC_5 based on SSD of 7 sp)	Acute	HC_5 96h-LC_{50}	0.0268 mg a.i./L	-
Fathead minnow	Chronic	Life cycle NOEC	0.0165 mg a.i./L	1
	ELS	Xd-NOEC	NA	1
Amphibians (based on fish HC_5 value)	Acute	96h-LC_{50}	0.0268 mg a.i./L	-
	Chronic	-	-	1
Aquatic vascular plants (Lemna sp)		7d-EC_{50}	6.35 mg/L	2
Algae (Selenastrum)		Xd-EC_{50}	0.1 mg/L	2
Saltwater invertebrates	Acute	96h-LC_{50}	0.00165 mg/L	2
	Chronic	Xd-NOEC	NA	1
Saltwater fish	Acute	96h-LC_{50}	0.19 mg/L	10
	Chronic	Xd-NOEC	NA	1
Saltwater algae		Xh-LC_{50}	0.09 mg/L	2

[1] as per the Guidance Manual

Table 6 Screening level risk assessment for captan fungicide to terrestrial Invertebrates and vascular plants (including Tier I drift refinement for plants)

Organism	Exposure	Endpoint value	EEC[2]	RQ[3]	Risk LOC[4] Exceeded
Invertebrates					
Earthworm	Acute	14-day LC_{50} ÷ 2 419.5 mg ai./kg soil	5.58 mg ai./kg soil (7.2 kg ai./ha × 5)	<0.02	NO
Bee[1]	Oral	NA	-		

Organism	Exposure	Endpoint value	EEC[2]	RQ[3]				Risk LOC[4] Exceeded
	Contact	>240.8 kg ai./ha (>215 µg a.i../bee)	36 kg a.i./ha (7.2 kg ai./ha × 5)	<0.15				NO
	Brood / hive							
Predatory arthropod	Contact	NOEC (field): > 26.4 kg a.i./ha (8x3.3 kg a.i./ha)	36 kg a.i./ha (7.2 kg ai./ha × 5)	<1.36				NO
Parasitic arthropod	Contact	NA	-	-				-
Vascular plants								
				Deposition rate				
Vascular plant	Seedling emergence	NOEC > 9 kg a.i./ha	36 kg a.i./ha (7.2 kg ai./ha × 5)	100%	6%	59%	74%[5]	NO
				<4	<0.24	<2.36	<2.96	
	Vegetative vigour			<4	<0.24	<2.36	<2.96	NO

[1]The LD_{50} in µg/bee is converted to the equivalent rate in kg/ha by multiplying by 1.12 according to Atkins et al. (1981)
[2]Estimated Environmental Concentration (EEC)
[3]Risk Quotient (RQ) = exposure/toxicity
[4]Level of Concern (LOC) Shaded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment.
[5] 74% drift occurs for early airblast applications only and at a rate of 7200 g a.i./ha.

Table 7 Risk Assessment on non-target birds and mammals for captan fungicide assuming an application rate of 5 × 7.2 kg a.i./ha on cherries (airblast application; 74% drift)

Avian Assessment						
Study type	**Toxicity endpoint (mg a.i./kg bw/d)[1]**	**Food Guild**	**Maximum Residue RQ[2]**		**Mean Residue RQ[2]**	
			On-field (100%)	**Off-field (74%)***	**On-field (100%)**	**Off-field (74%)***
Small Bird (0.02 kg)						
Acute	200	Insectivore (small insects)	**4.9229**	**3.6430**	**2.7455**	**2.0317**
	200	Granivore (grain and seeds)	**1.2307**	0.9107	0.5870	0.4344
	200	Frugivore (fruit)	**2.4615**	**1.8215**	**1.1739**	0.8687
Dietary	25.5	Insectivore (small insects)	**38.6113**	**28.5724**	**21.5332**	**15.9346**
	25.5	Granivore (grain and seeds)	**9.6529**	**7.1431**	**4.6037**	**3.4067**
	25.5	Frugivore (fruit)	**19.3058**	**14.2863**	**9.2074**	**6.8134**
Reproduction	56.6	Insectivore (small insects)	**17.3956**	**12.8727**	**9.7014**	**7.1790**
	56.6	Granivore (grain and seeds)	**4.3489**	**3.2182**	**2.0741**	**1.5348**
	56.6	Frugivore (fruit)	**8.6978**	**6.4364**	**4.1482**	**3.0697**
Medium Sized Bird (0.1 kg)						
Acute	200	Insectivore (small insects)	**3.8418**	**2.8430**	**2.1426**	**1.5855**
	200	Insectivore (large insects)	0.9605	0.7107	0.4581	0.3390

Avian Assessment						
Study type	**Toxicity endpoint (mg a.i./kg bw/d)[1]**	**Food Guild**	**Maximum Residue RQ[2]**		**Mean Residue RQ[2]**	
			On-field (100%)	**Off-field (74%)***	**On-field (100%)**	**Off-field (74%)***
	200	Granivore (grain and seeds)	0.9605	0.7107	0.4581	0.3390
	200	Frugivore (fruit)	**1.9209**	**1.4215**	0.9161	0.6779
Dietary	25.5	Insectivore (small insects)	**30.1320**	**22.2977**	**16.8044**	**12.4352**
	25.5	Insectivore (large insects)	**7.5330**	**5.5744**	**3.5927**	**2.6586**
	25.5	Granivore (grain and seeds)	**7.5330**	**5.5744**	**3.5927**	**2.6586**
	25.5	Frugivore (fruit)	**15.0661**	**11.1489**	**7.1854**	**5.3172**
Reproduction	56.6	Insectivore (small insects)	**13.5754**	**10.0458**	**7.5709**	**5.6024**
	56.6	Insectivore (large insects)	**3.3939**	**2.5115**	**1.6186**	**1.1978**
	56.6	Granivore (grain and seeds)	**3.3939**	**2.5115**	**1.6186**	**1.1978**
	56.6	Frugivore (fruit)	**6.7877**	**5.0229**	**3.2372**	**2.3955**
Large Sized Bird (1 kg)						
Acute	200	Insectivore (small insects)	**1.1217**	0.8300	0.6255	0.4629
	200	Insectivore (large insects)	0.2804	0.2075	0.1337	0.0990
	200	Granivore (grain and seeds)	0.2804	0.2075	0.1337	0.0990
	200	Frugivore (fruit)	0.5608	0.4150	0.2675	0.1979
	200	Herbivore (short grass)	**4.0088**	**2.9665**	**1.4237**	**1.0535**
	200	Herbivore (long grass)	**2.4477**	**1.8113**	0.7992	0.5914
	200	Herbivore (forage crops)	**3.7090**	**2.7446**	**1.2261**	**0.9073**
Dietary	25.5	Insectivore (small insects)	**8.7973**	**6.5100**	**4.9062**	**3.6306**
	25.5	Insectivore (large insects)	**2.1993**	**1.6275**	**1.0489**	0.7762
	25.5	Granivore (grain and seeds)	**2.1993**	**1.6275**	**1.0489**	0.7762
	25.5	Frugivore (fruit)	**4.3987**	**3.2550**	**2.0978**	**1.5524**
	25.5	Herbivore (short grass)	**31.4413**	**23.2666**	**11.1661**	**8.2629**
	25.5	Herbivore (long grass)	**19.1974**	**14.2061**	**6.2685**	**4.6387**
	25.5	Herbivore (forage crops)	**29.0900**	**21.5266**	**9.6165**	**7.1162**
Reproduction	56.6	Insectivore (small insects)	**3.9635**	**2.9330**	**2.2104**	**1.6357**
	56.6	Insectivore (large insects)	0.9909	0.7332	0.4726	0.3497
	56.6	Granivore (grain and seeds)	0.9909	0.7332	0.4726	0.3497
	56.6	Frugivore (fruit)	**1.9817**	**1.4665**	0.9451	0.6994
	56.6	Herbivore (short grass)	**14.1653**	**10.4823**	**5.0307**	**3.7227**
	56.6	Herbivore (long grass)	**8.6490**	**6.4003**	**2.8242**	**2.0899**
	56.6	Herbivore (forage crops)	**13.1059**	**9.6984**	**4.3325**	**3.2061**

