Re-evaluation Decision RVD2018-12

Captan and Its Associated End-use Products

Final Decision

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Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Captan is a contact and protectant fungicide that has a large use pattern, with commercial products registered for use on field, greenhouse and orchard crops, greenhouse and outdoor ornamentals, and turf (golf courses and sod farms only). All domestic-class products containing captan are co-formulations with the pesticide carbaryl. These products have been cancelled as a result of the carbaryl re-evaluation decision.[1] Therefore, domestic-class captan products are not considered in the captan re-evaluation decision. Registered products containing captan are listed in Appendix I.

This document presents the re-evaluation decision for captan. The regulatory approach for the re-evaluation of captan was first presented in Proposed Re-evaluation Decision PRVD2016-13, *Captan*.[2] This Re-evaluation Decision[3] describes this stage of the PMRA's regulatory process for the re-evaluation of captan and summarizes the Agency's decision and the reasons for it. Reference lists for all data used as the basis for the re-evaluation decision are included in this document, as well as in PRVD2016-13.

Comments received during the consultation process on health and value were taken into consideration. These comments and new data/information resulted in revisions to some parts of the risk assessments (see Science Evaluation Update in this document) and subsequently in some changes to the proposed regulatory decision as described in PRVD2016-13. Appendix II of this document summarizes comments received during the consultation period and provides the PMRA's responses.

Regulatory Decision for Captan

The PMRA has completed the re-evaluation of captan. Under the authority of the *Pest Control Products Act*, the PMRA has found the continued registration of products containing captan to be acceptable.

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1 Three domestic products (registration #9986, 14851, 14852) have been cancelled as a result of the carbaryl re-evaluation (Re-evaluation Decision Carbaryl, RVD2016-02, 31 March 2016). The last date of sale by retail is 31 March 2018; last date of use is 31 March 2019.

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

3 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

An evaluation of available scientific information found that the following uses of captan products meet current standards for protection of human health or the environment, when used according to the conditions of registration which include required amendments to label directions:

- Tree fruit (apple, cherry (sweet and sour), apricot, peach, pear, plum, prune, nectarine)
- Grape
- Field cucumber, pumpkin, squash, potato, field tomato
- Soil treatment (pre-plant) for broccoli, Brussels sprouts, cabbage, cauliflower, eggplant, kale, pea, pepper, rutabaga, tomato, turnip
- Blackberry, blueberry (highbush, lowbush), loganberry, raspberry, strawberry
- Turf (sod farm, golf course)
- Ginseng
- Greenhouse ornamentals (non-cut flowers)
- Outdoor ornamentals (cut and non-cut flowers)
- Rhubarb forcing sheds
- Greenhouse and field soil treatment (pre-plant): seedling or transplant of ornamentals (shrubs, trees, flowers), lawn seedbeds, and vegetables (bean, celery, crucifer, eggplant, pea, pepper, tomato)
- Commercial slurry seed treatment using liquid products for all currently registered seeds
- Commercial slurry seed treatment using wettable powder product for beans
- On-farm slurry seed treatment of bean, chickpea, corn, lentil, lupin, pea, soybean
- On-farm dry seed treatment of sweet corn
- Planting of imported seeds (sugar beet, broccoli, cabbage, cauliflower, Brussels sprouts)
- Flower bulb dip

Certain other uses of captan are being cancelled to address risks of concern to human health or due to inadequate data to assess risk. These uses are as follows:

- Ornamental stem dip
- Greenhouse ornamentals (cut flowers)
- Tobacco seedlings
- On-farm dry application to bean seeds
- Treatment of small-seeded vegetable seeds (broccoli, cabbage, Brussels sprouts, cauliflower, sugar beets). Planting of imported seeds still permitted.

Label amendments, as summarized below, as well as listed in Appendix III, are required for all technical grade of active ingredients and end-use products containing captan. No additional data are requested at this time.

Risk Mitigation Measures

Registered pesticide product labels include specific instructions for use. Directions include risk reduction measures to protect human and environmental health. These directions must be followed by law. The key risk-reduction measures required, as a result of the re-evaluation of captan, are summarized below. Refer to Appendix III for details.

Human Health

To protect mixer/loader/applicators:

- Require additional protective equipment and engineering controls when mixing/loading/applying to all crops, as well as during treatment of flower bulbs, and handling treated flower bulbs.
- Repackage all commercial wettable powders and wettable granules products in water soluble packaging.
- Limit the amount of captan used per day for mechanically pressurized handguns in greenhouses.
- Remove the commercial ornamental stem dip use.

To protect workers entering treated sites:

- Revise or establish restricted-entry intervals (REIs) for some crops.
- Require restrictions on number and timing 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 (greenhouse cut flowers and tobacco seedlings).

To protect workers involved in seed treatment:

- Require additional protective equipment for workers who treat and handle seeds treated with captan.
- Remove on farm dry application treatment on bean seeds from wettable powder formulation product.
- Remove vegetable seed treatment from commercial class products. Planting of imported captan-treated vegetable seeds will continue to be permitted.

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

To protect the environment, the following mitigations are required:

- Advisory statements to inform users that captan is toxic to non-target organisms including small mammals and aquatic organisms.
- Advisory statements to inform users of conditions that may favour runoff and leaching.
- Spray buffer zones to protect aquatic 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.

International Context

Captan is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the United States, Australia and European Union Member States. The approval of captan is currently being reviewed for renewal by the European Commission. Captan is also under registration review by the United States Environmental Protection Agency. No decisions have been identified by an OECD member country to prohibit all uses of captan for health or environmental reasons.

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all products labels sold by registrants no later than 24 months after the publication date of this document. Appendix I lists the products containing captan that are registered under the authority of the *Pest Control Products Act*.

Please note that water soluble packaging is required for all captan products registered as wettable powders and wettable granules. Should registrants of these specific products wish to keep their captan registration, an application to register a new product in water soluble packaging is required as soon as possible so that the new formulation will be approved and available for sale no later than 24 months after the publication date of this decision document. Additional label requirements are outlined in Appendix III.

Other Information

Any person may file a notice of objection[4] regarding this decision within 60 days from the date of publication of this re-evaluation decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[4] As per subsection 35(1) of the *Pest Control Products Act.*

Science Evaluation Update

1.0 Revised Health Risk Assessment for Captan

1.1 Toxicology Assessment

The toxicological assessment for captan was previously conducted and published in PRVD2016-13. Comments were received from the registrant regarding the interpretation of findings in the reproduction and developmental toxicity studies, the application of the *Pest Control Products Act* factor (PCPA factor) and the use of a chemical-specific adjustment factor (CSAF). Detailed responses to the comments are provided in Appendix II. Overall, no changes to the toxicology endpoints or uncertainty/PCPA factors outlined in PRVD2016-13 were deemed warranted by the PMRA.

1.2 Dietary Assessment

The dietary assessment for captan was previously conducted and published in PRVD2016-13. Comments were received from the Captan Task Force (CTF) requesting clarification on the process of establishing maximum residue limits (MRLs) as a result of the re-evaluation and also clarification on the residue chemistry data requirements. These comments and the PMRA responses are summarized in Appendix II. There were no changes to the dietary risk assessment outlined in PRVD2016-13 as a result of the comments.

A confirmatory laboratory study was proposed as a section 12 data requirement in PRVD2016-13, as the dietary risk assessment was based on surveillance data. However, these data are no longer required as the registrant is aware that prior to making any changes to MRLs or dietary use expansions, they are to provide the Agency with the multi-residue analytical methodology evaluation (a laboratory study).

1.3 Occupational and Non-occupational Assessment

The occupational and non-occupational assessments for captan were previously conducted and published in PRVD2016-13.

In PRVD2016-13, the PMRA had proposed cancellation of captan use on a number of greenhouse and field crops due to postapplication risks of concern. Calculated restricted-entry intervals (REIs) were not considered to be agronomically feasible for these crops and cancellation was proposed to mitigate these risks. Other commercial uses, such as ornamental stem and flower bulb dips were proposed for cancellation as adequate data to estimate exposure were not available. For seed treatment, on-farm hand mixing treatment of beans using wettable powder products was proposed for cancellation due to risks of concern.

During the proposed re-evaluation decision (PRVD) consultation period, additional information and studies were received from the registrant and grower groups. This included a worker exposure study in high density apples, additional dislodgeable foliar residue studies, further data for the existing human in vivo dermal absorption study, as well as extensive use and survey

information from growers, crop specialists, and grower groups, including the Canadian Horticulture Council. The use information included typical application rates and application equipment, timing of critical captan applications, timing and duration of postapplication activities, information on activities of professional scouters, as well as information on high density orchards in Canada. Data from the Agricultural Re-entry Task Force (ARTF) grower survey were also used; this survey collected information from various growing regions in Canada and the United States to determine the activities and clustering of transfer coefficients (TCs). These data and information were incorporated into the revised assessment and were critical in refining the risk assessment, to the extent possible. The PMRA responses to specific comments are in Appendix II. Details and tables regarding the revised occupational risk assessment are presented in Appendix IV.

No risks of concern were identified in PRVD2016-03 for application of commercial-class products in residential areas; therefore, the risk assessment for non-occupational exposure was not revised.

As a result of the comments received and additional data and information submitted, the outcome of the occupational risk assessment and mitigation proposed in PRVD2016-13 has changed for a number of scenarios:

- Most of the agricultural uses previously proposed for cancellation are now acceptable for continued registration provided the use pattern and mitigation measures outlined in Appendix III are followed (fruit trees, grapes, berries, field vegetables, bulb dip, field flowers).
- Personal protective equipment requirement was revised for some mixer/loader/applicator scenarios.

Risks of concern continue to be identified for the following uses, which will be cancelled:

- Greenhouse cut flowers
- Tobacco seedlings
- On-farm dry application to bean seeds

For commercial ornamental stem dip and planting of treated stems, adequate data to estimate exposure were not available. As no comments or data were submitted during the PRVD comment period, this use will be cancelled.

Data to assess the treatment of small seeded vegetable seeds was proposed as section 12 data requirement in PRVD2016-13. However, since the publication of the PRVD it has been determined that treatment of small-seeded vegetables is not occurring in Canada and therefore, this use will be cancelled. In turn, as only planting of imported treated seeds will be permitted, the Section 12 data is no longer be required.

2.0 Environmental Risk Assessment

No comments were received related to the environmental risk assessment presented in the proposed re-evaluation decision document (PRVD2016-13). Following consultation for the PRVD, the use pattern is reduced from that as the basis of the environmental risk assessment conducted for the PRVD. Buffer zones were recalculated to reflect the revised use pattern. The label statements proposed in PRVD2016-13 are still applicable, as these are related to the inherent toxicity and fate properties of captan.

The label statements and revised buffer zones are listed in Appendix III of this document.

3.0 Value Assessment

Captan is valued by growers as it is a broad spectrum fungicide with a multi-site mode of action which has a low risk of resistance development in susceptible fungal pathogens. It is applied as a foliar treatment to control a number of fungal diseases of economic importance and can be tank mixed or used in rotation with other registered fungicides as part of a season-long spray program. Captan is also applied as a dip to bulbs, as a soil treatment of ornamentals and vegetables, and as a seed treatment at planting or before storage.

Following the consultation for PRVD2016-13, comments and additional use information on captan were received from various stakeholders. The comments and information were analyzed and considered to further refine the human health assessment. The value of captan and impact of uses being removed from captan product labels are discussed in Appendix II.

List of Abbreviations

AD	animal to human extrapolation for toxicodynamics
ADI	acceptable daily intake
AHETF	Agricultural Handler Exposure Task Force
AK	animal to human extrapolation for toxicokinetics
a.i.	active ingredient
ARTF	Agricultural Re-entry Task Force
AUC	area under the curve
bw	body weight
CAF	composite assessment factor
CHC	Canadian Horticultural Council
CFIA	Canadian Food Inspection Agency
CSAF	chemical-specific adjustment factor
CTF	Captan Task Force
cm^2	centimetres squared
d	day(s)
DA	dermal absorption
DACO	data code
DIR	Directive
DF	dry flowable
DFR	dislodgeable foliar residue
EFSA	European Food Safety Authority
et al	and others
F1	first generation
F2	second generation
F3	third generation
ha	hectare
FQPA	Food Quality Protection Act
HD	human variation in toxicodynamics
HK	human variation in toxicokinetics
JMPR	Joint Meeting on Pesticide Residues
kg	kilogram(s)
L	litre(s)
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
mg	milligram(s)
M/L	mixer/loader
M/L/A	mixer/loader/applicator
mg	milligram(s)
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
PCPA	*Pest Control Products Act*
PHED	Pesticide Handlers Exposure Database
PHI	pre-harvest interval
PMRA	Pest Management Regulatory Agency

PPE	personal protective equipment
PRVD	proposed re-evaluation decision
REI	restricted-entry interval
REV	Re-evaluation Note
SPN	Science Policy Note
SU	Suspension
THPI	tetrahydrophthalimide
TC	transfer coefficient
TTR	turf transferable residues
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
µg	microgram
WDG	water dispersible granules
WP	wettable powder formulation
WSP	water soluble packaging

Appendix I Registered Captan Products as of 12 January 2018[5]

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
12028	Commercial	NORAC CONCEPTS INC.	AGROX FL	SUSPENSION	Captan 30%
14823	Commercial	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	CAPTAN 50W WETTABLE POWDER FUNGICIDE	WETTABLE POWDER	Captan 50%
18221	Technical	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	CAPTAN TECHNICAL FUNGICIDE	SOLID	Captan 88%
21107	Technical	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	CAPTAN TECHNICAL	DUST OR POWDER	Captan 95%
22819	Commercial	BAYER CROPSCIENCE INC.	CAPTAN 400 LIQUID SEED TREATMENT FUNGICIDE	SOLUTION	Captan 39.1%
23691	Commercial	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	CAPTAN 80 WDG WATER DISPERSIBLE GRANULE	WETTABLE GRANULES	Captan 80%
24613	Commercial	LOVELAND 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 FUNGICIDE	SOLID	Captan 95.2%

[5] Captan products registered in Canada as of 12 January 2018, excluding discontinued products or products with a submission for discontinuation. Up-to-date listings of registered products containing captan in Canada can be accessed through PMRA's label transcription service.