Mammalian Assessment						
Study type	**Toxicity endpoint (mg a.i./kg bw/d)[1]**	**Food Guild**	**Maximum Residue RQ[2]**		**Mean Residue RQ[2]**	
			On-field (100%)	**Off-field (74%)***	**On-field (100%)**	**Off-field (74%)***
Small Mammal (0.015kg)						
Acute	200	Insectivore (small insects)	**2.8315**	**2.0953**	**1.5791**	**1.1685**
	200	Granivore (grain and seeds)	0.7079	0.5238	0.3376	0.2498

Mammalian Assessment						
Study type	**Toxicity endpoint (mg a.i./kg bw/d)[1]**	**Food Guild**	**Maximum Residue RQ[2]**		**Mean Residue RQ[2]**	
			On-field (100%)	**Off-field (74%)***	**On-field (100%)**	**Off-field (74%)***
	200	Frugivore (fruit)	**1.4158**	**1.0477**	0.6752	0.4997
Reproduction	100	Insectivore (small insects)	**5.6630**	**4.1906**	**3.1582**	**2.3371**
	100	Granivore (grain and seeds)	**1.4158**	**1.0477**	0.6752	0.4997
	100	Frugivore (fruit)	**2.8315**	**2.0953**	**1.3504**	**0.9993**
Medium Sized Mammal (0.035 kg)						
Acute	200	Insectivore (small insects)	**2.4822**	**1.8368**	**1.3843**	**1.0244**
	200	Insectivore (large insects)	0.6205	0.4592	0.2960	0.2190
	200	Granivore (grain and seeds)	0.6205	0.4592	0.2960	0.2190
	200	Frugivore (fruit)	**1.2411**	0.9184	0.5919	0.4380
	200	Herbivore (short grass)	**8.8711**	**6.5646**	**3.1505**	**2.3314**
	200	Herbivore (long grass)	**5.4165**	**4.0082**	**1.7687**	**1.3088**
	200	Herbivore (forage crops)	**8.2077**	**6.0737**	**2.7133**	**2.0078**
Reproduction	100	Insectivore (small insects)	**4.9643**	**3.6736**	**2.7686**	**2.0487**
	100	Insectivore (large insects)	**1.2411**	0.9184	0.5919	0.4380
	100	Granivore (grain and seeds)	**1.2411**	0.9184	0.5919	0.4380
	100	Frugivore (fruit)	**2.4822**	**1.8368**	**1.1838**	0.8760
	100	Herbivore (short grass)	**17.7423**	**13.1293**	**6.3010**	**4.6627**
	100	Herbivore (long grass)	**10.8331**	**8.0165**	**3.5373**	**2.6176**
	100	Herbivore (forage crops)	**16.4154**	**12.1474**	**5.4266**	**4.0157**
Large Sized Mammal (1 kg)						
Acute	200	Insectivore (small insects)	**1.3263**	0.9815	0.7397	0.5474
	200	Insectivore (large insects)	0.3316	0.2454	0.1581	0.1170
	200	Granivore (grain and seeds)	0.3316	0.2454	0.1581	0.1170
	200	Frugivore (fruit)	0.6632	0.4907	0.3163	0.2340
	200	Herbivore (short grass)	**4.7401**	**3.5077**	**1.6834**	**1.2457**
	200	Herbivore (long grass)	**2.8942**	**2.1417**	**0.9451**	0.6993
	200	Herbivore (forage crops)	**4.3857**	**3.2454**	**1.4498**	**1.0729**
Reproduction	100	Insectivore (small insects)	**2.6526**	**1.9629**	**1.4793**	**1.0947**
	100	Insectivore (large insects)	0.6632	0.4907	0.3163	0.2340
	100	Granivore (grain and seeds)	0.6632	0.4907	0.3163	0.2340
	100	Frugivore (fruit)	**1.3263**	0.9815	0.6325	0.4681
	100	Herbivore (short grass)	**9.4803**	**7.0154**	**3.3668**	**2.4915**
	100	Herbivore (long grass)	**5.7885**	**4.2835**	**1.8901**	**1.3987**
	100	Herbivore (forage crops)	**8.7713**	**6.4908**	**2.8996**	**2.1457**

*Assuming 74% drift from airblast applications

1) Endpoints were divided by an Uncertainty Factor to account for varying protection goals (in other words, protection at the community, population, or individual level)

2) RQ = exposure/toxicity; RQs < 0.1 were not calculated to show all decimal points. RQs are based on estimated environmental concentrations (EEC): For birds and mammals, the EEC takes into account the maximum seasonal cumulative rate on vegetation and is calculated using PMRA standard methods based on the Hoerger and Kenaga nomogram as modified by Fletcher (1994) EDE = Estimated dietary exposure; calculated for each bird or mammal size based on the EEC on appropriate food item for each food guild (at the screening level, the most conservative EEC for each food guild was used). The EDE was calculated using the following formula: (FIR/BW) × EEC. For each body weight (BW), the food ingestion rate (FIR) was based on equations from Nagy (1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used; for mammals, the "all mammals" equation was used: Passerine Equation (body weight ≤200 g): FIR (g dry weight/day) = $0.398(\text{BW in g})^{0.850}$

All Birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$
All Mammals Equation: FIR (g dry weight/day) = 0.235(BW in g) 0.822
Conversion from a concentration (EEC) to a dose (EDE): [EDE (mg a.i./kg bw) = EEC (mg a.i./kg diet)/BW (g) × FIR (g et/day)]
Nagy, K.A. 1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecological Monographs 57:111-128

Table 8 Seed treatment application rate

Parameter	corn		bean	soybean	pea
	field, pop	sweet			
Max. treatment rate [a] (g a.i./25 kg seed)	29.81	30.6	25.2	25.2	25.2
mg a.i. per kg of seed [b]	1192.6	**1224.0**	1008.0	1008.0	1008.0

[a] Maximum rate for captan products normalised to 25 kg
[b] mg a.i./kg seed = seed treatment rate (g a.i./kg seed) / kg seeds treated

Table 9 Avian and mammalian risk assessment for seed treatment uses

	Toxicity Endpoint (mg a.i./kg bw/d)	EDE (mg a.i./kg bw/d) [a]	RQ
Small bird (0.02 kg)			
Acute	200.00	310.821	**1.55**
Reproduction	56.60	310.821	**5.49**
Medium bird (0.10 kg)			
Acute	200.00	244.154	**1.22**
Reproduction	56.60	244.154	**4.31**
Large bird (1.00 kg)			
Acute	200.00	71.180	0.36
Reproduction	56.60	71.180	**1.26**
Small mammals (0.015 kg)			
Acute	200.00	177.625	0.89
Reproduction	100.00	177.625	**1.78**
Medium mammals (0.035 kg)			
Acute	200.00	152.758	0.76
Reproduction	100.00	152.758	**1.53**
Large mammals (1.00 kg)			
Acute	200.00	84.110	0.42
Reproduction	100.00	84.110	0.84

[a] EDE = Estimated dietary exposure; calculated as EEC × (FIR/BW), where the EEC is the seed treatment application rate (sweet corn at 30.6 g a.i./25 kg seeds = 1224.0 mg a.i./kg seeds). For each body weight (BW), the food ingestion rate (FIR) was based on equations from Nagy (1987).

Table 10 Screening Level Risk and refined runoff risk to aquatic organisms exposed to captan fungicide

Organism	Exposure	Endpoint value*	EEC[1]	RQ[2]	LOC exceeded[3]
Screening Level Risk: Freshwater species Applied on cherries at 5 × 7200 g a.i./ha.					
Daphnia magna	Acute	96 hr LC_{50}: 4.2 mg/L	0.9 mg/L	0.2	No
	Chronic	21 d NOEC: 0.56 mg/L	0.9 mg/L	**1.6**	**Yes**
Rainbow trout	Acute	HC5: 0.0268 mg /L	0.9 mg/L	**33.6**	**Yes**
	Chronic	-	0.9 mg/L	-	No
Fathead minnow	Acute	HC5: 0.0268 mg /L	0.9 mg/L	**33.6**	**Yes**
	Chronic	NOEC: 0.0165 mg/L	0.9 mg/L	**54.5**	**Yes**
Freshwater alga	Acute	0.1 mg/L	0.9 mg/L	**9**	**Yes**
Vascular plant	Dissolved	6.35 mg/L	0.9 mg/L	0.14	No
	Over-spray	NA	-	**-**	
Amphibians[5]	Acute	0.0268 mg/L	4.8 mg/L	**180.5**	**Yes**
Screening Level Risk: Marine species					
Marine invertebrates	Acute	0.00165 mg/L	0.9 mg/L	**545**	**Yes**
Marine fish	Acute	0.19 mg/L	0.9 mg/L	**4.7**	**Yes**
Marine alga	Acute	0.09 mg/L	0.9 mg/L	**10**	**Yes**
Tier I refined assessment for runoff into a 15 cm deep water body (Application on potatoes at 7x 3000 g a.i./ha)					
Amphibians	Acute	0.0268 mg/L	0.772 mg/L	**28.8**	**Yes**
Tier I refined assessment for runoff into an 80 cm deep water body (Application on potatoes at 7x 3000 g a.i./ha)					
Invertebrates	Acute	96 hr LC_{50}: 4.2 mg/L	0.145 mg/L	0.03	No
	Chronic	21 d NOEC: 0.56 mg/L	0.0042 mg/L	0.0075	No
Fish	Acute HC_5	0.0268 mg/L	0.145 mg/L	**5.4**	**Yes**
	Chronic	0.0165 mg/L	0.0042 mg/L	0.25	No
Freshwater alga	Acute	0.1 mg/L	0.145 mg/L	**1.4**	**Yes**
Marine invertebrates	Acute	0.00165 mg/L	0.145 mg/L	**87**	**Yes**
Marine fish	Acute	0.19 mg/L	0.145 mg/L	0.7	No
Marine alga	Acute	0.09 mg/L	0.145 mg/L	**1.6**	**Yes**
Tier II refined assessment for runoff into a 80 cm deep water body (Application on peas at 1x 11280 g a.i./ha)[4]					
Fish	Acute HC_5	0.0268 mg/L	0.0032 mg/L	0.11	No
	Chronic	0.0165 mg/L	0.0001 mg/L	0.006	No
Marine invertebrates	Acute	0.00165 mg/L	0.0032 mg/L	**1.9**	**Yes**
Tier II refined assessment for runoff into a 15 cm deep water body (Application on peas at 1x 11280 g a.i./ha)[4]					
Amphibians	Acute	0.0268 mg/L	0.017 mg/L	0.63	No

* uncertainty factor applied ; [1]Estimated Environmental Concentration (EEC) in water. ;
[2]Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80 cm deep water body / (EC_{50} ÷ 10 or LC_{50} ÷ 10); for a chronic exposure: RQ = EEC in an 80 cm deep water body / NOEC; for amphibians, the EEC in a 15 cm deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80 cm deep water body / (EC_{50} ÷ 2 or LC_{50} ÷ 2); for a chronic exposure: RQ = EEC in a 80 cm deep water body / NOEC
[3]Level of Concern (LOC).

Table 11 Spray Drift Risk Assessment for Aquatic Organisms

Organism	Exposure	Endpoint Value[1]	Use Rate (g a.i./ha)	Screening EEC	RQ Drift deposition rate 6%[3]	RQ Drift deposition rate 59%[4]	RQ Drift deposition rate 74%[4]
Freshwater Species							
Amphibians[2]	Acute	HC5: (0.0268 mg a.i./L)	7200 x5	4.8 mg a.i./L	<1	**105.6**	**133.6**
Freshwater Fish	Acute	HC5: (0.0268 mg a.i./L)	7200 x5	0.9 mg/L	<1	**18.8**	**25**
Freshwater algae	Acute	0.1 mg a.i./L	7200 x5	0.9 mg/L	<1	**5.3**	**6.66**
Saltwater invertebrates	Acute	0.00165 mg a.i./L	7200 x5	0.9 mg/L	**5**	**321**	**403**
Saltwater fish	Acute	0.19 mg a.i./L	7200 x5	0.9 mg/L	<1	**2.8**	**3.6**
Saltwater algae	Acute	0.09 mg a.i./L	7200 x5	0.9 mg/L	<1	**5.9**	**7.4**

[1)] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (protection at the community, population, or individual level); [2] Endpoints from fish used as surrogate.

* Values in bold exceed the LOC (level of concern (1)); [3]Ground boom application on potatoes, 7x3000 g a.i./ha; . [4] Orchard airblast application on cherry (7200 g a.i./ha x5).

Table 12 Toxic Substances Management Policy Considerations – Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Captan Endpoints
Toxic or toxic equivalent as defined by the *Canadian Environmental Protection Act*[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]	Soil	Half-life ≥ 182 days	0.9 days (aerobic soil)
	Water	Half-life ≥ 182 days	1 d (aerobic water)
	Sediment	Half-life ≥ 365 days	no
	Air	Half-life ≥ 2 days or evidence of	Half-life or volatilisation is not an important route of dissipation and long-range

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Captan Endpoints
		long range transport	atmospheric transport is unlikely to occur based on the vapor pressure [4.2 × 10^{-6} mm Hg (25ºC)] and Henry's Law Constant (1.97x10^{-9} atm. m^3mol^{-1} 1/H= 1.23E7
Bioaccumulation[4]	Log $K_{OW} \geq 5$		2.73
	BCF ≥ 5000		NA
	BAF ≥ 5000		NA
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.

[1]All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criterion may be refined if required (in other words, all other TSMP criteria are met).
[2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4]Field data (for example, bioaccumulation factors [BAFs]) are preferred over laboratory data (for example, bioconcentration factors [BCFs]), which, in turn, are preferred over chemical properties (for example, log K_{OW}).

Appendix XI Water Monitoring and Modeling for use in Drinking Water Risk Assessment and Aquatic Ecoscenario.

Water Monitoring Sources of Data

A search for captan water monitoring data in Canada resulted in a number of samples with detections being reported. The Federal Provincial and Territorial representatives from all of the provinces and territories in Canada were contacted, requesting water monitoring data for the pesticides that are currently under re-evaluation. In addition, requests were submitted to Environment Canada, the Department of Fisheries and Oceans and the drinking water subcommittee through Health Canada. A response was received by all provinces and territories indicating that either monitoring data were not available or the available data were submitted. The transformation product THPI was not included in the request for monitoring data. THPI was not part of the analyte list in any of the monitoring studies available in the PMRA database.

American databases were searched for detections of captan and THPI. Data on residues present in water samples taken in the United States are important to consider in the Canadian drinking water assessment given the extensive monitoring programs that exist in the US. Runoff events, local use patterns, site specific hydrogeology as well as testing and reporting methods are probably more important influences on residue data rather than Northern versus Southern climate. As for the climate, if temperatures are cooler, residues may break down more slowly, on the other hand if temperatures are warmer, growing seasons may be longer and applications may be more numerous and frequent. Monitoring data from American databases were available for captan, but not for the transformation product THPI. Table 1 shows a summary of monitoring studies; Table 2 shows a summary of the drinking water modeling result.