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
31949	Commercial	SHARDA CROPCHEM LIMITED	SHARDA CAPTAN 80 WDG	WETTABLE GRANULES	Captan 80%
32196	Commercial	KAM'S GROWERS SUPPLY INC.	KAM'S KAPTAN 80 WDG	WETTABLE GRANULES	Captan 80%
32300	Commercial	SHARDA CROPCHEM LIMITED	SHARDA CAPTAN 48 SC	SUSPENSION	Captan 480 g/L

Appendix II Comments and Responses

1.0 Comments Related to the Health Risk Assessments

1.1 Comments Related to Toxicology

Comment 1. The selection of the NOAELs for the reproductive toxicity studies:

The Captan Task Force (CTF) expressed disagreement with the PMRA offspring NOAEL of 12.5 mg/kg bw/day in the one-generation reproduction study (PMRA #1217463) as well as the PMRA offspring LOAEL of 25 mg/kg bw/day (lowest dose tested) in the three-generation reproduction study (PMRA #1217473). The commenter acknowledged the presence of slight to very slight inhibition of pup weight at 25 mg/kg bw/day in both studies but considered the effect non-adverse due to its transient nature. Furthermore, the commenter indicated that the PMRA should use criteria for adversity used by other international agencies, that is, 10% difference in bodyweight or statistical significance when the difference in bodyweight was 5%.

PMRA response:

The PMRA considers the bodyweight effects at 25 mg/kg bw/day in both studies to be treatment-related and adverse, thus forming the basis for the offspring NOAEL of 12.5 mg/kg bw/day. The PMRA's reasons are as follows:

- Generally speaking, it is current the PMRA practice to consider treatment-related bodyweight reductions of greater than 5% to be adverse.
- The bodyweight of offspring was consistently reduced within each study at 25 mg/kg bw/day (see tables 1 and 2), achieving greater than 5% reductions at multiple time points.
- The reductions were consistent across the two reproductive toxicity studies in terms of dose level affected and magnitude of response.
- Although the magnitude of the bodyweight reductions was less by post-natal day 21, this does not diminish the importance of an effect on bodyweight during a critical window of development.
- The bodyweight findings at 25 mg/kg bw/day were considered treatment-related by the study authors.

It bears noting that the establishment of a NOAEL of 12.5 mg/kg bw/day based on the bodyweight effects at 25 mg/kg bw/day was consistent with the interpretation of other agencies (USEPA, Australia, JMPR and EFSA) for these studies.

Table 1 Reduction in Offspring Bodyweight at 25 mg/kg bw/day Compared to Controls in One-Generation Reproductive Toxicity Study (%)

Post Natal Day	1	4	7	14	21♂	21♀
F1	1.4	5.3	6.4	5.6	1.2	0.5

Table 2 Reduction in Offspring Bodyweight at 25 mg/kg bw/day Compared to Controls in Three-Generation Reproductive Toxicity Study (%)

Post Natal Day	1	4	7	14	21♂	21♀
F1A	6.8*	5.7	6.4	2.9	2.1	2.9
F1B	4.2	2.9	6.7*	5.0*	1.8*	1.9*
F2A	1.4	4.9	3.8	5.9	6.1	4.3
F2B	7.0**	6.7	4.9	5.9*	3.6	4.6
F3A	1.4	1.9	(+1.3)	0.0	2.5	1.3
F3B	1.4	1.9	5.4	5.8	2.7	5.4

*significant at $p \leq 0.05$, **significant at $p \leq 0.01$

Comment 2. Fetal findings in the rabbit developmental toxicity study:

The CTF expressed disagreement with the PMRA's interpretation of the fetal findings in the rabbit developmental toxicity study (PMRA #2359929). Although the commenter agreed with the PMRA that post-implantation loss and fetal weight was affected at 45 mg/kg bw/day, the commenter disagreed with the PMRA conclusion that malformations were present at the same dose level. The commenter indicated that the absent kidney and ureter in four fetuses from two litters at the 45 mg/kg bw/day dose level was very highly unlikely to be treatment-related as this observation was not reported in any other study.

PMRA Response:

It should be noted that the occurrence of post-implantation loss is concerning in that severely malformed fetuses are often resorbed; thus post-implantation loss can mask the true occurrence of malformations. In addition, post-implantation loss on its own is considered a serious endpoint that would warrant the same PCPA factor considerations as for malformations in risk assessment, that is, post-implantation loss in the presence of maternal toxicity would also warrant the application of a three-fold PCPA factor.

Notwithstanding the concern for post-implantation loss, the PMRA determined that the absent kidney and ureter were treatment-related at 45 mg/kg bw/day. This malformation had not been reported previously by the conducting laboratory, suggesting that this is not a common spontaneous finding. The occurrence of this malformation was also considered in light of the overall captan database which identified a low incidence of other malformations in another rabbit developmental toxicity study as well as in other species tested. The absence of the missing kidneys and ureter in other studies was addressed in PRVD2016-13. The PMRA noted in the PRVD that the lack of a consistent structural target in the developmental toxicity studies suggested that malformations may be secondary to maternal toxicity as opposed to a direct teratogenic effect.

Comment 3. The application of the PCPA factor:

The CTF stated that the application of the PCPA factor in occupational risk assessment had no basis in legislation. Furthermore, the commenter indicated that the PCPA factor was not scientifically justified since developmental and offspring toxicity were adequately addressed. The commenter stated that standard uncertainty factors should provide adequate safety as supported by other international agencies and cited endpoints selected by other agencies as support for not needing a PCPA factor.

PMRA Response:

In SPN2008-01 *The Application of Uncertainty Factors and the PCPA Factor in the Human Health Risk Assessment of Pesticides*, the PMRA states the following: "The PCPA does not specifically require the application of the PCPA factor in occupational risk assessment. Regardless, those exposed occupationally could include pregnant or lactating women; therefore, there is the potential for indirect exposure of their offspring to a pesticide. In keeping with the spirit of the legislation, it is necessary to protect these indirectly exposed young to a similar degree as their counterparts that are afforded protection through the application of the PCPA factor. Consequently, where warranted, an additional uncertainty factor will be applied to worker exposure scenarios if available data identify concerns for potential effects on the young or if appropriate data are not available to adequately address the concerns." Accordingly, the PMRA has applied a PCPA-like uncertainty factor to ensure the protection of a pregnant worker and her unborn fetus as per its stated policy.

Although the PMRA concurs that developmental and offspring toxicity have been adequately addressed, it is important to note that the PCPA factor addresses not only the completeness and adequacy of the data but also the nature of the findings; this includes a consideration of the evidence of sensitivity of the young as well as the seriousness of the effects. As discussed in the PCPA Hazard Characterization section of PRVD2016-13, the fetal effects, namely post-implantation loss and malformations, were considered serious endpoints. However, as the concern was tempered by the presence of maternal toxicity, the PCPA factor was reduced from 10-fold to three-fold in cases where the developmental endpoint was used as the point of departure for the risk assessment. The PMRA applied the factor consistent with current policy and practice.

With regards to international comparisons, it is the PMRA's understanding that with the exception of the USEPA, no other pesticide regulatory authority has a specific legislative mandate to afford additional protection for the young. Although the USEPA reduced the FQPA factor to one-fold, it is not uncommon for regulatory authorities to differ on the selection of toxicology endpoints or the application of factors for risk assessment. In fact, the USEPA used a lower endpoint (10 mg/kg bw) than the PMRA (20 mg/kg bw) for the acute reference dose for captan. As a result, the USEPA acute reference dose (0.1 mg/kg bw) is not substantially different from that of the PMRA (0.07 mg/kg bw).

Comment 4. The use of a chemical-specific adjustment factor:

The CTF supported the use of a chemical-specific adjustment factor (CSAF) to refine the default uncertainty factor for interspecies extrapolation. The commenter provided a rationale to support a reduction in the 10-fold uncertainty factor based on a comparison of animal and human data. Specifically, the commenter proposed that the portion of the default uncertainty factor typically ascribed to account for animal to human toxicokinetic differences (that is, four-fold) be reduced to 2.6 fold.

PMRA Response:

The CSAF approach supported by the commenter had some merit given the availability of rat and human toxicokinetic data (PMRA #1142421, 1142423, 1163235, 2408546, 2408570). The human toxicokinetic data were compliant with the PMRA requirements outlined in SPN2016-01 *Restricted Use of Human Studies for Regulatory Purposes.* The PMRA concurs that the cumulative urinary excretion of the tetrahydrophthalimide (THPI) metabolite could be used to compare the toxicokinetic profiles of rat and humans. It is agreed that urinary excretion profiles in rats and humans suggest similar internal dose metrics. Likewise, both species exhibit a low volume of distribution with little evidence of tissue retention or protein binding. As a biomarker, THPI is specific to captan, stable in urine and detectable at low levels. Although all of these points are conducive to the consideration of a CSAF approach, the PMRA notes a number of limitations which are discussed below.

The commenter assumed that the effects associated with captan were area under the curve (AUC)-mediated. It is the PMRA's contention that the developmental effects may be related to peak concentration. There was no information regarding plasma levels in rats to compare with plasma levels in humans. Accordingly, the CSAF approach may be valid only for risk assessments not based on the developmental endpoint. Furthermore, the commenter's rationale for derivation of the toxicokinetic factor for interspecies extrapolation was restricted to the oral route (consideration of the human toxicokinetic data for refinement of the dermal absorption value is discussed below). Thus, the PMRA has considered the CSAF approach within the context of the acceptable daily intake (ADI) only.

The low level of THPI excreted in humans (< 5% of administered dose) calls into question its use as an adequate urinary biomarker. Typically, levels this low would be considered unacceptable to support use of a metabolite as a biomarker. However, THPI degrades to the hydroxylated form, which is the most prevalent urinary metabolite in the rat following administration of ^{14}C-cyclohexane-labelled captan. Hydoxylated-THPI was not measured in human urine but assuming similar metabolism between species, greater than 33% of captan in human urine (as measured in PMRA# 2408546) would be in the form of THPI or its subsequent hydroxylated derivative on average. Although there is a possibility that THPI may have been underestimated, the PMRA considers that it is representative of a significant path of metabolism and sufficient to support as a biomarker.

It was reported that quantification of THPI in rat urine was undertaken on a 6–36 hour post-dose sample. Although unclear in the study, it was assumed that the 6–36 hours referred to the sample collection intervals rather than the sampling duration and that in fact, the THPI was quantified

for 0–36 hours post-dose. Rat data indicate that some radioactivity is excreted in the urine after 36 hours (≤ 1% of administered single dose, ≤ 3% of administered repeat dose). Given these low levels, it is not anticipated that THPI would have been significantly underestimated and thus, this was considered a minor limitation.

Although the commenter identified the THPI urinary recovery in rats to be 10.6%, the range of urinary THPI recovery was 6.1–15.4% when examining the sex and dosing regimens separately (see Table 3). Likewise, the commenter used the mean urinary radioactivity recovery of 81.8% from the single-dose rat study at 96 hours (both sexes combined) to adjust the THPI urinary recovery data to yield the cumulative THPI excreted as a percent of the administered dose. The PMRA used the sex-specific and regimen-specific urinary radioactivity recoveries for adjustment. Furthermore, the PMRA used urinary radioactivity recoveries up to the 36-hour time-point to more appropriately correspond with the time interval of THPI quantification. Notwithstanding the limitations noted, the upper range of the CSAF's that the PMRA derived (that is, 94-fold) approximates the default factor of 100-fold for interspecies extrapolation. There does appear to be some difference in the CSAFs derived from male and female rats, with males having a higher level of urinary THPI excretion; it should be noted that human data were based on male volunteers.

In conclusion, the PMRA acknowledges that the CSAF approach for captan has some merit. However, given that the derived CSAF approaches the default value, coupled with the limitations noted above that could lead to potential underestimation, it is the PMRA position that there is an insufficient basis upon which to deviate from the default approach.

Table 3 Parameters for CSAF Consideration

Dosing Regimen	Single ♂	Single ♀	Repeat ♂	Repeat ♀
Mean Urinary Excretion 0–36 hr as % Administered Dose in Rat	80.7[1]	76.0[1]	85.3[2]	89.8[2]
THPI (% urinary recovery 0– 36 hr) in Rat	15.4	6.97	12.4	6.1
Cumulative % THPI Excreted in Rat	12.4	5.3	10.6	5.5
CSAF (Cumulative % THPI Excreted in Rat/Cumulative % THPI Excreted in Human[3]	3.78	1.61	3.23	1.68
CAF[4] without PCPA factor	94×	40×	81×	42×
CAF with PCPA factor	282×	120×	243×	126×

[1]Total recovery was approximately 91% of administered dose; urinary excretion more variable with coefficients of variation of 16-19%.

[2]Total recovery was approximately 98% of administered dose; urinary excretion less variable with coefficients of variation of 3–5%.
[3]%THPI excreted in humans was 3.28
[4]CAF = $UF_{AK} \times UF_{AD} \times UF_{HK} \times UF_{HD}$ where UF_{AK} is the derived CSAF and UF_{AD}, UF_{HK} and UF_{HD} are default factors of 2.5, 3.16 and 3.16, respectively.

Additional Information

In PRVD2016-13, it was noted that the registrant had previously considered the toxicity of THPI to be orders of magnitude less than captan. The PMRA had concluded that the toxicity of THPI was not well-characterized but that it could be ~50% less toxic relative to captan based on the comparison of the captan and THPI developmental toxicity studies. An acute oral toxicity study in the rat with THPI (in cottonseed oil) was submitted via the Incident Reporting Program (PMRA #2679222). All animals died at the dose of 2000 mg/kg bw and animals at 300 mg/kg bw showed clinical signs of toxicity; the LD_{50} cut-off for THPI was established at 500 mg/kg bw. Conversely, the LD_{50} for captan (in corn oil) in rats was > 5000 mg/kg bw with some mortality and clinical signs observed at 5000 mg/kg bw (PMRA #1237387). Thus, the data suggest that THPI is more acutely toxic than captan but the extent is difficult to quantify due to the methods used.

Despite the evidence of greater acute toxicity than captan, THPI did not demonstrate a similar pattern in the sole repeat-dose study, namely the rabbit developmental toxicity study. In that study, THPI-treated maternal animals showed reductions in bodyweight gain and food consumption at 22.5 mg/kg bw/day, but to a lesser degree than maternal animals similarly treated with 10 mg/kg bw/day captan. Accordingly, captan toxicology reference values selected for repeat-exposure scenarios would likely be protective of THPI toxicity. The inclusion of THPI in the residue definition for risk assessment helps to mitigate concerns regarding the acute toxicity of THPI.

1.2 Comments Related to Dietary Exposure

Comment 1. The change of the residue definition and establishment of MRLs:

Regarding the proposed change to the residue definition, the CTF asked for clarification on the PMRA process to submit the requested residue studies in accordance with the new residue definition. The CTF also recommended that “PMRA adopt(s) an orderly and transparent approach to the change of the residue definition”.

PMRA Response:

Clarification was provided to the CTF regarding the residue chemistry data requirements and the process for submission of these studies. As the change in residue definition is not associated with risk to consumers, revision of the residue definition and MRLs for captan will be addressed through a separate submission process.

Comment 2. Crop rotation restrictions:

The CTF submitted a confined crop rotation study, seeking to waive the 12-month plantback restriction (default) proposed in the PRVD.

PMRA Response:

The PMRA agreed to review the submitted study within the framework of a separate submission (see comment above). Plantback interval label statements will be addressed following review of the submitted study. (The 12-month plant-back interval proposed as a label statement in PRVD2016-13 will not be required at this time).

Comment 3. Multi-residue method testing:

The CTF asked for clarification regarding the purpose of the PMRA's request for validation of the Canadian Food Inspection Agency's (CFIA) analytical method used for the monitoring of residues of captan and its metabolites.

PMRA Response:

As noted in PRVD2016-13, the PMRA requested a laboratory study which quantifies the individual recovery efficiency for captan and its metabolites by typical multi-residue methods used in food surveillance programs. The current dietary risk assessment was based on food residues measured by surveillance programs, including those conducted by the CFIA. These data were used to refine or determine a more realistic level of exposure of captan and its metabolite THPI to Canadians. Based on these data, the risk from exposure to captan and its metabolite was not of concern. However, there was some uncertainty in using these data, regarding the recovery of captan and THPI using the CFIA multi-residue method. In order to ascertain the PMRA's use of these data in the dietary risk assessment and the subsequent risk conclusions, a laboratory study is required for any subsequent submission for use expansions or to revise/establish MRLs of captan (see Section 1.2 of Science Evaluation Update).

1.3 Comments Related to Occupational Exposure

Comment 1. Dermal absorption

The CTF and grower groups indicated that the PMRA should consider available 2012 dermal human toxicokinetic studies in assessing the dermal absorption of captan in humans.

PMRA Response:

The PMRA had considered the specified studies as part of a weight-of-evidence approach in determining a value of 25% dermal absorption that was proposed in PRVD2016-13; major limitations in these studies had precluded them from being used quantitatively. However, many of these limitations were addressed by the data and comments submitted during the consultation period.

The PMRA revisited the entire database of dermal absorption studies available for captan in consideration of the comments received, as well as information submitted for the toxicology evaluation. In particular, based on the human in vivo pharmacokinetic studies and supporting data in the human in vitro dermal absorption study, a dermal absorption value of 1% was selected for mixers/loaders of commercial-class (non-seed treatment) products. The re-analysis was based on a comparison of the concentrations of the commercial-class captan products and the dose solution used in the human in vivo and in vitro studies.

This 1% dermal absorption value was not considered to be appropriate for applicator, seed treatment, or residential scenarios as the dose solution used in the human in vivo study was more concentrated than the dilute spray solutions of captan used in the field, and may underestimate exposure since percent dermal absorption of captan increases with decreasing dose. In addition, the 1% dermal absorption value was not considered to be applicable for postapplication workers as their exposure is due to the transfer of residues from treated foliage and the relationship between dermal dose ($\mu g/cm^2$) and the spray solution has not been established. Using a weight-of-evidence approach from the available human and rat in vivo and in vitro studies, the dermal absorption value of 15% was selected for the applicator, postapplication, seed treatment, and residential scenarios. This value is considered to be protective, given the conservatisms in the supporting data; a lower value could not be quantitatively supported based on the limitations with the data available.

At this time, the standard approach for dermal absorption is to use the same value for postapplication workers and for workers applying the pesticide. This is consistent with regulatory agencies in other countries, such as the European Union and the United States. Research is currently being conducted on absorption from dried residues, which may be applicable to postapplication workers. The PMRA will continue to keep abreast of this research and revisit policies as required.

Comment 2. Handset/Handline irrigation

Grower groups submitted use information to the PMRA which indicated that handset/handline irrigation is not used for a number of crops, including berries.

PMRA Response:

The PMRA acknowledges receipt of this information and has considered it with other information available to the Agency, which indicates that handset/handline irrigation continues to be used on some farms. It is important that the postapplication risk assessment include all possible activities; as such, the handset/handline irrigation activity was retained in the risk assessment. However, as with all activity-specific REIs, the REI for a given activity must be followed **only** if that activity is being performed. If handline irrigation is not used on a farm, then the REI for handset/handline irrigation related activities is not applicable.

Comment 3. Application rate

Grower groups commented that captan is often applied at rates less than the maximum application rate on the label.

PMRA Response:

In the risk assessment, the registered Canadian use pattern was assessed, which includes the maximum application rate and number of applications currently on Canadian labels or supported by the registrant. As the number of applications and application rates can vary from year to year and region to region across Canada, depending on the weather and pest pressures, the risks to workers applying captan for the registered use pattern must be acceptable. If risks of concern are identified, then mitigation is required for continued registration. For tree fruit (apples, cherries, apricots, peaches, pears, plums, prunes, nectarines), grape and strawberry crops for which risks of concern were identified using the maximum application rate, a lower rate supported by the registrant was incorporated in the revised assessment and is part of the change in use pattern that is required for these crops to remain on the label. These revised rates are outlined in Appendix III.

Comment 4. Protective equipment for postapplication workers

Grower groups commented that Health Canada should consider personal protective equipment (PPE) for postapplication workers.

PMRA Response:

Studies that are used currently to estimate postapplication worker exposure are based on workers wearing long-sleeved shirts, long pants, socks and footwear. It is also understood that many postapplication workers may wear gloves for their own personal comfort or for food safety purposes (to reduce food contamination). However, there is no reliable data to indicate the degree of protection gloves may provide to postapplication workers, or conversely, the extent that gloves may enhance exposure under certain conditions (see below).

Before the PMRA can estimate risk for workers wearing gloves or other PPE, worker exposure studies comparable to those currently used by the PMRA are required. Studies that are currently used are discussed further in the Regulatory Proposal PRO2014-14 *Updated Agricultural Transfer Coefficients for Assessing Occupational Postapplication Exposure to Pesticides*. Most, if not all, studies conducted by the Agricultural Re-entry Task Force (ARTF), submitted by registrants, or available in the scientific literature and used to determine the PMRA transfer coefficients did not include personal protective equipment. Gloves may be worn, but they function as dosimeters to measure hand exposure, rather than exposure as a result of protection from the glove. Some available studies suggest that exposure actually increases when wearing gloves (Brouwer, 2000; Boman et al., 2005; Garrigou et al., 2011; Graves et al., 1995; Keifer, 2000; Rawson et al., 2005).

Besides the lack of scientific studies to estimate postapplication exposures while using specific PPE, the feasibility of postapplication workers wearing PPE must also be considered. As such, compliance, enforcement, training, regulatory jurisdiction, labelling, and communication are all aspects that need to be in place.

The PMRA is currently exploring some of these issues, including the feasibility of obtaining postapplication exposure studies for workers wearing certain PPE, for the purpose of estimating risk under these conditions.

Comment 5. Early season application in grape

L'Association des vignerons du Québec commented that there is an early season application of captan on grapes at the phenological growth stage BBCH 05 and BBCH 11, when there is minimal foliage and a period of rapid growth, and that the risk assessment should take these early season applications into account.

PMRA Response:

In PRVD2016-13, captan use on grapes was proposed for cancellation as calculated REIs were not considered to be agronomically feasible. Based on the comments received, the early season applications on grapes were considered separately from later applications in the revised risk assessment. Postapplication exposure during this crop stage is considered to be low as there is minimal foliage, and residues on leaves will quickly become diluted as foliage is rapidly growing. As a result, these early season applications do not have risks of concern at the minimum REI of 12 hours and are acceptable for continued registration.

Comment 6. Impact of leaf texture and climate on grape TC and DFR:

L'Association des vignerons du Québec commented that the ARTF grouped all exposure calculations for grapes under the hypothesis that all vines are smooth. However, there are varieties grown in Canada that have hairy foliage. As such, it was recommended that dissipation of captan residues due to regional differences in weather (rain, moisture, temperature) be taken into account.

PMRA Response:

Transfer coefficients, developed by the ARTF, are a measure of residue transferability from the foliage of plants or turf onto a worker's skin or clothing through contact. They are determined from worker exposure studies and concurrent dislodgeable foliar residues (DFR) or turf transferrable residues studies. DFRs are influenced by leaf texture; however, other factors also have an impact on DFRs and TCs. These include, but are not limited to: application rate, application equipment, product formulation and general crop morphology (for example, tree, trellis, field crop). In addition, the dissipation of DFRs over time is influenced by climatic conditions and crop growth. At this time, the transfer coefficients developed by the ARTF are the best available data for generic postapplication risk assessments for grapes.

No Canadian data were available or submitted to the PMRA to estimate the DFR of captan on grapes. Two literature studies, conducted in California, were available to determine peak DFR and daily dissipation for this crop. While studies from California are generally considered to provide a conservative estimate of residue dissipation relative to Canada, due to the arid conditions, it is not possible to quantify the impact that the Canadian climate would have on DFR values without a study. DFR data from other crops, such as orchard or field crops, are not

considered an appropriate surrogate for trellis crops, such as grapes, as crop morphology can impact DFR. Postapplication worker exposure studies for grapes were also considered for captan; however, the available studies had major limitations and could not be used quantitatively to refine the risk assessment. In PRVD2016-13, DFR and worker exposure studies representative of Canadian conditions were listed as data that could be used to refine the risk assessment; however, no data specific to grapes were submitted during the comment period. Therefore, this aspect of the postapplication risk assessment could not be refined.

In PRVD2016-13, captan use on grapes was proposed for discontinuation. However, with the information provided by growers, as discussed above (response to comment 5), as well as in consideration of the reduced dermal absorption value (response to comment 1), two early season applications (BBCH 05 and BBCH 11) and one additional application will continue to be permitted for captan.

2.0 Comments Related to Value Assessment

Stakeholder responses to PRVD2016-13 included the Carstone Group Inc., who was engaged by the CTF, ADAMA Agricultural Solutions Canada Ltd., and Arysta Life Science, and who was primarily responsible for coordinating the stakeholder surveys conducted through the Canadian Horticulture Council (CHC). The CHC response included growers' surveys with information provided by Ontario and Quebec grower associations for the pome fruit, tender fruits, berries, grapes, vegetables and potatoes sectors. Other stakeholders provided comments including the British Columbia Blueberry Council and Saskatchewan Ministry of Agriculture.

Comment 1.

Respondents stated that by discontinuing the use of captan in: greenhouses (except for soil treatments and rhubarb in forcing sheds), tree fruits, grapes, mature pumpkin/squash, field tomato, and berries, the proposed decisions would significantly impact fruit and vegetable producers in Canada. Captan has been used for many years in Canada and other countries to control diseases in agricultural, ornamental and residential crops and plants. Its multi-site mode of action makes it a critically important tool for growers for both disease management and resistance management. If growers in Canada lose access to captan, they will be put at an economic disadvantage when compared to growers in the United States, Europe and Australia where the national assessment have fully supported the continued registration and use of captan products. Concerns were also raised about limiting the maximum number of applications to one per season for cucumber, potato, and young pumpkin/squash.

PMRA Response:

The PMRA acknowledges the importance of captan and other multi-site fungicides for disease control and resistance management in Canadian crop production. During the consultation period, the PMRA received additional information related to crop production practices from stakeholders. As well, in July 2017, the PMRA asked the CTF to obtain additional postapplication exposure information from Provincial Crop Specialists, including more detailed descriptions of postapplication worker activities that were not in the initial stakeholder consultation. Information received from these two stakeholder consultations allowed the

occupational risk assessment to be further refined, and as a result certain uses were retained, the number of applications increased from what was originally proposed in PRVD2016-13, or for certain uses a reduction in the number of applications and/or rates, or increases in the REIs and/or pre-harvest intervals (PHIs) were required to mitigate risks.

Refinement of the risk assessments resulted in the following uses retained: greenhouse soil treatment, rhubarb in forcing sheds, tree fruits, grapes, pumpkin and squash, field tomato, berries and field cut flowers. Refinement of the occupational risk assessment also allowed for multiple applications per year to be retained on most crops. For crops which have a reduction in application rates, stakeholders' information suggested growers would still use this rate under conditions of low disease pressures. To mitigate efficacy concerns related to the rate reduction, label changes will be made to limit the applications to low and moderate disease pressures, and to tank mix or switch to another fungicide under conditions of high disease pressures. With respect to some of the increases in REIs and PHIs, the changes may negatively impact some producers by limiting when the product can be used during the growing season. While this would require alternative products to be used closer to harvest, or limiting the use to mechanical harvesting only, it will still allow growers to access this active if needed.

Additional analysis on other changes in captan's use pattern:

In response to PRVD2016-13, comments were not received concerning the value of captan to tobacco production, and no proprietary information is currently available to help assess the impact of the cancellation of use on tobacco seedlings. Limited alternatives are available, including the biological fungicide *Bacillus subtilis* MBI 600, which is registered to reduce Pythium damping off on tobacco seedlings.

Based on communications with Flowers Canada, very few growers of greenhouse cut flowers use captan as a foliar application. It is noted that there are several foliar-applied alternatives registered for listed diseases on greenhouse ornamentals (cut flowers) including for damping-off diseases. With respect to ornamental stem dip applications, no information was available concerning the use of captan, and there are no registered alternatives for this particular use. The ornamental bulb dip application method, which was identified as being of major importance to growers, will be retained however, as will the soil-applied application method.

While the use of captan in Canada for treatment of vegetable seeds (sugar beets, broccoli, Brussels sprouts, cabbage and cauliflower), is being cancelled, planting of imported treated vegetable seeds will be permitted and will still be an option for growers.

Although, the on-farm dry application use of captan is being cancelled, Canadian bean growers will still have access to on-farm slurry applications of captan, and in addition there are other alternative active ingredients that are registered for the listed diseases.

Appendix III Revised Label Amendments for End-Use and Technical Grade Active Ingredient Products Containing Captan

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

1.0 Statements to Protect Human Health

1.1 Label Amendments for Technical Products

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.