Table 1 Summary of the Monitoring Studies Available

Summary of the Monitoring Studies Available											
Data Source	**DETECTION FREQUENCY**							**CONCENTRATION PERCENTILES (③g/L)**			
	Location			**Min detection or detection limit (③g/L)**	**# of systems tested (or absolute number of samples)**	**# of systems or samples with detections**	**% Detection frequency**	**Mean detection**	**95th**	**Absolute Max**	**Arithmetic Mean Including non-detects at ½ LOD**
Captan residues in municipal drinking water sources and groundwater											
PMRA 1307567	Groundwater in PEI			1.0	12	0	0	--	--	--	--
PMRA 1307578	Wells in apple growing region of Quebec (1994-1996)			0.02-0.05	72 samples from 42 wells	6	8.3	0.25	0.75	0.9	0.038
PMRA 1311119, 1311120	Wells in potato growing region of Quebec (1999-2001)			0.04-0.05	126 samples from 79 private wells	0	0	--	--	--	0.022
PMRA 1345591	Groundwater in Lower Fraser Valley, British Columbia (2001)			1	66	0	0	--	--	--	0.05
PMRA 1311104, 1311110, 1311111, 1311112	Groundwater in British Columbia (2003-2004)	Lower Fraser Valley		NR (varied with each sample)	11	0	0	--	--	--	--
		Okanagan basin		NR (varied with each sample)	2	0	0	--	--	--	--
Captan residues in ambient water that may serve as a drinking water source											
PMRA 1307578	Streams in the apple growing region of Quebec	Déversant du Lac	1994	0.02	12	0	0.0	--	--	--	0.01
			1995	0.05	15	1	6.7	--	--	4	0.29
			1996	0.05	23	13	56.5	0.27	1.09	2.2	0.16
		Boffin	1994	0.02	12	0	0	–	–	–	0.01
			1995	0.05	13	0	0	–	–	–	0.025
			1996	0.05	24	2	8.3	0.08	--	0.11	0.030

Summary of the Monitoring Studies Available											
Data Source	**DETECTION FREQUENCY**							**CONCENTRATION PERCENTILES (③g/L)**			
	Location			**Min detection or detection limit (③g/L)**	**# of systems tested (or absolute number of samples)**	**# of systems or samples with detections**	**% Detection frequency**	**Mean detection**	**95th**	**Absolute Max**	**Arithmetic Mean Including non-detects at ½ LOD**
		Abbott's Corner	1994	0.02	12	0	0	–	–	–	0.01
PMRA 1307581	Corbin stream		1996	0.05	17	5	29.4	0.10	0.16	0.18	0.047
			1997	0.05	40	2	5.0	0.05	0.05	0.05	0.026
	De l'Achigan River		1996	0.05	18	0	0	--	--	--	0.025
			1997	0.05	29	0	0	--	--	--	0.025
PMRA 1307580	Mouth of the Grand, Saugeen and Thames Rivers, Ontario (1981-1985)			<0.002	446	0	0	--	--	--	0.001
PMRA 1307590	Alberta surface water (1984-1988)			0.05	176	0	0		--	--	0.025
PMRA 1739329	Surface water in British Columbia (2003-2005)			0.00259	40 samples from 10 sites	0	0	--	--	--	0.00130
PMRA 1401898	Lake Erie tributaries (1998)			NR	76	0	0	--	--	--	--
PMRA 1311104, 1311110, 1311111, 1311112	Surface water in British Columbia (2003-2004)	Lower Fraser Valley		NR (varied with each sample)	14	1	7.1	--	--	0.68-1.83	--
		Okanagan basin		NR (varied with each sample)	7	0	0	--	--	--	--
Captan residues in water that is unlikely to be used as a drinking water source											
PMRA 1311110, 1311111, 1311112,	Runoff in Lower Fraser Valley, British Columbia (2003-2004)			0.2	13	0	0	--	--	--	0.1

Table 2 Level 1 estimated environmental concentrations of captan parent and combined residues in potential drinking water

Compound	Groundwater EEC (⌡g a.i./L)		Surface Water EEC (⌡g a.i./L)			
			Reservoir		Dugout	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]	Daily[3]	Yearly[4]
Captan parent	0	0	522	1.7	164	0.58
Combined residues	701	602	1110	149	1058	199

Notes:
1 90th percentile of daily average concentrations
2 90th percentile of yearly average concentrations
3 90th percentile of yearly peak concentrations
4 90th percentile of yearly average concentrations

Aquatic Ecoscenario Assessment: Level 1 Modelling

For Level 1 aquatic ecoscenario assessment, estimated environmental concentrations (EECs) of captan from runoff into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m

A total of six standard regional scenarios were modeled to represent different regions of Canada. Several initial application dates between early April and late July were modeled. Table 2.1-1 lists the application information and the main environmental fate characteristics used in the simulations. The EECs are for the portion of the pesticide that enters the water body via runoff only; deposition from spray drift is not included. The models were run for 50 years for all scenarios. The EECs are calculated from the model output from each run as follows. For each year of the simulation, PRZM/EXAMS calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day, and 1 year). The 90th percentiles over each averaging period are reported as the EECs for that period.

Tables 3.1 and 3.2 show runoff concentrations (EECs) of captan in surface waters of 80cm depth and 15cm depth, when used on cherries and potatoes, respectively. Table 3.3 shows runoff EECs of captan in surface waters when applied using soil incorporation.

Table 3-1 Level 1 aquatic ecoscenario modeling EECs (µg a.i./L) for captan in a water body 0.8 m deep, excluding spray drift

Region	EEC					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Use on cherry, 5 × 7.2 kg a.i./ha, at 7-day intervals						
BC	12	1.5	0.29	0.10	0.068	0.017
ON	40	5.6	1.1	0.49	0.33	0.081
QC	92	12	2.5	0.89	0.60	0.15
Atlantic	34	4.5	0.87	0.31	0.20	0.050
Use on potato, 7 × 3.0 kg a.i./ha, at 7-day intervals						
Atlantic	126	17	4.2	1.9	1.3	0.31
Prairie	145	19	4.1	1.5	1.0	0.25

Table 3-2 Level 1 aquatic ecoscenario modeling EECs (µg a.i./L) for captan in a water body 0.15 m deep, excluding spray drift

Region	EEC					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Use on cherry, 5 × 7.2 kg a.i./ha, at 7-day intervals						
BC	62	8.1	1.6	0.55	0.36	0.090
ON	215	30	5.9	2.6	1.7	0.43
QC	493	64	14	4.8	3.2	0.78
Atlantic	183	24	4.6	1.6	1.1	0.27
Use on potato, 7 × 3.0 kg a.i./ha, at 7-day intervals						
Atlantic	675	88	23	10	6.7	1.7
Prairie	772	101	22	8.1	5.4	1.3

Table 3-3 Level 1 aquatic ecoscenario modeling EECs (µg a.i./L) for captan in a water body, excluding spray drift

Scenario	Weather	Peak	96 hour	21 day	60 day	90 day	Yearly
EECs of captan in 80 cm wetlands (µg/L)							
Corn-ON	Windsor	3.2	0.42	0.081	0.028	0.019	0.005
Potato-MB	Winnipeg	2.8	0.54	0.1	0.036	0.024	0.006
EECs of captan in 15 cm wetlands (µg/L)							
Corn-ON	Windsor	17	2.3	0.43	0.15	0.1	0.025
Potato-MB	Winnipeg	15	2.9	0.54	0.19	0.13	0.031

PRZM/EXAMS CAM-4; soil incorporated uniformally in 8cm of soil.

Appendix XII Proposed Label Amendments for Products Containing Captan

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements given below.

Note: The following information is divided according to product type. Please read each section carefully and make appropriate changes to your product labels.

1. Label Amendments for Technical Class Products Containing Captan

Captan is a severe eye irritant causing irreversible effects and is a potential dermal sensitizer. Consequently, the labels of the technical products should be revised to include the following signal words and hazard statements on the principal display panel:

DANGER – CORROSIVE TO EYES

POTENTIAL SKIN SENSITIZER

On the secondary display panel, Precaution Statements should include the following:

CORROSIVE to the eye. DO NOT get in eyes.

Potential skin sensitizer.

2. Label Amendments for Commercial Class End-use Products Containing Captan

2.1 Wettable Powder or Wettable Granules in Water Soluble Packaging (WSP):

It is proposed that all captan products currently formulated as wettable powders or wettable granules be reformulated in water soluble packaging. Label language would need to be clarified to indicate directions for the use of water soluble packaging. Registrants would need to ensure that the sizes of the water soluble packets are reconciled with the registered/required use-specific application rates.

2.2 PRECAUTIONS

2.2.1 General Label Improvements

The following label statements are added to the **PRECAUTIONS** of all commercial end-use product labels:

> "Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into

consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

2.2.2 Personal Protective Equipment

Label statements must be amended (or added) to include the following directions to the appropriate labels:

A. Mixing and Loading Liquids

"Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, goggles and, during mixing/loading, clean-up and repair, a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides."

"When mixing and loading for aerial application, workers must also use a closed system."

B. Mixing and Loading Wettable Powders in Water Soluble Packaging or Wettable Granules in Water Soluble Packaging

"Wear long-sleeved shirt, long pants, chemical-resistant gloves, goggles and, during mixing/loading, clean-up and repair, a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides."

C. Airblast Application of All Formulations

"Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, goggles, chemical-resistant hat that covers the neck (e.g Sou'Wester) and a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides."

D. Groundboom Application of All Formulations

"Wear a long-sleeved shirt, long pants, shoes plus socks, goggles, and a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides. Chemical-resistant gloves are not required to be worn during application but are required for clean-up, calibration and repair."

Wettable powder formulation only: "If handling more than 389 kg active ingredient in a day (114 ha at the rate of 3.4 kg a.i./ha), also wear coveralls."

Wettable granule formulation only: "If handling more than 389 kg active ingredient in a day (114 ha at the rate of 3.4 kg a.i./ha), use a closed cab that provides both a physical barrier and respiratory protection (i.e. dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical-resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Respirators and chemical-resistant gloves are not required to be worn inside the closed cab, but have them ready for leaving the cab during calibration, repair or cleaning of equipment.

E. Aerial Application of All Formulations

"Wear a long-sleeved shirt, long pants, and shoes plus socks. Have ready for leaving the cab during calibration, repair or cleaning of equipment the following: goggles, chemical-resistant gloves and a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides."

F. Handheld Application of All Formulations

"Wear a long-sleeved shirt, long pants, shoes plus socks, goggles, chemical-resistant gloves and a respirator with a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides."

Wettable powder and wettable granule formulations only: "For mechanically-pressured handguns: Also wear coveralls. In greenhouses, do not handle more than 0.62 kg a.i./person in a day. These restrictions are in place to minimize exposure to individual applicators. Application may need to be performed over multiple days or using multiple applicators."

G. Commercial Seed Treatment Facilities (alfalfa, clover, Brussels sprouts, cabbage, cauliflower, sugar beet, corn, corn (field), corn (sweet), bean, soybean)

"Use closed transfer for commercial seed treatment (in facilities or with mobile treaters). Closed transfer includes closed mixing, loading, calibrating and closed treatment equipment. No open transfer is permitted. Treaters should wear a long-sleeved shirt, long pants, shoes plus socks, goggles, chemical resistant gloves, and a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides."

"For all other activities involving the handling of treated seeds (e.g. bagging, stacking) workers should wear a long-sleeved shirt, long pants, shoes plus socks, goggles, chemical resistant gloves, and a NIOSH approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested."

"When cleaning seed treatment equipment, workers should wear chemical resistant coveralls over long sleeved shirt, long pants, chemical resistant footwear, socks, goggles, chemical resistant gloves and a respirator with a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides."

Treated seed bags must be labelled or tagged with the following instructions for workers planting treated seed. If seed is not bagged, then the following information must be provided in writing to the farmer through another means, such as pamphlet:

"For all activities involving handling of treated seeds (including planting), wear a long sleeved-shirt, long pants, jacket, chemical-resistant gloves, goggles and a NIOSH approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit

tested. Closed cabs must be used for planting treated seeds. Respirators and chemical-resistant gloves are not required to be worn within the closed cab as long as the cab is equipped with equivalent respiratory protection (dust/mist filtering and/or vapour/gas purification system), but have them ready for leaving the cab during calibration, repair or cleaning of equipment."

H. Commercial Seed Treatment Facilities (pea, lentil, chickpea, lupin)

"When handling and treating seeds for commercial seed treatment (in facilities or with mobile treaters), workers should wear a long-sleeved shirt, long pants, shoes plus socks, goggles, chemical-resistant gloves, and a respirator with a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides. "

"When cleaning seed treatment equipment, workers should wear chemical resistant coveralls over long sleeved shirt, long pants, chemical resistant footwear, socks, goggles, chemical resistant gloves and a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides."

Treated seed bags must be labelled or tagged with the following instructions for workers planting treated seed. If seed is not bagged, then the following information must be provided in writing to the farmer through another means, such as pamphlet:

"For all activities involving handling of treated seeds (including planting), wear a long sleeved-shirt, long pants, chemical-resistant gloves, goggles and a NIOSH approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. Closed cabs must also be used for planting treated seeds. Respirators and chemical-resistant gloves are not required to be worn within the closed cab as long as the cab is equipped with equivalent respiratory protection (dust/mist filtering and/or vapour/gas purification system), but have them ready for leaving the cab during calibration, repair or cleaning of equipment."

I. On-Farm Seed Treatment (liquid formulation) (beans, chickpea, corn, lentil, lupin, peas, soybeans, sugar beet)

"When treating seeds, handling and planting treated seeds, workers should wear a long-sleeved shirt, long pants, shoes plus socks, goggles, and chemical-resistant gloves. When treating seeds, workers should also wear a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides. When handling and planting treated seeds, workers should also wear a NIOSH approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested."

J. On-Farm Seed Treatment (WP formulation, dry treatment) (sweet corn)

"When treating seeds, handling and planting treated seeds, workers should wear a long-sleeved shirt, long pants, shoes plus socks, goggles, and chemical-resistant gloves. When treating seeds, workers should also wear a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides. When handling

treated seeds, workers should also wear a NIOSH approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested."

"Use a closed cab for planting. Respirators and chemical-resistant gloves are not required to be worn within the closed cab as long as the cab is equipped with equivalent respiratory protection (dust/mist filtering and/or vapour/gas purification system), but have them ready for leaving the cab during calibration, repair or cleaning of equipment."

2.3 ENVIRONMENTAL HAZARDS

The following statements are added to the **ENVIRONMENTAL HAZARDS** section of the labels of commercial end-use products that are registered for foliar application**:**

"TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

Toxic to small wild mammals.

Treated seed is toxic to small wild mammals.

This product demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of captan fungicide in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay. Avoid application when heavy rain is forecast. Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

The following statement must appear on the product label as well as the bag of treated seed (follow instructions under birds):

"Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface."

2.4 DIRECTION FOR USE

2.4.1 Uses

The following uses are removed from all commercial class end-use labels:

- Greenhouse crops (except rhubarb in forcing sheds, potted flowers and soil treatment);
- Tree fruits (apple, pear, cherry, plum, prune, peach, nectarine, and apricot);
- Grapes;
- Pumpkin, squash (mature)
- Field tomato

- Berries (strawberry, raspberry, blueberry, blackberry, loganberry)
- Field cut flowers
- Ornamental stem dip and flower bulb dip;
- On-farm seed treatment use of wettable powder formulation products as a dry hopper box treatment on beans.