1.2 Label Amendments for the Commercial Class End-use Products

1.2.1 Precautions

1.2.1.1 General Label Improvements

The following label statements are to be added to the **PRECAUTIONS** of all agricultural commercial-class end-use product labels (This is not required for seed treatment 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."

For agricultural commercial-class end-use products that have label directions discussing entry into treated areas prior to expiry of the REI (This is not required for seed treatment labels):

Replace the following, or similar statement:

"If re-entry into treated areas is required, workers must wear long pants, long-sleeved shirt, chemical-resistant gloves, work books and goggles" and "No re-entry shall occur in treated greenhouses without an approved respirator unless it has been fully ventilated."

With:

"**DO NOT** enter or allow worker entry into treated areas during the restricted-entry interval (REI) on the label. Employers should make every effort to schedule pesticide applications and worker tasks in order to avoid early entry of workers into treated areas. Under exceptional circumstances, certified pesticide applicators 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, 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 is worn. Time spent in the treated area cannot exceed 1 hour in a 24-hour period or until restricted-entry interval is over."

1.2.1.2 Agricultural Liquid Commercial-Class Products

A) Liquid Commercial-Class Products for Uses Other Than Seed Treatment

For commercial-class liquid agricultural products not for use as a seed treatment (for example, products with registration # 9922, and 32300), label statements must be amended (or added) to include the following directions under **PRECAUTIONS**, unless the current label mitigation is more restrictive:

"During mixing/loading, application, clean-up and repair, wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and 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." [For products with aerial application on the label (for example, product with registration #9922), also add "Goggles and gloves are not required to be worn inside the cockpit. Respirators are also not required to be worn inside the cockpit as long as it is equipped with an air filtration mechanism."]

"When applying using groundboom, use a closed cab when handling more than 42 kg a.i./day. A closed cab must have 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, goggles, and chemical-resistant gloves are not required to be worn inside the closed cab, but need to be available for exiting the cab."

"When applying using open cab airblast equipment or for overhead spray, also wear chemical-resistant headgear. Chemical-resistant headgear includes Sou'Wester hat, chemical-resistant rain hat or large brimmed waterproof hat and hood with sufficient neck protection."

B) Liquid Commercial-Class Seed Treatment Products

For commercial-class liquid products registered for use as a seed treatment (for example, products with registration # 12028, 22819, 24684) label statements must be amended (or added) to include the following directions under **PRECAUTIONS**, for the seeds currently listed on the label, which will still be permitted to be treated in Canada, unless the current label mitigation is more restrictive:

> **Commercial Seed Treatment Facilities**
> "Use closed transfer for commercial seed treatment (facilities and mobile treaters). Closed transfer includes closed mixing, loading, calibrating and closed treatment equipment. No open transfer is permitted. When treating seeds 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 (for example, bagging, stacking) 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, 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 a 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 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 need to be available for exiting the cab during calibration, repair or cleaning of equipment."

In addition to the above, for products where treatment of seeds on-farm is permitted or not specifically excluded (for example, product with registration # 12028), label statements must be amended (or added) to include the following directions under **PRECAUTIONS** for the seeds currently listed on the label, which will still be permitted to be treated in Canada, unless the current label mitigation is more restrictive.

The statements below referring to "On-Farm Seed Treatment" do not need to be added to the label if the registrant prohibits on-farm treatment of seeds by adding "For Use By Commercial Seed Treaters Only (facilities and mobile treaters)" to the label.

> **On-Farm Seed Treatment (liquid formulation) (beans, chickpea, corn, lentil, lupin, peas, soybeans)**
> "When treating seeds, handling and planting treated seeds, wear a long-sleeved shirt, long pants, shoes plus socks, goggles, and chemical-resistant gloves. When treating seeds, also wear a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides. When handling and planting treated seeds, also wear a NIOSH-approved N95 (minimum) filtering face piece respirator (dust mask) that is properly fit-tested."

1.2.1.3 Wettable Powder or Water Dispersible Granule (WDG) Formulations in Water Soluble Packaging (WSP):

All captan products currently formulated as wettable powders or water dispersible granules (agricultural and seed treatment products) must be discontinued and reformulated in water soluble packaging (WSP). Label language will need to be updated to indicate directions for the use of water soluble packaging. Registrants will need to ensure that the sizes of the water soluble packets are reconciled with the registered/required use-specific application rates.

The following additional label statements, as well as other appropriate statements in other sections of this appendix, are required for end-use products formulated in water soluble packaging.

A) Agricultural Wettable Powder and Wettable Granular Commercial-Class Products in WSP for Uses Other Than Seed Treatment

For commercial-class wettable powder or wettable dispersible granules repackaged in WSP that are not registered for use as a seed treatment, label statements must be amended to include the following directions under **PRECAUTIONS**, unless the current label mitigation is more restrictive:

> "During mixing/loading, application, clean-up and repair, wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and 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." [For products that have directions for aerial application on labels, also add "Goggles and gloves are not required to be worn inside the cockpit. Respirators are also not required to be worn inside the cockpit as long as it is equipped with an air filtration mechanism."]
>
> "When applying using groundboom, use a closed cab when handling more than 57 kg a.i./day. A closed cab must have 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, goggles, and chemical-resistant gloves are not required to be worn inside the closed cab, but need to be available for exiting the cab."

"When applying using open cab airblast equipment or for overhead spray, also wear chemical-resistant headgear. Chemical-resistant headgear includes Sou'Wester hat, chemical-resistant rain hat or large brimmed waterproof hat and hood with sufficient neck protection."

"When applying using a mechanically-pressurized handgun, also wear coveralls over a long-sleeved shirt and long pants. Also, during greenhouse application with this equipment, do not handle more than 0.71 kg a.i. per person per 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."

"When preparing flower bulb dip solutions and for all related cleaning and repair tasks, workers must also wear chemical-resistant coveralls over long-sleeved shirt, long pants, goggles, and chemical-resistant footwear and socks. When handling treated bulbs and when touching surfaces that have contacted or may have been contaminated by the dipping solution, workers must wear long-sleeved shirt, long pants, goggles, socks and shoes, and chemical-resistant gloves."

B) Wettable Powder Commercial-Class Seed Treatment Products in Water Soluble Packaging

For commercial-class wettable powder products in water soluble packaging registered for use as a seed treatment, label statements must be amended (or added) to include the following directions under **PRECAUTIONS**, unless the current label mitigation is more restrictive:

Commercial Seed Treatment Facilities (slurry machines for beans)
"Use closed transfer for commercial seed treatment (facilities and mobile treaters). Closed transfer includes closed calibrating and closed treatment equipment. No open transfer is permitted. When treating seeds 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 (for example, bagging, stacking) wear a long-sleeved shirt, long pants, shoes plus socks, goggles, chemical-resistant gloves, and a NIOSH-approved N95 (minimum) filtering face piece respirator (dust mask) that is properly fit-tested."

"When cleaning seed treatment equipment, 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 a 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 face piece 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 need to be available for exiting the cab during calibration, repair or cleaning of equipment."

In addition to the above, for products where treatment of seeds on-farm is permitted or not specifically excluded (for example, product with registration # 26987), label statements must be amended (or added) to include the following directions under **PRECAUTIONS** for the seeds currently listed on the label, unless the current label mitigation is more restrictive. The statements below referring to "On-Farm Seed Treatment" do not need to be added to the label if the registrant prohibits on-farm treatment of seeds by adding "For Use By Commercial Seed Treaters Only (facilities and mobile treaters)" to the label.

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

On-Farm Seed Treatment (WP formulation in water soluble packaging, seed box treatment for sweet corn)
"When treating seeds, handling and planting treated seeds, wear a long-sleeved shirt, long pants, shoes plus socks, goggles, and chemical-resistant gloves. When treating seeds, also wear a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides. When handling treated seeds, also wear a NIOSH-approved N95 (minimum) filtering face piece 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 need to be available for exiting the cab during calibration, repair or cleaning of equipment."

1.2.1.4 Restricted-Entry Interval (under Precautions)

Table 1 below lists the maximum number of applications, minimum interval and REI to be added to captan agricultural labels.

Note: some of the activities in the REI table may not be routinely conducted in every farm for every crop. The REIs specified for an activity must be followed only if that activity is being performed. For example, there is an REI for hand harvesting, but if the crop is to be mechanically harvested, then the PHI should be followed if there is no contact with treated foliage or surfaces.

The REI text on the label should be modified as follows:

Where REIs are currently specified on the labels, remove the following, or similar wording from the label:

"DO NOT reenter treated blueberries, caneberries (raspberries and blackberries), and grapes within 72 hours of application. DO NOT reenter ornamentals within 4 days of treatment. DO NOT reenter all other treated areas within 48 hours of application.

For agricultural products, update **PRECAUTIONS** section of the label with information on restricted-entry as per the following:

- "**DO NOT** enter or allow worker entry into treated areas during the restricted-entry intervals (REIs) specified in the following table."
- Include a table on each label that include activities and REIs from Appendix III Table 1 for the crops registered on that label, as per the following example. **Ensure that only registered crops from the following table are included in your particular product label.**

Example of Restricted-Entry Interval Table

Crop	Postapplication Activity	Restricted Entry Interval[a]
example crop 1	corresponding activity for crop 1 from Table 1	corresponding REI from Table 1
example crop 2	corresponding activity for crop 2 from Table 1	corresponding REI from Table 1
	corresponding activity for crop 2 from Table 1	corresponding REI from Table 1
	corresponding activity for crop 2 from Table 1	corresponding REI from Table 1

[a] REIs longer than 12 hours apply to hand labour tasks. If the REI for hand harvesting and the pre-harvest interval (PHI) are different, follow the longer of the two intervals. Mechanical harvesting could occur after the PHI provided there is no worker contact with treated foliage. If the REI is 12 hours and a PHI is not specified, entry is not permitted until after 12 hours.

Additional updates to the use pattern (application rate, maximum number of applications, re-treatment interval, additional application instructions) included in Appendix III Table 1 are to be added to the product label text or in a table where applicable.

Table 1 Restricted-Entry Intervals, Maximum Number of Applications and Application Timing for Captan

Crop	Activity	Maximum Application Rate(s)	REI[a]	Maximum Number of Applications per year, Minimum RTI	Additional Application Instructions
Greenhouse ornamentals[b] (non-cut flower): foliar applications to aster, camellia, carnation, chrysanthemum, dahlia, lilac, rose and tulip	All activities	1.0–1.2 kg a.i./ha	12 hours	6 applications, 7 days apart	Apply preventatively, when conditions are favourable to disease development.
Rhubarb (in forcing sheds)	All activities	1.6 kg a.i./1000 L	12 hours	6 applications, 7 days apart	Apply preventatively, when conditions are favourable to disease development.
Soil and greenhouse bench treatment (soil treatment): seedlings or transplants of roses and other flowers, shrubs, trees, lawn seedbeds, beans, broccoli, Brussels sprouts, cabbage, cauliflower, celery, crucifers, eggplants, kale, peas, tomatoes, pepper, rutabaga, turnip, turf (ornamental, sport)	All activities	8.5–11.3 kg a.i./ha	12 hours	1 application	None
Apple and pear orchards that have high density production where the maximum canopy width per tree is 2 m (1 m to reach center or	Hand thinning fruit, hand harvesting	2.4 kg a.i./ha	15 days	10 applications, 7 days apart	Remove application rates greater than 2.4 kg a.i./ha. Initiate applications preventatively before infection becomes established. Add: Apply 2.4 kg a.i./ha under conditions of low to moderate disease pressure only. If disease
	Hand pruning, training		6 days		
	All other activities		2 days[c]		

Crop	Activity	Maximum Application Rate(s)	REI[a]	Maximum Number of Applications per year, Minimum RTI	Additional Application Instructions
trunk from the row alley). These tree architectural restrictions are to minimize worker contact with treated foliage.					pressure is high or conditions are conducive for high disease pressure, either tank mix captan at the 2.4 kg a.i./ha rate with another fungicide registered for control of the same disease, or switch to another fungicide registered for control of the same disease.
Non-High Density Apple and Pear Orchards: Apple and pear orchards that do not meet the requirements specified for high density apple and pear orchards.	Hand thinning fruit	2.4 kg a.i./ha	24 days	Apply a maximum of 2 applications per year. Minimum RTI 7 days. When hand thinning is performed, make 1 application beforehand thinning fruit and 1 application after hand thinning fruit.	Remove application rates greater than 2.4 kg a.i./ha. Add: Initiate applications preventatively before infection becomes established. Apply 2.4 kg a.i./ha under conditions of low to moderate disease pressures only. If disease pressure is high or conditions are conducive for high disease pressure, either tank mix captan at the 2.4 kg a.i./kg rate with another fungicide registered for control of the same disease, or switch to another fungicide registered for control of the same disease.
	Hand harvesting		19 days		
	Hand pruning, training		4 days		
	All other activities		2 days[c]		
Cherry, peach, plum apricot, nectarine trees	Hand thinning fruit	3.2 kg a.i./ha	29 days	1 application. Cherry trees are permitted 1 additional application after harvest	Remove application rates greater than 3.2 kg a.i./ha. Apply preventatively when conditions are favourable for disease development. An application can be made, starting as soon as pink bud, up to pre-harvest. Apply 3.2 kg a.i./ha under conditions of low to moderate disease pressure. If disease pressure is high or conditions are conducive for high disease pressure, either tank mix captan at the 3.2 kg a.i./ha rate with another fungicide registered for control of the same disease, or switch to another fungicide registered for control of the same disease.
	Hand harvesting		15 days		
	All other activities		1 day		
Grape	Turning, girdling	2.4 kg a.i./ha	78 days	3 applications	Remove application rates greater than 2.4 kg a.i./ha. For grapes a maximum of 3 applications/year are allowed with 2 applications/year for dead arm (*Phomopsis viticola)*
	Hand harvesting, training, tying, leaf pulling		55 days		

Crop	Activity	Maximum Application Rate(s)	REI[a]	Maximum Number of Applications per year, Minimum RTI	Additional Application Instructions
	All other activities		12 hours		and one application/year to target either black rot (G*uignardia bidwellii)* or downy mildew (*Plasmopara viticola).* Minimum re-treatment interval: 7 days. For dead arm apply when new shoots are 1 to 5 centimetres long and again when 10 to 15 centimetres long. For downy mildew or black rot, application can be made just before bloom, just after bloom and in first cover.
Cucumber (field grown)	Hand set/hand line irrigation related activities involving foliage contact	3.4 kg a.i./ha	10 days	3 applications, 7 days apart	Apply preventatively, when conditions are favourable to disease development.
	Hand harvesting, mechanically-assisted harvesting, training, tying		3 days		
	All other activities		12 hours		
Potato	Hand set/hand line irrigation related activities involving foliage contact	3 kg a.i./ha	7 days	3 applications, 7 days apart	Apply preventatively, when conditions are favorable to disease development.
	Roguing		6 days		
	All other activities		12 hours		
Pumpkin, squash	Hand set/hand line irrigation related activities involving foliage contact	3.4 kg a.i./ha	10 days	3 applications, 7 days apart	Apply preventatively, when conditions are favourable to disease development.
	Hand harvesting, mechanically-assisted harvesting, turning, training		3 days		
	All other activities		12 hours		