In addition uses not supported by the registrant, i.e. turf (lawn seed beds, ornamental, sport), are to be removed.

The following statements are added to the appropriate labels:

For seed treatment products:

"Do not plant treated seed by hand."

For greenhouse flower uses:

"Only for use with potted plants. Not for use on cut flowers."

For commercial products that have crops that may be found in greenhouses (*e.g.* cucumber):

"For outdoor use only."

For commercial products that have label directions discussing entry into treated areas prior to expiry of the REI, it is proposed that this text be modified to be consistent with current practices. This text may appear as follows (PCP#4559, 9582, 23691, 24613, 26408):

Replace:
"If reentry into treated areas is required, workers must wear long pants, long-sleeved shirt, chemical resistant gloves, work books and goggles"

With:
"DO NOT enter treated areas before the restricted-entry interval. If required, individuals may enter treated areas for short-term tasks not involving hand labour if at least 4 hours have passed since application and a long-sleeved shirt, long pants, rubber boots, socks, goggles, gloves and a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides is worn. Time spent in the treated area cannot exceed 1 hour in a 24 hour period.'

2.4.2 Restricted-Entry Interval:

The Table below lists the maximum number of applications, minimum interval and proposed restricted-entry intervals (REI) for captan.

Proposed Restricted-Entry Intervals and Maximum Number of Applications for Captan

Crop	Activity	Maximum Rate(s)[a]	Restricted-entry Interval	Maximum Number of Applications
Greenhouse potted flowers	All	1-1.2 kg a.i./ha	12 hours	4 applications, 7 days apart
Rhubarb in forcing sheds	Transplant	1.6 kg a.i./1000 L (100 L dilution)	12 hours	6 applications, 7 days apart
		1.6 kg a.i./1000 L (1000 L dilution)	12 hours	2 applications, 7 days apart
Soil treatment (pre-plant) to field soil and greenhouse benches	All activities	8.5-10.6 kg a.i./ha	12 hours	1 application
Soil treatment (ornamentals, roses)	All activities	11.25-11.28 kg a.i./ha	12 hours	1 application
Soil treatment (broccoli, Brussels sprouts, cabbage, cauliflower, eggplant, kale, pea, rutabaga, tomato, turnip)	All activities	11.25-11.28 kg a.i./ha	12 hours	1 application
Cucumber (mature)	Hand harvesting, mechanically-assisted harvesting	2.8 kg a.i./ha [a]	2 days	1 application
	Moving irrigation pipes by hand		10 days	
	All other activities		12 hours	
Cucumber (young plants)	Training	2.6 kg a.i./ha	2 days	1 application
	Moving irrigation pipes by hand		10 days	
	All other activities		12 hours	
Potato	Roguing	3 kg a.i./ha	7 days	1 application
	All other activities		12 hours	
Pumpkin, squash (young)	Turning (pumpkin only), training	2.5 kg a.i./ha	2 days	1 application
	Moving irrigation pipes by hand		9 days	
	All other activities		12 hours	
Outdoor potted plants	All activities (except moving irrigation pipes by hand)	1-1.2 kg a.i./ha	12 hours	6 applications, 7 days apart
	Moving irrigation pipes by hand		7 days	
Golf course	Transplanting/planting sod	4.72-4.8 kg a.i./ha	2 days	1 application
	All other activities		12 hours	
Sod farm	Transplanting/planting sod, harvesting	4.72-4.8 kg a.i./ha	2 days	1 application
	All other activities		12 hours	

[a] Registrant proposed rate

2.4.3 Crop Rotation

The following statement is required under the **DIRECTIONS FOR USE**:

> A minimum rotational crop plantback interval of 12 months must be observed for all crops other than those registered for use with captan.

2.4.5 Buffer Zone

Label statements must be amended (or added) to include the following directions to the appropriate labels:

> Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.
>
> Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.
>
> Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.
>
> **Buffer zones:**
>
> Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.
>
> The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Buffer zone table for captan fungicide

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Broccoli, brussel sprout, cabbage, cauliflower, rutabaga, turnip and other crucifers, eggplant, kale, ornemental, pea, pepper, rose, tobacco seedlings.		10	1	**25**	**10**	1
	Bean, celery, shrub and seedling, tree and seedling.		10	1	**20**	**10**	1
	Carnation, chrysanthemum, Aster, camellia, dahlia, lilac, tulip		2	1	**4**	**2**	0
	Strawberry, potato, cucumber, tomato and ginseng		4	1	**10**	**4**	1
	Turf (golf course)		5	1	**10**	**5**	0
Airblast	Apple, apricot, peach, nectarine, plum and prune	Early growth stage	35	5	**45**	**35**	1
		Late growth stage	25	3	**35**	**25**	1
	Cherry	Early growth stage	40	15	**50**	**40**	2
		Late growth stage	30	5	**40**	**30**	1
	Grape	Early growth stage	30	5	**40**	**30**	0
		Late growth stage	20	3	**30**	**35**	0
	Pear	Early growth stage	30	5	**40**	**25**	0
		Late growth stage	20	3	**30**	**25**	0
	Blackberry, blueberry, loganberry	Early growth stage	25	3	**35**	**30**	0
		Late growth stage	15	2	**25**	**20**	0
	Raspberry	Early growth stage	25	3	**40**	**30**	0
		Late growth stage	20	2	**30**	**20**	0
Aerial	Apple and pear	Fixed wing	80	2	**300**	**100**	0
		Rotary wing	55	1	**175**	**70**	0
	Apricot, cherry, peach, nectarine, plum and prune	Fixed wing	100	5	**300**	**150**	0
		Rotary wing	90	15	**175**	**85**	1
	Cucumber, tomato and	Fixed wing	100	5	**350**	**150**	0

	strawberry	Rotary wing	65	0	**200**	**90**	0
	Grape	Fixed wing	80	1	**350**	**100**	**0**
		Rotary wing	70	10	**175**	**70**	0
	Blueberry	Fixed wing	125	15	**225**	**45**	0
		Rotary wing	50	0	**150**	**40**	0
	Potato	Fixed wing	90	3	**350**	**125**	0
		Rotary wing	55	0	**200**	**80**	0

*For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pesticides and Pest Management portion of Health Canada's website.

3. Label Amendments for Domestic Class End-use Products Containing Captan

3.1 PRECAUTIONS

3.1.1 Personal Protective Equipment

Although not required for risk mitigation, for good hygiene purposes, maintain current label wording regarding the wearing of rubber gloves, goggles, and clothing that completely covers arms and legs to minimize exposure.

3.2 ENVIRONMENTAL HAZARDS

The following statement is proposed to be added to the **ENVIRONMENTAL HAZARDS:**

Toxic to small wild mammals.
Toxic to aquatic organisms.

3.3 DIRECTION FOR USE

3.3.1 Uses

The following uses are proposed to be removed from all domestic class end-use labels:

- All dust product uses;
- Fruit (blackberries, strawberries);
- Vegetables (cucumbers, peppers, tomatoes);
- Flowers;
- Outdoor ornamental trees and shrubs (rate of 2 g a.i./L);
- Fruit trees (apples, apricots, cherries) (rate of 2 g a.i./L).

The following statement is proposed to be added to all domestic product labels:

> "For outdoor use only."

3.2.2 Restricted-Entry Interval

The following label wording should be added to domestic class wettable powder end-use products applied as a liquid, if not already specified:

"Do not enter or allow others (*e.g.* children, pets) to enter treated areas until spray has dried."

References

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E. Information Considered for the Environmental Risk Assessment of captan fungicide

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PMRA Document #	Data Numbering code	Reference/Title
1217553	8.2.1	Captan Hydrolysis Products
1217557	8.2.1	Studies On The Degradation Of Captan, Phaltan And Difolatan By Sunlight And Uv Light
1217559	8.2.1	Photolysis Of Captan In Sterile Aqueous Solution
1217560	8.2.1	Waiver Request - Captan Soil Photodegradation
1217561	8.2.1	Captan Air Photodegradation
1237396	8.2.1	Captan Air Photodegradation (722.2)
1237397	8.2.1	Soil Surface Photolysis Of [14c-Trichloromethyl] Captan In Natural Sunlight (Ptrl 231)
1237398	8.2.1	Soil Surface Photolysis Of [14c] Captan In Natural Sunlight (Ptrl 232)
1237400	8.2.1	Captan Volatility From Soil - Laboratory Study (Mef-0027 8704537)
1237402	8.2.1	Stability Of Captan In Soil/Water Mixtures (Pms-316/Wrc 88-71)

1237439	8.2.1	[Trichloromethyl-C-14] Captan Hydrolysis Products (Mef-0002, 8702383)
1237446	8.2.1	[Trichloromethyl-14c] Captan Hydrolysis At 25'c (Wrc 89-44)
1237447	8.2.1	[Ring-1-14c] Captan Hydrolysis At 25'c (Wrc-89-265)
1237448	8.2.1	Photolysis Of Captan In Sterile Aqueous Solution (Mef-0001)
1237449	8.2.1	Estimation Of Soil Adsorpstion Coefficient Of Captan From Tlc Data (Mef-0073/8726836)
1217568	8.2.3.1	The Soil Metabolism Of Carbonyl-14c-Captan
1217570	8.2.3.1	Stability Of Captan In Microaerophillictaro Soils
1217572	8.2.3.1	Comparative Stabilities Of Dyrene,1-Fluro-2,4-Dinitrobenzene Dichlone And Captan In A Silt Loam Soil
1217576	8.2.3.1	The Effect Of The Soil Reaction On The Degradation And Persistence Of Thiuram, Ferbam And Captan In The Soil
1217578	8.2.3.1	On The Duration Of The Effect Of Thiuram, Ferbam And Captan In Forest Soils
1217579	8.2.3.1	The Anaerobic Soil Metabolism Of [Carbonyl-14c]-Captan
1217581	8.2.3.1	The Fate Of Select Pesticides In The Aquatic Environment
1217586	8.2.3.1	Substitute Chemical Program - Initial Scientific And Mini-Economic Review Of Captan - Residues In Soil
1237403	8.2.3.1	The Anaerobic Soil Metabolism Of [Carbonyul-14c] Captan (721.14)
1237404	8.2.3.1	Aerobic Soil Metabolism Of [Tricloromethyl-14c] Captan)Mef-0060/8809887)
1237405	8.2.3.1	An Aerobic Soil Metabolism Of [Tricloromethyl-14c] Captan)Mef-0061/8809887)
1163898	8.2.3.4.2	Aerobic Metabolism Of [Trichloromethyl-14c] Captan In Soil.(Wrc-90-401;Rr90-334b;F3.1/10;Pms320;Ref#22).(Maestro,Captan Instapak)

1163899	8.2.3.4.2	Anaerobic Metabolism Of [Trichloromethyl-14c] Captan In Soil.(Wrc-90-530;Rr90-416b;F3.1/11;Pms321;Ref#23).(Maestro,Captan Instapak)
1163900	8.2.3.4.2	Tetrahydrophthalimide: Laboratory Soil Degradation Study (Bba).(Rj1440b;92jh143;Ref#24).(Maestro,Captan Instapak)
1163901	8.2.3.4.2	Cis-Tetrahydrophthalmic Acid: Laboratory Soil Degradation Study (Bba).(Rj1441b;92jh171;Ref#25).(Maestro,Captan Instapak)
1163905	8.2.3.5.2	Captan: Degradation In Sediment-Water Systems Under Laboratory Conditions.(Rj1439b;92jh101;Ref#28).(Maestro,Captan Instapak)
1217565	8.2.4.1	Soil Mobility Of Captan, Folpet And Captafol As Determined By Soil Thin-Layer Chromatography
1237399	8.2.4.1	Predicted Bioconcentration Factors And Soil Absorption Coefficients Of Pesticides And Other Chemicals (Ees-4-26-80)
1237401	8.2.4.1	Soil Mobility Of Captan, Folpet And Captafol As Determined By Soil Thin-Layer Chromatography (722.0)
1163896	8.2.4.2	Captan: Adsorption And Desorption Properties Of Soil Metabolites Thpi And Thpam.(Rj1448b;92jh086;Ref#20).(Maestro,Captan Instapak)
1163897	8.2.4.4	Captan: Mobility Of Captan And Its Degradation Products In Prepared Soil Columns.(Rj1641b;93jh129;Ref#21).(Maestro,Captan Instapak)
1237690	8.3.2.3	Captan 50-Wp Field Dissipation Study On Oregon Grapes (Pal-Ef-87-17d)
1237691	8.3.2.3	Captan 50-Wp Field Dissipation Study On New York Apples (Pal-Ef-87-17a)
1163904	8.5.1	Captan: Overview Of Soil Behaviour.(Tmj3492b;Ref#27).(Maestro,Captan Instapak)

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1311112	8.6	Unpublished National Water Monitoring Data. Pesticide Science Fund (2004).
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1163923	9.2.3.1	Captan: Toxicity To The Earthworm Eisenia Foetida Of An 83 Wp Formulation.(Rj1561b;93jh220;Ref#29).(Maestro,Captan Instapak)
1142430	9.2.4.1	Captan: Acute Contact And Oral Toxicity To Honey Bees Of Technical Material And Of A Wp Formulation (Rj0909b)
1217584	9.2.4.1, 9.2.5, 9.5.2.1	Substitute Chemical Program - Initial Scientific And Mini-Economic Review Of Captan - Effects On Beneficial Insects
1163914	9.2.5	Effects Of Captan 83wp On Chrysoperla Carnea Steph. (Neuroptera, Chrysopidae) In Laboratory.(Rcc425204;G4.2/02;Ref#22).(Maestro,Captan Instapak)
1163917	9.2.5	Final Report On The Field Study For Testing The Ici 90410 F-O-Wp (Captan 83wp) Pesticide In Predatory Mites (Typhodromus Pyri) In Viticulture (Test Title).(9301ici1;G4.2/05;Ref#23).(Maestro,Captan Instapak)
1163918	9.2.5	Testing The Effect Of Captan 83wp On The Predatory Bug Orius Insidiosus (Say)(Anthocoridae) Using Ventilated Glass Cages ('Coffin Cells').(Mz001;G4.2/03;Ref#24).(Maestro,Captan Instapak)
1163919	9.2.5	Testing The Effect Of Captan 83wp On The Predaceous Mite Typhlodromus Pyri Scheuten (Acari:Phytoseiidae) Using Ventilated Glass Cages (Coffin Cells).(Mz002;G4.2/04;Ref#25).(Maestro,Captan Instapak)