Crop	Activity	Maximum Application Rate(s)	REI[a]	Maximum Number of Applications per year, Minimum RTI	Additional Application Instructions
Tomato (field grown – foliar applications)	Hand set/hand line irrigation related activities involving foliage contact	3.4 kg a.i./ha	10 days	3 applications, 7 days apart	Apply preventatively, when conditions are favourable to disease development.
	Hand harvesting, training, tying		7 days		
	All other activities		12 hours		
Strawberry (field grown)	Hand set/hand line irrigation related activities involving foliage contact	2.8 kg a.i./ha	9 days	6 applications, 7 days apart	Remove application rates greater than 2.8 kg a.i./ha. Add: Apply preventatively, when conditions are favourable to disease development. Apply 2.8 kg a.i./ha under conditions of low to moderate disease pressure only. If disease pressure is high or conditions are conducive for high disease pressure, either tank mix captan at the 2.8 kg a.i./ha rate with another fungicide registered for control of the same disease, or switch to another fungicide registered for control of the same disease.
	Hand harvesting		6 days		
	All other activities		12 hours		
Raspberry	Hand set/hand line irrigation related activities involving foliage contact	2 kg a.i./ha	7 days	6 applications, 7 days apart	Apply preventatively, when conditions are favourable to disease development.
	Hand harvesting, training/ tying (full foliage)		6 days		
	All other activities		12 hours		
Highbush blueberry, blackberry, loganberry	Hand set/hand line irrigation related activities involving foliage contact	1.8 kg a.i./ha	6 days	6 applications, 7 days apart	Apply preventatively, when conditions are favourable to disease development.
	Hand harvesting, training/ tying (full foliage)		5 days		
	All other		12 hours		

Crop	Activity	Maximum Application Rate(s)	REI[a]	Maximum Number of Applications per year, Minimum RTI	Additional Application Instructions
	activities				
Lowbush blueberry	Hand set/hand line irrigation related activities involving foliage contact	1.8 kg a.i./ha	6 days	6 applications, 7 days apart	Apply preventatively, when conditions are favourable to disease development.
	All other activities		3 days[c]		
Ginseng	Hand set/hand line irrigation related activities involving foliage contact	2.0 kg a.i./ha	7 days	8 applications, 7 days apart	None
	Hand harvesting		4 days		
	All other activities		12 hours		
Outdoor Ornamentals: Foliar (cut flower)	Hand harvesting, disbudding, hand pruning (full foliage)	1.2 kg a.i./ha	7 days	1 application	None
	All other activities		1 day		
Outdoor Ornamentals: Foliar (non-cut flower)	Hand harvesting, disbudding, hand pruning (full foliage)	1.2 kg a.i./ha	4 days	6 applications, 7 days apart	None
	All other activities		12 hours		
Turf (golf course, sod farms only)	All activities	4.8 kg a.i./ha	12 hours	1 application	Apply preventatively, when conditions are favourable to disease development.

RTI = retreatment interval (time between applications)

[a] REI = Restricted-Entry Interval. REIs longer than 12 hours apply to hand labour tasks. If the REI for hand harvesting and the pre-harvest interval (PHI) are different, follow the longer of the two intervals. Mechanical harvesting could occur after the PHI provided there is no worker contact with treated foliage. If the REI is 12 hours and a PHI is not specified, entry is not permitted until after 12 hours.

[b] Only applies to non-cut flower, as there is a label statement that will prohibit the use on cut flowers.

[c] Current label REI.

1.2.2 Directions For Use

a) The following uses and any references to these uses must be removed from all agricultural commercial class end-use labels:

- Tobacco Seedlings

- Ornamental stem dip (including 'Stem rot, Damping-off, Rot of cuttings' for all ornamentals including azalea, carnation, chrysanthemum)

b) The following uses must be removed from the commercial class wettable powder seed treatment end-use product label in water soluble packaging:

- Dry application (hand mixing) of beans from the wettable powder seed treatment product.

c) The following statements are to be added to the appropriate labels:

- For seed treatment products, the following statement is required:
  - "**DO NOT** plant treated seed by hand."
- For agricultural products that are registered for use on flowers (for example, camellia, carnation, chrysanthemum, rose, aster, dahlia, lilac, tulip), the following statement is required:
  - "**DO NOT** use on greenhouse cut flowers."
- For agricultural products that are registered for use as a flower bulb dip (for example, begionia, daffodil, dahlia, gladiolus, iris, narcissus, tulip), the following statement is required:
  - "**DO NOT** dip flower bulbs by hand. Only mechanical or automated dipping equipment must be used (for example, conveyor belt, forklift)."
- For agricultural products that are registered for use on cucumber, tomato, and strawberry, the following statement is required:
  - "**DO NOT** use on greenhouse cucumber, tomato, and strawberry."
- For agricultural products that are registered for use in rhubarb forcing sheds, the following statement is required:
  - "Maximum spray volume of 150 L/ha for rhubarb in forcing sheds."

d) For Seed Treatment Products Registered for Use On Sugar Beets, Broccoli, Cabbage, Cauliflowers, Brussels Sprouts (for example, products with registration #: 12028, 22819, 24684):

Create a new section in the label titled '**For Imported Treated Seed**' under 'Directions for Use'. Then:

- Add the following statement (for applicable seeds):
  "**DO NOT** treat sugar beets, broccoli, cabbage, cauliflower, and Brussels sprouts seeds in Canada"

- When planting imported seeds **(**sugar beets, broccoli, cabbage, cauliflower, and Brussels sprouts**),** add the following instructions:

  "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 a 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 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 need to be available for exiting the cab during calibration, repair or cleaning of equipment."

- Move specific directions for use for sugar beets, broccoli, cabbage, cauliflower, and Brussels sprouts seeds (for applicable seeds) from other parts of the label to this section.

2.0 Statements To Protect The Environment (All End-Use Product Labels)

2.1 For Commercial class end-use products used for foliar application:

Add to ENVIRONMENTAL PRECAUTIONS:

Toxic to small wild mammals.

TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

Add to DIRECTIONS FOR USE:

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 S572.1) 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 S572.1) 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:

Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer	Outdoor ornamentals (cut and non-cut flowers)		2	1	4	2
	Highbush or lowbush blueberry, blackberry, loganberry		2	1	5	2
	Ginseng, raspberry		2	1	5	3
	Strawberry		3	1	5	3
	Cucumber, pumpkin, squash, tomato, potato		3	1	10	4
	Turf (golf course, sod farms only)		5	1	10	5
Airblast	Highbush or lowbush blueberry, blackberry, loganberry	Early growth stage	25	3	35	30
		Late growth stage	15	2	25	20
	Raspberry	Early growth stage	25	3	40	30
		Late growth stage	20	2	30	20
	Apple and pear orchards, grape	Early growth stage	30	4	40	30
		Late growth stage	20	2	30	20
	Peach, plum, prune, apricot, nectarine, cherry trees.	Early growth stage	30	5	40	35
		Late growth stage	20	3	35	25
Aerial	Highbush or lowbush blueberry	Fixed wing	40	1	250	50
		Rotary wing	30	1	125	40
	Apple and pear orchards	Fixed wing	55	1	275	70
		Rotary wing	40	1	150	50
	Grape	Fixed wing	65	1	325	85
		Rotary wing	45	1	175	55
	Strawberry	Fixed wing	80	1	350	100
		Rotary wing	55	1	175	70

	Peach, plum, prune, apricot, nectarine trees	Fixed wing	85	3	300	125
		Rotary wing	55	1	175	75
	Cherry trees	Fixed wing	85	3	300	125
		Rotary wing	60	1	175	75
	Potatoes	Fixed wing	90	3	350	125
		Rotary wing	60	1	175	75
	Cucumber, tomato	Fixed wing	100	5	350	150
		Rotary wing	70	2	200	90

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 Pest Management Regulatory Agency web site.

2.2 For Commercial class end-use products used for seed treatment:

Add to ENVIRONMENTAL PRECAUTIONS

TOXIC to aquatic organisms.

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.

In addition to the above, the following must appear on the product label as well as the bag of treated seed:

Under ENVIRONMENTAL PRECAUTIONS add the following statement:
“Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.”

Also add a section entitled “Labelling of Treated Seed” and add the following text under it: “All bags containing treated seed for sale or use in Canada must be labeled or tagged as follows: Toxic to small wild mammals. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.”

3.0 Additional Label Improvements To All End-Use Product Labels

3.1 Principal Display Panel

- All labels must be amended from ‘GROUP M FUNGICIDE’ to ‘GROUP M4 FUNGICIDE ’

3.2 DIRECTION FOR USE Sections

- Remove use directions from the label for the uses being cancelled, as described above.
- Remove all references to concentrate and semi-concentrate equipment.
- Retain application rate ranges stated on labels but do not exceed maximum application rates as indicated in Appendix III Table 1.
- As per section 3.10 of regulatory directive DIR2016-02, Notifications/Non-notifications, remove any vague or non-specific claims that the product can be tank mixed with another pesticide (fungicide, insecticide or herbicide). For example, under the compatibility section of Registration No. 9922, remove the statement indicating that “… can be used safely and effectively at recommended rates with most of the commonly used insecticides and fungicides with the exception of oil and strongly alkaline materials”.
- All tank mix partners specifically named on the product labels must be verified that a) they are still registered and have not been removed from the market, b) that they are still registered for the specific use indicated on the captan labels, and c) that the name of the tank mix partner is still valid (for example on Registration number 26408, it states that captan is to be tank mixed with Nova 40W Agricultural Fungicide, however, this product is now called Nova Fungicide, and as such the label should be updated.
- As per Regulatory Directive DIR2013-04, Pesticide Resistance Management Labelling Based on Target Site / Mode of Action, verify that the resistance management statement on each end use product label is updated to reflect the wording in there.
- Any statement indicating that re-treatment of the pesticide can be made “as needed” or “as required” should be removed, or replace with more specific label directions as per Appendix III. For example, “Re-apply on 7-10 day intervals, or as needed” must be replaced with “Re-apply on 7-10 day intervals if disease pressure continues, or if environmental conditions are conducive to disease development.
- Any statement that suggests that the re-treatment interval can be shortened to lower than the shortest interval, such as “shorten spray interval…, must be removed. For example on Registration number 4559, ‘treat weekly or bi-weekly before and during flowering season, especially following rain or damp weather.”
- Common names of plant pathogen to be updated to include the causative pathogen (for example, replace “Botrytis fruit rot” with “Botrytis fruit rot (*Botrytis cinerea)”*.

Appendix IV Revised Occupational Mixer/Loader/Applicator (MLA) and Postapplication Exposure and Risk Estimates for Captan

Details and tables for the revised risk assessment are included in this appendix. Please refer to PRVD2016-13 for additional information.

Dermal Absorption

Based on comments received regarding the dermal absorption value of 25% used for the risk assessments in PRVD2016-13, the dermal absorption value was revised to 1% for mixers and loaders of commercial-class (non-seed treatment) products, and 15% for all other scenarios. Refer to Appendix II for more information.

Seed Treatment

Captan is registered for use as a seed treatment. The surrogate seed treatment studies described in PRVD2016-13 were used to estimate worker exposure from commercial and on-farm seed treatment, as well as from planting treated seeds. As risks were not of concern for most seed treatment scenarios described in the PRVD, only the bean wettable powder on-farm hand mixing treatment scenario was updated using the new dermal absorption value. Data to assess the treatment of small seeded vegetable seeds was proposed as Section 12 data requirement in PRVD2016-13. However, since the publication of the PRVD it has been determined that treatment of small-seeded vegetables is not occurring in Canada and therefore, this use will be cancelled. In turn, as only planting of imported treated seeds will be permitted, the Section 12 data is no longer be required.

Flower Bulb Treatment and Handling

For commercial bulb treatment and handling of treated bulbs, no comments or data were submitted during the PRVD comment period. However, information about commercial flower bulb treatment in Canada was available. Although treatment in Canada is reported to be highly automated, worker exposure is still expected. Exposure to workers mixing the dip solution was calculated using mixing/loading data from the Pesticide Handlers Exposure Database and the Agricultural Handlers Exposure Task Force. For workers dipping bulbs, a published study that monitored exposure to the hands of workers for both manual and mechanical dip treatment (that is, using a forklift to dip crates of bulbs) was used. Limitations were identified in this study, such as that only hand exposure was monitored for a limited number of workers. However, the study was considered to be sufficiently reliable to inform the risk assessment. The results of the study indicated that worker exposure would be relatively low for mechanical dipping. Modelled exposure estimates conducted by the Dutch Board for the Authorisation of Plant Protection Products and Biocides also indicated that worker exposure would be low when handling bulbs while wearing chemical-resistant gloves. The PMRA considered the use information and the results from the studies in a qualitative manner taking into consideration the limitations of the studies.

To mitigate potential exposure, additional PPE will be required for workers preparing dipping solutions, contacting treated bulbs and contaminated surfaces, and conducting cleaning activities, as outlined in Appendix IV Tables 9–11 summarizes the risk assessment for bulb treatment scenarios.

Postapplication Exposure in High Density Apple and Pear Orchards

For workers performing postapplication activities in high density apple and pear orchards, potential exposure was estimated based on the worker exposure study submitted during the PRVD comment period.

Dislodgeable Foliar Residue (DFR)

Chemical-specific DFR studies and default values described in PRVD2016-13 were used in the postapplication risk assessment for agricultural field crops. Although new orchard DFR studies conducted in Europe were submitted during the PRVD comment period, they were not used in the revised risk assessment, as the previously available DFR studies conducted in Northern United States were considered to be more representative of Canadian growing regions. As discussed in the PRVD, no chemical-specific data were available for greenhouse ornamental crops; therefore, the current default values were used (peak DFR of 25% of the application rate, with a 2.3% dissipation rate per day).