1163920	9.2.5	Field Study For Testing The Effects Of Ici-90410-F-1-Wp On Predatory Mites (Typhlodromus Pyri) In Vines With Two Pre-Blooming And Six Post-Blooming Stage Applications. Final Report.(Ici04;Ici-90410-F-1-Wp;G4.2/07;Ref#26).(Maestro,Captan Instapak)
1163921	9.2.5	Field Study For Testing The Effects Of Ici-90410-F-1-Wp On Predatory Mites (Typhlodromus Pyri) In Vines With Two Pre-Blooming And Six Post-Blooming Stage Applications. Final Report.(Ici01;Ici-90410-F-1-Wp;G4.2/06;Wi No.21759;Ref#27).(Maestro,Captan Instapak)
1163913	9.2.5, 9.2.6	Captan: Residual Toxicity Of A 50% Wp Formulation To The Carabid Beetle Pterostichus Melanarius And The Hymenopteran Parasite Trybliographa Rapae.(Rj1104b;90jh237;Ref#21).(Maestro,Captan Instapak)
1163922	9.2.5, 9.2.6	Captan: A Review Of Effects On Beneficial Arthropods Relevant To Integrated Pest Management Programmes In Canadian Apple Orchards. Br Mclennan. December 1995.(Ca/Rd/95/042;Ref#28).(Maestro,Captan Instapak)
1145937	9.3.1	Chronic Toxicity To Daphnia Magna (Bl4102/B;T505/F;Ft11/91)(Captan Technical)
1163925	9.3.1	Captan: Acute Toxicity Of The Technical Material To First Instar Daphnia Magna.(Rj1116b;91jh187;Ref#31).(Maestro,Captan Instapak)
1163926	9.3.1	Thpi: Acute Toxicity To Daphina Magna.(Aa0427/D;Bl5239/B;G6.1/05;Ref#32).(Maestro,Captan Instapak)
1163928	9.3.1	Thpam: Acute Toxicity To Daphnia Magna.(Ab0085/B;Bl5442/B;Ref#33).(Maestro,Captan Instapak)
1145934	9.5.2.1	Acute Toxicity To Mirror Carp (Bl4153/B;5c.4/8;T505;Ft77/90)(Captan Technical)

1145935	9.5.2.1	Acute Toxicity To Rainbow Trout (Bl3995/B;T505/A;Ft76/90)(Captan Technical)
1170704	9.5.2.1	Acute Tox Of Captan In Trout Exposed For 96 Hours In The Bath Fluid
1170715	9.5.2.1	Acute Tox Of Captan In Carp Exposed For 96 Hours In The Bath Fluid
1170727	9.5.2.1	Acute Tox Study Of Captan In Daphnia Magna - Acute Immobilization Test
1217622	9.5.2.1	Preliminary Feeding Study Data On Zebra Fish And Guppies
1217623	9.5.2.1	Static And Flow-Through 96-Hour Toxicity Tests
1145936	9.5.3.1	The 21 Day Lc50 To Rainbow Trout (Bl4100/B;5c.4/7;T505/E;Ft10/91)(Captan Technical)
1163911	9.5.5	Bioconcentration And Elimination Of 14c-Residues By Bluegill (Lepomis Macrochirus) Exposed To Trichloromethyl 14c-Captan.(T-13069;Sls#87-12-2574;723.0387.6108.140/240;G5.3/02;Ref#8).(Maestro,Captan Instapak)
1163912	9.5.5	Bioconcentration And Elimin. 14c-Residues By Bluegill (Lepomis Macrochirus) Exposed To Cyclohexane 14c-Captan.(T-13068;Sls#87-11-2558;723.0387.6109.140/240;G5.3/01;Ref#20).(Maestro,Captan Instapak)
1142425	9.6.2.1	Captan: Acute Oral Toxicity (Ld50) To The Mallard Duck (Isn227/901244)
1142426	9.6.2.1	Captan: Acute Oral Toxicity (Ld50) To The Bobwhite Quail (Isn228/901245)
1142427	9.6.2.1	Captan: Dietary Toxicity (Lc50) Study With The Bobwhite Quail (Isn230/901123)
1163910	9.6.2.1	Captan: Dietary Toxicity (Lc50) To The Mallard Duck.(Isn229/901208;G2.1/02;Ref#19).(Maestro,Captan Instapak)

1170682	9.6.2.1	Acute Tox Study Of Captan After Oral Application To The Greenfinch
1170693	9.6.2.1	Acute Tox Study Of Captan After Oral Application To Quail
1217605	9.6.2.1	Acute Oral Ld50 - Bobwhite Quail
1217609	9.6.2.4, 9.6.3.1	Subacute Feeding Study - Reproduction Screening Bioassay - Bobwhite Quail
1217610	9.6.2.4, 9.6.3.1	Addendum To Subacute Pilot Feeding Study... In Bobwhite Quail
1163907	9.6.3.1	One-Generation Reproduction Study- Mallard Duck. Captan Technical (Sx-1086) Final Report.(S-1716;162-128;G2.2/04;Ref#3).(Maestro,Captan Instapak)
1163908	9.6.3.1	One-Generation Reproduction Study- Bobwhite Quail. Captan Technical (Sx-1086) Final Report.(S-1717;162-127;G2.2/03;Ref#4).(Maestro,Captan Instapak)
1163909	9.6.3.1	Addendum To One-Generation Reproduction Study With Captan (Sx-1086) In Bobwhite Quail And Mallard Ducks-Wildlife International Ltd. Projects 162-127,162-128 Chevron S-1716, S-1717 Diet Analyses.(721.11/S-1716,1717;Ref#5).(Maestro,Captan Instapak)
1217607	9.6.3.1	Assessment Of Diet Stability In Game Bird Ration
1217608	9.6.3.1	Addendum To Assessment Of Diet Stability In Game Bird Ration
1217611	9.6.3.1	1-Generation Reproduction Study - Bobwhite Quail
1217612	9.6.3.1	1-Generation Reproduction Study - Mallard Duck
1217614	9.6.3.1	Addendum To 1-Generation Reproduction Study - In Bobwhite Quail And Mallard Duck
1163929	9.8.2	Thpi: Toxicity To The Green Alga Selenastrum Capricornutum.(Aa0427/C;Bl5238/B;G8.1/03;Ref#34).(Maestro,Captan Instapak)
1163930	9.8.2	Thpam: Toxicity To The Green Alga Selenastrum Capricornutum.(Ab0085/D;Bl5428/B;Ref#35).(Maestro,Cap

		tan Instapak)
1170738	9.8.2	Algal Growth Inhibition Test With Captan
1142429	9.8.2, 9.8.3	Captan: Toxicity To The Green Alga Selenastrum Capricornutum (T505/C(Ft78/90)Bl3954/B)

Studies/Information Provided by the Applicant/Registrant (Published)

PMRA Document #	Data Number Code	Reference/Title
1217552	8.2.1	Captan Hydrolysis
1217555	8.2.1	Study Of The Degradation Of Captan, Phaltan And Difoloatan Under The Influence Of Light
1217556	8.2.1	The Effect Of Uv Light On 141 Pesticide Chemicals By Paper Chromatography
1217574	8.2.1, 8.2.4.1	Investigation Into Degradation And Vertical Movement Of Agricultural Chemicals In Soil
1217573	8.2.3.1	The Persistence In Soil Of The Fungicidal Seed Dressings Captan And Thiram
1217577	8.2.3.1	Persistence Of Captan And Its Effects On Microflora, Respiration And Nitrification Of A Forest Nursery Soil
1217587	8.2.3.1, 8.2.4.1	Predicted Bioconcentration Factors And Soil Sorption Coefficients Of Pesticides And Other Chemicals
1217564	8.2.4.1	Pesticide Mobility: Determination By Soil Thin-Layer Chromatography
1217566	8.2.4.1	Movement Of Non-Volatile Diffusible Fungicides Through Columns Of Soil
1142431	9.2.3.1	Acute Toxicity Of The Fungicide Captan To The Earthworm (Savigny)
1217615	9.3.1, 9.5.2.1	Note On The Response Of Zebra Fish Larvae To Folpet And Difolatan
1217514	9.3.1, 9.5.5	Toxicity Of The Fungicide Captan To The Dungeness Crab

1217617	9.5.2.1	Handbook Of Acute Toxicity Of Chemicals To Fish And Aquatic Invertebrates
1217618	9.5.2.1	Bioassay Of Captan By Zebra Fish Larvae
1217620	9.5.3.1	Toxic Effects Of Organic And Inorganic Pollutants On Young Salmon And Trout
1217621	9.5.3.1	Captan Toxicity To Fathead Minnows, Bluegills And Brook Trout
1217606	9.6.2.1	Lethal Dietary Toxicities Of Environmental Pollutants To Birds

Foreign Reviews

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2265692	Review Report for the Active Substance Captan, 2006. European Commison Health and Consumer Protection Directorate-General (EFSA).

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