Table 1 Revised MLA Short-Term Exposure and Risk Assessment for Groundboom Application

Applicator	Form	Crop	Rate (kg ai/ha)	ATPD[a] (ha)	Exposure (ug/kg bw/day)		MOE		
					Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[bd] (T=300)
Open M/L, Open Cab, Single Layer, CR Gloves (MLA), Respirator (MLA)									
All scenarios had MOEs that were greater than the target MOE at this level of mitigation, unless otherwise indicated below.									
Custom	WG	Potato	3	360	62.8	31.7	319	44	212
Farmer	WP	Soil treatment-lawn seed beds	10.6	50	60.4	38.3	331	37	202
Farmer	WP	Soil treatment-bean	10.6	25	30.2	19.2	662	73	405
Farmer	WP	Soil treatment-ornamentals	11.25	20	25.7	16.3	779	86	477
Farmer	WP	Soil treatment-ornamentals +celery	10.6	20	24.2	15.3	827	91	506
Open M/L, Closed Cab, Single Layer, CR Gloves (M/L), Respirator (M/L),[e] CR gloves not required in closed cab									
Custom	WG	Potato	3	360	33.7	30.2	593	46	313
Farmer	WP	Soil treatment-	10.6	50	46.2	37.6	433	37	239

Applicator	Form	Crop	Rate (kg ai/ha)	ATPD[a] (ha)	Exposure (ug/kg bw/day)		MOE		
					Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[bd] (T=300)
		lawn seed beds							
Farmer	WP	Soil treatment-bean	10.6	25	23.1	18.8	866	74	477
Farmer	WP	Soil treatment-ornamentals	11.25	20	19.6	16.0	1020	88	562
Farmer	WP	Soil treatment-ornamentals + celery	10.6	20	18.5	15.1	1080	93	597
Closed M/L, Open Cab, Single Layer, CR Gloves (MLA), Respirator (MLA)									
Farmer	WSP[f]	Soil treatment-lawn seed beds	10.6	50	26.7	11.2	750	124	527
Farmer	WSP[f]	Soil treatment-bean	10.6	25	13.3	5.62	1500	249	1060
Farmer	WSP[f]	Soil treatment-ornamentals	11.25	20	11.3	4.78	1770	293	1240
Farmer	WSP[f]	Soil treatment-ornamentals+celery	10.6	20	10.7	4.50	1870	311	1320
Closed M/L, Closed Cab, Single Layer, CR Gloves (M/L), Respirator (M/L),[e] CR gloves not required in closed cab									
Custom	WSP[f]	Potato	3	360	25.3	1.05	791	1330	759

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

Form = Formulation, ATPD = Area Treated Per Day, MOE = Margin of Exposure, T = target MOE; MLA = Mixer/Loader/Applicator, M/L = mix/load; A = applicator; CR = Chemical-resistant, LQ=Liquid, WG = water dispersible granule and dry flowable formulations, WP=Wettable Powder, WSP=water soluble package; Single layer = long sleeved shirt, long pants

[a] ATPD values are refined where possible.

[b] Based on a NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300. A dermal absorption value of 1% for mixers/loaders and 15% for applicators was incorporated into the dermal route of exposure.

[c] Based on a NOAEL of 1.4 mg/kg bw/day from a rat inhalation toxicity 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.

[f] Wettable powder and/or water dispersable granule and/or dry flowable in water soluble package.

Table 2 Revised MLA Intermediate-Term Exposure and Risk Assessment for Groundboom Application

Application Method	Form	Crop	Rate (kg/ ha)	ATPD[a] (ha)	Exposure (ug/kg bw/day)		MOE (Target MOE =300)		
					Dermal	Dermal[b] (T=300)	Dermal [b]	Inhalation [c]	Combine
Open M/L, Open Cab, Single Layer, CR Gloves (MLA), Respirator (MLA)									
Custom	LQ	Strawberry	2.8	26	4.00	0.21	5000	190	4750
Custom	WG	Blackberry, blueberry, loganberry	1.8	26	2.72	1.37	7350	29	4880
Open M/L, Closed Cab, Single Layer, CR Gloves (M/L), Respirator (M/L),[e] CR gloves not required in closed cab									
Custom	LQ	Strawberry	2.8	26	2.04	0.11	9800	357	9290
Custom	WG	Raspberry	2	26	1.62	1.46	12300	27	6490
Custom	WG	Strawberry	2.8	26	2.27	2.04	8800	20	4640
Custom	WP	Blackberry, blueberry, loganberry	1.8	26	4.08	3.32	4900	12	2700
Custom	WP	Raspberry	2	26	4.53	3.69	4410	11	2430
Closed M/L, Closed Cab, Single Layer, CR Gloves (M/L), Respirator (M/L),[e] CR gloves not required in closed cab									
Custom	WSP [f]	Blackberry, blueberry, loganberry	1.8	26	1.10	0.05	18200	877	17500
Custom	WSP [f]	Raspberry	2	26	1.22	0.05	16400	789	15800
Custom	WSP [f]	Strawberry	2.8	26	1.70	0.07	11700	564	11300

Shaded cells indicate MOEs that are less than the target MOE.
Form = Formulation, ATPD = Area Treated Per Day, MOE = Margin of Exposure, MLA = Mixer/Loader/Applicator, M/L = mix/load; A = applicator; CR = Chemical-resistant, LQ=Liquid, WG = water dispersible granule and dry flowable formulations, WP=Wettable Powder, WSP=water soluble package; Single layer = long sleeved shirt, long pants

[a] ATPD values are refined where possible.

[b] Based on a NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300. A dermal absorption value of 1% for mixers/loaders and 15% for applicators was incorporated into the dermal route of exposure.

[c] Based on a NOAEL of 0.04 mg/kg bw/day from a rat inhalation toxicity study and an intermediate-term target MOE of 300.

[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.

[f] Wettable powder and/or water dispersable granule and/or dry flowable in water soluble package.

Table 3 Revised MLA Short-Term Exposure and Risk Assessment for Airblast Application

Form	Crops	Rate (kg ai/ha)	ATPD[a] (ha)	Exposure (ug/kg bw/day)		MOE		
				Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[bd] (T=300)
Open M/L, Open Cab, Single Layer, CR Gloves (MLA), Respirator (MLA)								
LQ	Apple	2.4	20	340	0.58	59	2400	59
LQ	Apricot	3.2	2	45.3	0.08	442	18000	441
LQ	Cherry	3.2	11	249	0.43	80	3280	80
LQ	Grape	2.4	20	340	0.58	59	2400	59
LQ	Peach	3.2	20	453	0.78	44	1800	44
LQ	Plum, prune	3.2	3	67.9	0.12	294	12000	294
WG	Apple	2.4	20	340	1.85	59	756	59
WG	Apricot	3.2	2	45.3	0.25	442	5670	439
WG	Blackberry, loganberry, blueberry	1.8	20	255	1.39	78	1010	78
WG	Cherry	3.2	11	249	1.36	80	1030	80
WG	Grape	2.4	20	340	1.85	59	756	59
WG	Nectarine	3.2	20	453	2.47	44	567	44
WG	Peach	3.2	20	453	2.47	44	567	44
WG	Pear	2.4	5	84.9	0.46	235	3020	234
WG	Plum, prune	3.2	3	67.9	0.37	294	3780	293
WG	Raspberry	2	5	70.8	0.39	283	3630	281
WP	Apple	2.4	20	342	3.92	58	357	58
WP	Apricot	3.2	2	45.7	0.52	438	2680	433
WP	Blackberry, loganberry, blueberry	1.8	20	257	2.94	78	477	77
WP	Cherry	3.2	11	251	2.87	80	487	79
WP	Grape	2.4	20	342	3.92	58	357	58
WP	Peach	3.2	20	457	5.22	44	268	43
WP	Pear	2.4	5	85.6	0.98	234	1430	231
WP	Plum, prune	3.2	3	68.5	0.78	292	1790	289
WP	Raspberry	2	5	71.3	0.82	280	1720	277
Open M/L, Open Cab, Single Layer, CR Gloves (MLA), Respirator (MLA), CR Hat (A)								
MOEs were greater than the target MOE for all crops and formulations at this level of mitigation								

Shaded cells indicate MOEs that are less than the target MOE.
Form = Formulation, ATPD = Area Treated Per Day, MOE = Margin of Exposure, MLA = Mixer/Loader/Applicator, CR = Chemical-resistant, LQ=Liquid, WG = water dispersible granule and dry flowable formulations,, WP=Wettable Powder, WSP=water soluble package, Single layer = long sleeved shirt, long pants

[a] ATPD values are refined where possible.

[b] Based on a NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300. A dermal absorption value of 1% for mixers/loaders and 15% for applicators was incorporated into the dermal route of exposure.

[c] Based on a NOAEL of 1.4 mg/kg bw/day from a rat inhalation toxicity 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.

Table 4 Revised M/L/A Short-Term Exposure and Risk Assessment for Aerial Application

Application Method	Form	Crop	Rate (kg/ha)	ATPD[a] (ha)	Exposure (ug/kg bw/day)		MOE		
					Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[b][d] (T=300)
Single Layer,[e] CR gloves not required in cockpits.									
All applicator scenarios had MOEs that were greater than the target MOE at this level of mitigation									
Open M/L Single Layer, CR Gloves (ML), Respirator (ML)									
All mixer/loader scenarios had MOEs that were greater than the target MOE at this level of mitigation, unless otherwise indicated below.									
Mixer/Loader	WG	Apple, pear	2.4	280	7.07	18.3	2830	76	788
Mixer/Loader	WG	Apricot, cherry, peach, plum, prune	3.2	280	9.42	24.4	2120	57	591
Mixer/Loader	WG	Blueberry	1.8	340	6.44	16.7	3110	84	865
Mixer/Loader	WG	Cucumber, field tomato	3.4	200	7.15	18.5	2800	76	779
Mixer/Loader	WG	Potato	3	400	12.6	32.7	1580	43	441
Mixer/Loader	WG	Strawberry	2.8	340	10.0	25.9	2000	54	556
Closed M/L Single Layer, CR Gloves (ML), Respirator (ML)									
Mixer/Loader	WSP[f]	Apple, pear-	2.4	280	1.82	1.51	11000	926	6010
Mixer/Loader	WSP[f]	Apricot, cherry, peach, plum, prune	3.2	280	2.42	2.02	8260	694	4510
Mixer/Loader	WSP[f]	Blueberry	1.8	340	1.65	1.38	12100	1020	6600
Mixer/Loader	WSP[f]	Cucumber, field tomato	3.4	200	1.84	1.53	10900	915	5940
Mixer/Loader	WSP[f]	Potato	3	400	3.24	2.70	6170	519	3370
Mixer/Loader	WSP[f]	Strawberry	2.8	340	2.57	2.14	7780	654	4240

Shaded cells indicate MOEs that are less than the target MOE.
Form = Formulation, ATPD = Area Treated Per Day, MOE = Margin of Exposure, MLA = Mixer/Loader/Applicator, M/L = mix/load; A = applicator; CR = Chemical-resistant, LQ=Liquid, WG = water

dispersible granule and dry flowable formulations, WSP=water soluble package; Single layer = long sleeved shirt, long pants

[a] ATPD values are refined where possible.

[b] Based on a NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300. A dermal absorption value of 1% for mixers/loaders and 15% for applicators was incorporated into the dermal route of exposure.

[c] Based on a NOAEL of 0.04 mg/kg bw/day from a rat inhalation toxicity study and an intermediate-term target MOE of 300.

[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 for applicators as they are in cockpits.

[f] Water dispersable granule and/or dry flowable in water soluble package.

Table 5 Revised MLA Short-Term Exposure and Risk Assessment for Handheld Application

Application Method	Form	Crop	Rate (g ai/L)	ATPD[a] (L)	Exposure (ug/kg bw/day)		MOE		
					Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[bd] (T=300)
Open M/L, Single Layer, CR Gloves (MLA), Respirator (MLA)									
All handheld scenarios had MOEs that were greater than the target MOE at this level of mitigation, unless otherwise indicated below.									
MPHG	WG	Field Soil treatment	2.26	3800	89.9	1.85	223	756	218
MPHG	WG	Field Soil treatment	1.7	3800	67.7	1.40	295	1000	289
MPHG	WG	GH Soil treatment	1.7	3800	67.7	1.40	295	1000	289
MPHG	WP	Field Soil treatment	2.25	3800	90.1	2.21	222	632	217
MPHG	WP	Field Soil treatment	2.12	3800	84.9	2.09	236	671	230
MPHG	WP	GH Soil treatment	2.12	3800	84.9	2.09	236	671	230
Open M/L, Single Layer, Coveralls (A), CR Gloves (MLA), Respirator (MLA)									
MPHG	WG	Field Soil treatment	1.7	3800	29.8	1.40	671	1000	641
MPHG	WG	GH Soil treatment	1.7	3800	29.8	1.40	671	1000	641
MPHG	WG	Field Soil treatment	2.26	3800	29.5	1.85	506	756	483
MPHG	WP	Field Soil	2.26	3800	39.3	1.61	501	632	475

Application Method	Form	Crop	Rate (g ai/L)	ATPD[a] (L)	Exposure (ug/kg bw/day)		MOE		
					Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[bd] (T=300)
		treatment							
MPHG	WP	Field Soil treatment	2.12	3800	37.1	1.52	532	671	504
MPHG	WP	GH Soil treatment	2.12	3800	37.1	1.52	532	671	504

Shaded cells indicate MOEs that are less than the target MOE.
Form = Formulation, ATPD = Area Treated Per Day, MOE = Margin of Exposure, MLA = Mixer/Loader/Applicator, CR = Chemical-resistant, WG = water dispersible granule and dry flowable formulations, WP=Wettable Powder, Single layer = long sleeved shirt, long pants
[a] Default ATPD values used.
[b] Based on a NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300. A dermal absorption value of 15% was incorporated into the dermal route of exposure.
[c] Based on a NOAEL of 1.4 mg/kg bw/day from a rat inhalation toxicity 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.

Table 6 Revised MLA Intermediate-Term Exposure and Risk Assessment for Handheld Application

Application Method	Form	Crop	Rate (g a.i./L)	ATPD[a] (L)	Exposure (ug/kg bw/day)		MOE		
					Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[bd] (T=300)
Open M/L, Single Layer, CR Gloves (MLA), Respirator (MLA)									
All handheld scenarios had MOEs that were greater than the target MOE at this level of mitigation, unless otherwise indicated below.									
MPHG	WG	GH Flowers	1.2	3800	47.8	0.98	418	41	410
MPHG	WG	GH Soil treatment	1.7	3800	67.7	1.40	295	29	289
MPHG	WG	GH-tobacco seedling	0.624	3800	24.9	0.51	805	78	788
MPHG	WG	GH-Rhubarb in forcing sheds	1.62	3800	64.5	1.33	310	30	304
MPHG	WP	GH Flowers	1.2	3800	48.1	1.18	416	34	406
MPHG	WP	GH Soil treatment	2.12	3800	84.9	2.09	236	19	230
MPHG	WP	GH-Rhubarb in	1.62	3800	64.9	1.59	308	25	301

Application Method	Form	Crop	Rate (g a.i./L)	ATPD[a] (L)	Exposure (ug/kg bw/day)		MOE		
					Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[bd] (T=300)
		forcing sheds							
MPHW	WP	GH Flowers	1.2	150	6.66	0.32	3000	125	2860
MPHW	WP	GH Soil treatment	2.12	150	11.8	0.57	1700	71	1620
MPHW	WP	GH-Rhubarb in forcing sheds	1.62	150	9.00	0.43	2220	93	2120
Open M/L Coveralls over Single Layer, CR Gloves (MLA), Respirator (MLA)									
MPHG	WG	GH Flowers	1.2	3800	21.0	0.98	951	41	908
MPHG	WG	GH Soil treatment	1.7	3800	29.8	1.40	671	29	641
MPHG	WG	GH-Rhubarb in forcing sheds	1.62	3800	28.4	1.33	704	30	673
MPHG	WP	GH Flowers	1.2	3800	21.3	1.18	939	34	890
MPHG	WP	GH-Rhubarb in forcing sheds	1.62	3800	28.7	1.59	696	25	659
Closed M/L, Single Layer, CR Gloves (MLA), Respirator (MLA)									
Backpack	WSP[e]	GH Flowers	1.2	150	1.84	0.01	10900	2860	10800
Backpack	WSP[e]	GH Soil treatment	2.12	150	3.25	0.02	6160	1620	6110
MPHG	WSP[e]	GH-tobacco seedling	0.624	3800	24.8	0.45	805	89	791
MPHW	WSP[e]	GH Flowers	1.2	150	0.32	0.01	62800	3930	60900
MPHW	WSP[e]	GH Soil treatment	2.12	150	0.56	0.02	35600	2230	34500
Closed M/L, Coveralls over Single Layer (A), CR Gloves (MLA), Respirator (A)									
MPHG	WSP[e]	GH Flowers	1.2	3800	21.0	0.86	953	46	915
MPHG	WSP[e]	GH	1.2	3800	21.0	0.86	953	46	915

Application Method	Form	Crop	Rate (g a.i./L)	ATPD[a] (L)	Exposure (ug/kg bw/day)		MOE		
					Dermal	Inhalation	Dermal[b] (T=300)	Inhalation[c] (T=100)	Combined[bd] (T=300)
		Flowers							
MPHG	WSP[e]	GH Soil treatment	2.12	3800	37.1	1.52	539	26	518
MPHG	WSP[e]	GH Soil treatment	1.7	3800	29.7	1.22	673	33	646
MPHG	WSP[e]	GH-Rhubarb force sheds	1.62	3800	28.3	1.16	706	34	678
MPHG	WSP[e]	GH-Rhubarb in forcing sheds	1.62	3800	28.3	1.16	706	34	678

Shaded cells indicate MOEs that are less than the target MOE.
Form = Formulation, ATPD = Area Treated Per Day, MOE = Margin of Exposure, MLA = Mixer/Loader/Applicator, CR = Chemical-resistant, LQ=Liquid, WG = water dispersible granule and dry flowable formulations,, WP=Wettable Powder, WSP = water soluble package, Single layer = long sleeved shirt, long pants
[a] Default ATPD values used.
[b] Based on a NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300. A dermal absorption value of 15% was incorporated into the dermal route of exposure.
[c] Based on a NOAEL of 0.04 mg/kg bw/day from a rat inhalation toxicity study and an intermediate-term target MOE of 300.
[d] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure), as both the dermal and inhalation exposure could contribute to the oral endpoint.
[e]Wettable powder and/or water dispersable granule and/or dry flowable in water soluble package.

Table 7 Summary of Amount Handled per Day

Application Equipment	Proposed PPE	Amount Handled per Day Threshold[a]	Crop where MOE < Target MOE at proposed PPE	Additional Mitigation to Reach Target MOE	Outcome	Additional Mitigation
Wettable Powder						
Groundboom	Open M/L, Open cab, wearing baseline PPE, respirator	194 kg a.i./day	Soil Treatment: lawn seedbed, beans, ornamentals	Requires WSP	MOEs met with higher mitigation	
Manually-Pressurized Handwand	Open M/L, wearing baseline PPE, CR gloves, respirator	0.07 kg a.i./day (intermediate-term)	GH: soil treatment, flowers, rhubarb in forcing sheds	Requires WSP	MOEs met with higher mitigation	
Mechanically-Pressurized Handgun	Open M/L, wearing baseline PPE, CR gloves,	6.2 kg a.i./day (short-term) 0.51 kg a.i./day (inter-term)	Outdoor crops (short-term)	Requires coveralls and WSP	MOEs met with higher mitigation	
			GH crops	Required	MOEs **not**	Do not

	respirator		(intermediate-term)	coveralls and WSP	met with higher mitigation.	handle more than 0.71 kg a.i./day
Water Dispersible Granule and Dry Flowables						
Groundboom	Open M/L, Open cab, wearing baseline PPE, respirator	477 kg a.i./day	Potato (custom)	Requires WSP and closed cab	MOEs met with higher mitigation	
Aerial- M/L	Open M/L, wearing baseline PPE, CR gloves	514 kg a.i./day	Apricot, cherry, peach, plum, prune, cucumber, field tomato, potato	Requires WSP	MOEs met with higher mitigation	
Mechanically-Pressurized Handgun	Open M/L, wearing baseline PPE, CR gloves, respirator	6.2 kg a.i./day (short-term) 0.62 kg a.i./day (intermediate-term)	Outdoor crops (short-term)	Requires coveralls	MOEs met with higher mitigation	
			GH crops (intermediate-term)	Required coveralls and WSP	MOEs **not** met with higher mitigation.	Do not handle more than 0.71 kg a.i./day

M/L = mix/load; WSP = water soluble package; baseline PPE = long sleeved shirt, long pants; PPE = personal protective equipment; CR = chemical-resistant; GH = greenhouse

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

Table 8 Revised 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, CR coveralls over single layer, CR gloves								
Beans	WP (dust)[h]	Mix/load, plant	93.6	8300	361	13	N/A	121

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.

[c] Based on an oral NOAEL of 20 mg/kg bw/day from a rabbit development toxicity study and dermal absorption of 15%.

[d] Based on a NOAEL of 1.4 mg/kg bw/day from a rat inhalation toxicity study and target MOE of 100.

[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% for a filtering facepiece respirator (dust mask) was used.

[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 9 Mixer/Loader Exposure and Risk Assessment for Bulb Treatment

Form	Max Rate	L/day[a]	MOE		
			Dermal[b] Target = 300	Inhalation (ST)[c] Target = 100	Combined[bd] Target = 300
				Resp	Resp
Open mixing/loading wearing baseline PPE, respirator, chemical-resistant gloves					
WP	7.6 g ai/L	5000	6930	524	3600
WG			43,800	1350	13,400

Form =formulation, max = maximum

[a] Value assumed by the Netherlands for this scenario.

[b] Based on a NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300. The dermal route incorporates a1% dermal absorption value.

[c] Based on a NOAEL of 1.4 mg/kg bw/day from a rat inhalation toxicity 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.

Table 10 Exposure and Risk Assessment for Bulb Treatment and Handling

Activity	Input		Dermal Exposure (mg/kg bw/day)	Dermal MOE[a] Target = 300
Bulb Treatment (Exposure Study-Hand only data) [b]				
Manual Dip Treatment (no gloves)[c]	67.8 mg a.i. (max)[d]		127[e]	157
Drive-in Dip Treatment (no gloves)[f]	8.4 mg a.i. (max)[d]		15.8 [e]	1270
Handling Treated Bulbs (Netherlands Model- Hand only data)				
Contacting treated bulbs and equipment (gloves)	3.24 mL dipping fluid/working day[g]	Captan Dipping Fluid concentration = 7.6 g a.i./L[h]	0.0462[i]	433

Shaded cells indicate where MOEs are less than the target MOE

N/A = not applicable

[a] Where MOE = NOAEL/exposure. Based on a NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300.

[b] Only hand exposure was monitored in the study. This value likely underestimates exposure for the entire body. Maximum values from the study were used.

[c] Baskets containing about 35 kg of bulbs were dipped into a 200 L dipping bath.

[d] Maximum exposure value reported in study was used. Exposure was measured for at least 5 dip cycles.

[e] Exposure = dermal exposure from exposure study × %DA (15%))/80 kg bw.

[f] Cubic cases containing as much as 550 kg of bulbs were dipped into a 2200 L dipping bath.

[g] Value for handling treated wet bulbs from Netherland exposure model (Dutch Board for the Authorisation of Plant Protection Products and Biocides. 2017).

[h] Maximum concentration of captan dip solution from Canadian labels.

[i] Exposure = 3.24 mL dipping fluid/working day × dipping fluid concentration (g/L = mg/mL) × %DA (15%))/80 kg bw.

Table 11 Combined Mixing and Treating/Handling Exposure for Bulb Dip

Scenario	Dermal MOE		Combined MOE[c] (Target = 300)
	Mixing Dip Solution[a]	Treating/Handling Bulbs[b]	
Drive-in Dip Treatment	6930	1270	1070
Netherlands Dipping Model		433	410

[a] Lowest MOE from Appendix IV Table 9 for the wettable powder formulation.
[b] Values from Appendix IV Table 10.
[c] MOEs combined using the following equation: Combined MOE = $1/(1/MOE_{mixing/loading})+(1/MOE_{treating/handling\ bulbs})$

Table 12 Summary of the Revised Postapplication Exposure and Risk Assessment

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI[c] (days)
USC 5/6: Greenhouse Crops					
Tobacco Seedlings (1 application)					
Transplanting	230	12.48 kg a.i./ha	WG	186	21
Cut Flowers (1 application)					
Cut flowers: hand harvesting, disbudding, hand pruning (tall height)	4000	1.2 kg a.i./ha	WG/WP	111	43
		1 kg a.i./ha		133	35
Irrigation (non-handset), mechanical weeding	No TC	REI not required [d]			
Potted Flowers (6 applications, 7 days apart)					
Potted plants, all activities	230	1.2 kg a.i./ha	WG/WP	466	12 hours
		1 kg a.i./ha		559	
Rhubarb in Forcing Sheds (1 application)					
Hand harvesting	1100	0.162 kg a.i./1000L (1000 L/ha)	WG/WP	299	12 hours
Transplanting	230			1430	
Scouting	210			1570	
Hand weeding	70			4700	
Rhubarb in Forcing Sheds (6 applications, 7 days apart)					
Hand harvesting	1100	0.162 kg a.i./1000L (150 L/ha)	WG/WP	333	12 hours
Transplanting	230			1590	
Scouting	210			1750	
Hand weeding	70			5230	
USC 13/14: Food and feed Crops					
High Density Fruit Trees[j] Orchards (apples and pears)- 10 applications, 7 days apart					
Hand Thinning Fruit, hand harvesting	Exposure Study[g]	2.4 kg a.i./ha[e]	All	124	15
		1.5 kg a.i./ha[h] (apple only)	All	198	7
Hand pruning, training	Exposure	2.4 kg a.i./ha[e]	All	205	5

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI[c] (days)
	Study[g]	1.5 kg a.i./ha[h] (apple only)	All	327	12 hours
Scouting	Exposure Study[g]	2.4 kg a.i./ha[e]	All	MOE at 2 days = 246[f]	2
		1.5 kg a.i./ha[h] (apple only)	All	327	12 hours
Hand weeding, propping, bird control, orchard maintenance	100[i]	2.4 kg a.i./ha[e]	All	1050	12 hours
		1.5 kg a.i./ha[h] (apple only)	All	1680	12 hours
Mechanical weeding, mechanical harvesting, irrigation (non-handset), frost control, spreading bins, fertilizing	No TC	REI not required [d]			
Standard Density[j] Fruit Trees Orchards (Apples, Peaches, Plums, Prunes, Pear, Nectarines, Apricots, Cherries)- 1 application					
Hand thinning fruit	3000	3.2 kg a.i./ha[e]	All	56	29
		2.4 kg a.i./ha[e]	All	74	24
		1.5 kg a.i./ha[h] (apple only)	All	119	16
Hand harvesting	1400	3.2 kg a.i./ha[e]	All	119	15
		2.4 kg a.i./ha[e]	All	159	10
		1.5 kg a.i./ha[h] (apple only)	All	254	2
Hand pruning, scouting, training	580	3.2 kg a.i./ha[e]	All	287	1
		2.4 kg a.i./ha[e]	All	383	12 hours
		1.5 kg a.i./ha[h] (apple only)	All	613	12 hours
Hand weeding, propping, bird control, orchard maintenance	100	3.2 kg a.i./ha[e]	All	1670	12 hours
		2.4 kg a.i./ha[e]	All	2220	12 hours
		1.5 kg a.i./ha[h] (apple only)	All	3560	12 hours

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI[c] (days)
Mechanical weeding, mechanical harvesting, irrigation (non-handset), frost control, spreading bins, fertilizing	No TC	REI not required[d]			
Standard Density[j] Fruit Trees Orchard (Apples, Peaches, Plums, Prunes, Pear, Nectarines, Apricots, Cherries)- 2 applications					
Hand Thinning Fruit	3000	3.2 kg a.i./ha[e]	All	33	37
		2.4 kg a.i./ha[e]	All	44	32
		1.5 kg a.i./ha[h] (apple only)	All	71	24
Hand harvesting	1400	3.2 kg a.i./ha[e]	All	71	24
		2.4 kg a.i./ha[e]	All	95	19
		1.5 kg a.i./ha[h] (apple only)	All	152	11
Hand pruning, training	580	3.2 kg a.i./ha[e]	All	172	9
		2.4 kg a.i./ha[e]	All	230	4
		1.5 kg a.i./ha[h] (apple only)	All	368	12 hours
Scouting	580	3.2 kg a.i./ha[e]	All	MOE at 4 days = 217[k]	4 days
		2.4 kg a.i./ha[e]	All	MOE at 2 days = 258[k]	2 days
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	1330	12 hours
		1.5 kg a.i./ha[h] (apple only)	All	2130	12 hours
Grapes (2 application before BBCH 13)					
All activities	Postapplication exposure is expected to be low as foliage is minimal and residues on foliage will be quickly diluted as the leaves grow				12 hours
Grapes (1 application after BBCH 13)					
Turning, girdling (table grapes)	19,300	2.4 kg a.i./ha[e]	All	18	78
		1.6 kg a.i./ha[h]	All	27	67
Hand harvesting, training, tying, leaf pulling	8500	2.4 kg a.i./ha[e]	All	41	55
		1.6 kg a.i./ha[h]	All	61	44

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI[c] (days)
Scouting, hand weeding, hand pruning, propagating, bird control, trellis repair	640	2.4 kg a.i./ha[e]	All	543	12 hours
		1.6 kg a.i./ha[h]	All	814	12 hours
Transplanting	230	2.4 kg a.i./ha[e]	All	1510	12 hours
		1.6 kg a.i./ha[h]	All	2260	12 hours
Irrigation (non-handset), mechanical harvesting, mechanical weeding, burn down, ditching, mechanical pruning	No TC	REI not required [d]			
Cucumber (3 applications, 7 days apart)					
Handset irrigation	1750	3.4 kg a.i./ha	WG/WP	64	10
		2.8 kg a.i./ha[e]		78	9
		2.6 kg a.i./ha[l]		84	9
Hand harvesting, training, mechanically-assisted harvesting	550	3.4 kg a.i./ha		204	3
		2.8 kg a.i./ha[l]		247	1
Training	550	2.6 kg a.i./ha[l]		266	1
Transplanting	230	2.8 kg a.i./ha[e]		592	12 hours
		2.6 kg a.i./ha[l]		637	12 hours
Scouting, hand weeding	90	3.4 kg a.i./ha		1250	12 hours
		2.8 kg a.i./ha[e]		1510	12 hours
		2.6 kg a.i./ha[l]		1630	12 hours
Irrigation (non-hand set), mechanical weeding	No TC	REI not required [d]			
Potato (3 applications, 7 days apart)					
Handset irrigation	1750	3 kg a.i./ha	WG	73	7
Roguing	1100			115	6
Scouting	210			605	12 hours
Hand weeding	70			1810	12 hours
Irrigation (non-handset), mechanical weeding, mechanical harvesting	No TC	REI not required [d]			
Pumpkin, Squash (3 applications, 7 days apart)					
Handset irrigation	1750	3.375 kg a.i./ha	WP	65	10

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI[c] (days)
		2.5 kg a.i./ha[l]		87	8
Hand harvesting, turning (pumpkin), training, mechanically assisted harvesting	550	3.375 kg a.i./ha		205	3
Turning (pumpkin), training	550	2.5 kg a.i./ha[l]		277	1
Transplanting	230	2.5 kg a.i./ha[l]		663	12 hours
Scouting, thinning fruit, hand weeding	90	3.75 kg a.i./ha		1250	12 hours
		2.5 kg a.i./ha[l]		1690	12 hours
Mechanical weeding, irrigation (non-handset), fertilizing	No TC	REI not required [d]			
Field tomato (3 application, 7 days apart)					
Handset irrigation	1750	3.4 kg a.i./ha	WG/WP	64	10
		2.4 kg a.i./ha[e]		91	8
Hand harvesting, training, tying	1100	3.4 kg a.i./ha		102	7
		2.4 kg a.i./ha[e]		144	5
Transplanting	230	3.4 kg a.i./ha		487	12 hours
		2.4 kg a.i./ha[e]		690	12 hours
Scouting	210	3.4 kg a.i./ha		534	12 hours
		2.4 kg a.i./ha[e]		756	12 hours
Hand pruning, hand weeding	70	3.4 kg a.i./ha		1600	12 hours
		2.4 kg a.i./ha[e]		2270	12 hours
Irrigation (non-handset), mechanical weeding, mechanical harvesting	No TC	REI not required [d]			
USC 14: Food Crops					
Strawberry (6 applications, 7 days apart)					
Handline Irrigation	1750	2.8 kg a.i./ha[e]	All	75	9
Hand harvesting	1100		All	119	6
Transplanting	230		All	567	12 hours
Scouting	210		All	622	12 hours
Hand weeding, canopy management	70		All	1860	12 hours
Irrigation (non-hand set), mechanical weeding	No TC	REI not required [d]			

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI[c] (days)
Raspberry (6 applications, 7 days apart)					
Handset irrigation	1750	2 kg a.i./ha	WG/WP	104	7
Hand harvesting, tying/training (full foliage)	1400			131	6
Scouting, hand pruning, hand weeding, tying/training (minimum foliage)	640			286	12 hours
Transplanting	230			794	12 hours
Irrigation (non-hand set), mechanical weeding, mechanical harvesting, burn down, frost control	No TC	REI not required[d]			
High Bush Blueberry, Blackberry (6 applications, 7 days apart)					
Handset irrigation	1750	1.8 kg a.i./ha	WG/WP	116	6
Hand harvesting, tying/training (blackberry, full foliage)	1400			145	5
Scouting, hand pruning, hand weeding, tying/training (blackberry, minimum foliage), frost control (blueberry), bird control (blueberry)	640			317	12 hours
Transplanting	230			883	12 hours
Irrigation (non-handset, mechanical harvesting, mechanical weeding, burn down, frost control (blackberry)	No TC	REI not required[d]			
Loganberry (6 applications, 7 days apart)					
Handset irrigation	1750	1.8 kg a.i./ha	WG/WP	116	6
		1.1 kg a.i./ha		190	4
Hand harvesting, tying/training (full foliage)	1400	1.8 kg a.i./ha		145	5
		1.1 kg a.i./ha		237	2
Scouting, hand pruning, hand weeding, tying/training (minimum foliage)	640	1.8 kg a.i./ha		317	12 hours
		1.1 kg a.i./ha		519	12 hours
Transplanting	230	1.8 kg a.i./ha		883	12 hours
		1.1 kg a.i./ha		1440	12 hours
Irrigation (non-handset, mechanical harvesting, mechanical weeding, burn down	No TC	REI not required[d]			

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI[c] (days)
Low Bush Blueberry (6 applications, 7 days apart)					
Handset irrigation	1750	1.8 kg a.i./ha	WG/WP	116	6
Hand harvesting, scouting	1100			185	3
Transplanting	230			883	12 hours
Hand weeding	70			2900	12 hours
Irrigation (non-hand set), mechanical weeding, mechanical harvesting	No TC	REI not required [d]			
Ginseng (8 applications, 7 days apart)					
Handset Irrigation	1750	2.0 kg a.i./ha	WDG	347	7
Deflowering and hand harvesting berries	1100			303	3
Transplanting	230			793	12 hours
Scouting	210			869	12 hours
Hand weeding, canopy management	70			2610	12 hours
Irrigation (non-hand set), mechanical weeding, mechanical harvesting	No TC	REI not required [d]			
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	117	7[m]
		1 kg a.i./ha		140	5[m]
Handset irrigation	1750	1.2 kg a.i./ha		267	1
		1 kg a.i./ha		320	12 hours
Irrigation (non-handset), mechanical weeding	No TC	REI not required [d]			
Flowers (6 applications, 7 days apart)					
Handset irrigation	1750	1.2 kg a.i./ha	WG/WP	174	4
		1 kg a.i./ha		209	2
Potted plants, all activities (except handset irrigation)	230	1.2 kg a.i./ha		1330	12 hours
		1 kg a.i./ha		1590	12 hours

Activity	TC cm^2/hr[a]	Rate	Form	MOE[b] (Day 0) Target = 300	REI[c] (days)
USC 30: Turf					
Golf course and sod farm (1 application)					
Transplanting/planting, harvesting (sod farm only)	6700	4.8 kg a.i./ha	WG	415	12 hours
		4.75 kg a.i./ha	WP	419	12 hours
Mowing, watering, irrigation (sod farm only), [cup changing, irrigation repair, miscellaneous grooming- golf course only]	3500	4.8 kg a.i./ha	WG	794	12 hours
		4.75 kg a.i./ha	WP	802	12 hours
Aerating, fertilizing, hand pruning, scouting, mechanical weeding	1000	4.8 kg a.i./ha	WG	2780	12 hours
		4.75 kg a.i./ha	WP	2810	12 hours
Roll harvesting	No TC	REI not required [d]			

Shaded cells indicate where the MOE is unacceptable (i.e. not above or in range of the target MOE) or where the REI was not considered to be 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. PMRA Agricultural TC values, based on ARTF data.
[b] Based on an oral NOAEL of 20 mg/kg bw/day from a rabbit development toxicity study with a target of 300. Calculated value incorporates a dermal absorption of 15%.
[c] Day at which the calculated MOE reaches the target MOE. Where the calculated REI is less than the current label REI, it will be increased to match the current label REI. Shaded cells indicate MOEs that are not considered to be agronomically feasible.
[d] Dermal exposure is expected to be minimal due to limited contact with treated foliage, so an REI is not required.
[e] Registrant proposed rate.
[f] The MOE of 246 for scouting at the current label REI of 2 days was considered to sufficiently approach the target MOE of 300 and is not of concern based on the survey information received for scouting, as well as conservatisms in the risk assessment.
[g] Exposure is based on a worker exposure study that monitored workers hand thinning and pruning on Day 1 after 10 applications of captan, 7 days apart at 1.4-1.9 kg ai/ha. Hand thinning was considered to be an appropriate surrogate for hand harvesting. Pruning was considered to be an appropriate surrogate for training. Exposure was also extrapolated to the Canadian application rates using the lowest application rate in the study for each activity (1.4 for thinning and 1.5 for pruning).
[h] Rate based on information on the label. Similar to the average rate reported in the CHC survey.
[i] As there were no appropriate surrogates for low exposure activities in the worker exposure study, postapplication exposure was calculated using the TC for standard density orchards and the peak DFR following 8 applications. Peak DFR for 8 applications was considered to be similar to that following 10 applications, as the contribution from the early application is considered to be minimal, especially given by how much the MOE exceeds the target MOE.
[j] High density orchards are those orchards that have transitioned to high density trellis production architecture (for example, spindle or super spindle trees). Standard density orchards are those that have not transitioned to high density trellis production architecture (for example, dwarf, semi-dwarf and full sized trees).
[k] The MOE of 258 for scouting at the current label REI of 2 days after 2 applications was considered to sufficiently approach the target MOE of 300 and is not of concern based on the survey information received for scouting, as well as conservatisms in the risk assessment. The MOE of 217 for scouting at a 4 day REI after 2 applications was not considered to be sufficiently close enough to the target of 300, and risks may be of concern.
[l] Application rate for young plants.
[m] Cut flowers include a large variety of perennial and annual plants. For many varieties of cut flowers the seven day REI is not feasible as disbudding and hand pruning activities are required, while for other varieties these activities many not be required. If an application is needed closer to harvest than an alternative would be required. Retaining the use on outdoor cut flowers is of value to growers because few active ingredients are registered, and several are proposed for discontinuation.

References

A. Information Considered for the Toxicological Risk Assessment

A.1 List of Studies/Information Submitted by Registrant – Toxicology

PMRA Document Number	Reference
2679222	2015, Acute Oral Toxicology (Acute Toxic Class Method) in the Rat with Tetrahydrophthalimide, DACO: 4.2.1

B. Information Considered in the Occupational and Residential Assessment

B.1 List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2666836	2016, The Use of Human Toxicokinetic Studies to Define the Dermal Absorption Factor for Captan, DACO: 5.8
1163235	CAPTAN: BIOTRANSFORMATION STUDY IN THE RAT.(CTL/P/2951;S2/89;Y01716/012/001;UR0285;C2.7/10;REF.24)., DACO: 6.4
2793811	2017, Interim report of responses to follow-up questions about captan fungicide related to post-application occupational exposure, DACO: 5.14
2793812	2017, Results of survey of Provincial Minor Use Coordinators and Crop Specialists regarding post-application activities in fields and orchards treated with captan fungicide, DACO: 5.14
2666837	2015, Determination of worker re-entry exposure associated to typical crop maintenance activities in apple orchards following treatment with captan 80 wdg (800 g/kg captan) in Spain and the Netherlands, 2015, DACO: 5.6(A)
1913109	2009, Agicultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays, DACO: 5.3,5.4
2172938	2012, Agricultural Handler Exposure Scenario Monograph: Closed Cockpit Aerial Application of Liquid Sprays, DACO: 5.3,5.4
2572745	2015, Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid Formulations, DACO: 5.3,5.4
2572744	2015, Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading Dry Flowable Formulations, DACO: 5.3,5.4
2572746	2015, Agricultural Handler Exposure Scenario Monograph: Closed Cab Airblast Application of Liquid Sprays, DACO: 5.3,5.4
1130997	2005, Determination of Dermal and Inhalation Exposure to Reentry Workers During Maintenance Activities in Golf Courses, DACO: 5.4

B.2 Additional Published Information Considered

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Garrod, A.N.I, Martinex, M., Pearson, J., Proud, A. Rimmer, D.A. 1999. Exposure to Preservatives Used in the Industrial Pre-treatment of Timber. Ann. Occup Hyg. 43(8): 543-555.
Garrigou, A., Baldi I.,Le Frious P., Anselm R., Vallier M. 2011. Ergonomic contribution to chemical risks prevention: an ergotoxicological investigation of the effectiveness of coverall against plant pest risk in viticulture. 42: 321-330.
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B.3 Additional Unpublished Information Considered

PMRA Document Number	Reference
2674757	BC Blueberry Council. 2016. Comments on 'Proposed Re-evaluation Decision PRVD2016-13, Captan. July 18, 2016.
2674745	CHC. 2016. Response of the Canadian Horticulture Council to the Pest Management Regulatory Agency Consultation on the Proposed Re-evaluation Decision for Captan. PRVD2016-13. July 29, 2016.
2674746	CHC. 2016. Appendix to Response of the Canadian Horticulture Council to the Pest Management Regulatory Agency Consultation on the Proposed Re-evaluation Decision for Captan. PRVD2016-13. July 29, 2016.
2786601	2011, Berthet, 2011 - raw data - Toxicokinetics of captan and folpet biomarkers in orally exposed volunteers. Journal of Applied Toxicology, Volume 32, Pages 194 to 201, DACO: 5.8