Proposed Re-evaluation Decision PRVD2010-14

Myclobutanil

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Overview

Proposed Re-evaluation Decision for Myclobutanil

After a re-evaluation of myclobutanil, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing continued registration of myclobutanil products for sale and use in Canada.

An evaluation of available scientific information found that myclobutanil products have value in the food and crop industry and do not pose unacceptable risks to human health or the environment. As a condition of the continued registration, new risk reduction measures are proposed. Additional data are being requested.

The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment.

This proposal affects all end-use products containing myclobutanil registered in Canada. Once the final re-evaluation decision is made, registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for myclobutanil and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment. PMRA is soliciting information on the feasibility of the proposed mitigation measures, such as restricted-entry intervals.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessment of myclobutanil.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act* (http://laws.justice.gc.ca/en/P-9.01/92455.html)

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

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[2] The Act also requires that products have value[3] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the pesticides and pest management part of Health Canada's website at www.healthcanada.gc.ca/pmra.

Before making a re-evaluation decision on myclobutanil, the PMRA will consider all comments received from the public in response to this consultation document.[4] The PMRA will then publish a Re-evaluation Decision[5] on myclobutanil, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

What is Myclobutanil?

Myclobutanil is a systemic fungicide with protective and curative action. It is classified as a Resistance Management Group Number 3 (demethylation inhibitors) fungicide used to control a number of fungal diseases on a wide variety of plant species. The mode of action is by inhibition of fungal ergosterol biosynthesis (steroid demethylation inhibition) which is essential for cell wall formation. The registered uses of myclobutanil belong to the following use site categories:

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

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

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

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

greenhouse food crops, greenhouse non-food crops, terrestrial feed crops, terrestrial food crops, ornamentals outdoor and turf. It is applied by ground application equipment such as commercial air blast equipment and hand or pressurized sprayers by farm, orchard, greenhouse and nursery workers as well as professional applicators.

The wettable powder formulation of myclobutanil is no longer supported by the technical registrant, and as such, uses based on this formulation were not included in the risk assessment.

Health Considerations

Can Approved Uses of Myclobutanil Affect Human Health?

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

Potential exposure to myclobutanil may occur through diet (food and water) or when handling and applying the product, or through non-occupational exposure at golf courses and pick your own (PYO) operations.

When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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

An acute overexposure to myclobutanil can produce a variety of symptoms in animals and humans. Symptoms may include ataxia, abdominal breathing, prostration, convulsions, passiveness, salivation, scant droppings, and stained muzzle and anogenital areas. Local effects of an acute dermal exposure may include erythema, edema, and skin sensitization. Contact with the eye may cause vascularization of the cornea, corneal haziness and irritation to both the iris and conjunctiva. To prevent overexposure, label directions must be followed.
Additional toxic effects on the liver, testes, kidney, adrenal gland and other organs, as well as effects noted in pregnant females (increased abortions and reduced body weight or body weight gain) and in the fetuses (increased resorptions, reduced viability indices, increased skeletal variations, reduced litter size and reduced fetal weight), were observed in animals at very high doses only; therefore, they would not occur when myclobutanil products are used according to label directions. Based on the weight of evidence, myclobutanil is considered non-carcinogenic. A cancer risk assessment was not required.

Due to the skin sensitizing potential of myclobutanil and increased risk from greenhouse uses, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to myclobutanil. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

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

Dietary exposure to myclobutanil was estimated from residues in treated crops and drinking water for different subpopulations representing different ages, genders and reproductive status. Acute exposure estimates were determined for females 13-49 years old; chronic exposure estimates were determined for all subpopulations including infants and children.

The aggregate acute exposure to myclobutanil from food and drinking water represents 88% of the acute reference dose when using drinking water concentrations generated from water modelling; the aggregate chronic exposure represents 17% of the chronic reference dose for the general population and is in the range 13% -51% of the chronic reference dose for all subpopulations, the most exposed subpopulation being all infants less than 1 year old. Thus, acute and chronic dietary risks are below the level of concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk. MRLs are currently established on registered domestic and import agricultural uses and published in Health Canada's List of MRLs Regulated under the *Pest Control Products Act* on the Maximum Residue Limits for Pesticides webpage. No modification of the MRLs was proposed during the course of this re-evaluation.

Triazole metabolites

Dietary exposure to triazolyl-1-alanine (TA) and triazolyl-1-acetic acid (TAA) may occur from the use of myclobutanil on food commodities. Residues of TA in plant commodities are regulated in Canada not to exceed 2.0 ppm. These metabolites are common to all triazole fungicides, including myclobutanil. The cumulative risks from TA and TAA will be addressed in a separate document.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern.

There are currently no registered residential uses of myclobutanil, and therefore a risk assessment for this scenario was not required.

An assessment of the potential risk of exposure incurred by the public at "Pick-Your-Own (PYO)" operations or at public golf courses was conducted. A quantitative analysis was performed for these scenarios to ensure that there was no risk of concern for the public.

Aggregate exposure estimates were calculated to determine the risk of exposure for the public from all known potential sources: diet, drinking water and non-occupational exposure events such as fruit harvesting at PYO or golfing. The combined exposures resulted in margins of exposure (MOEs) greater than the target MOE and are not of concern.

Occupational Risks from Handling Myclobutanil

Occupational mixer/loader/applicator risks are not of concern.

Based on the precautions and directions for use on the current labels, and based on use information received from the registrant, risk estimates associated with mixing, loading and applying activities did meet current standards and are not of concern. However, in the interest of clarity and consistency, recommendations will include updating the current end use product label language requirements regarding personal protective Equipment.

Most occupational postapplication risks are not of concern provided proposed mitigation measures are followed.

Postapplication occupational risk assessments consider exposures to workers entering treated sites. Most occupational post-application risks are not of concern if proposed protective measures are followed. Based on the precautions and directions for use on the current product labels for registered use scenarios, postapplication risks to workers performing certain activities, such as thinning, pruning and harvesting of most crops, did not meet current standards and are of concern. However, when the proposed mitigation measures such as lengthened restricted-entry intervals (REIs) and reduced application frequencies are considered, the risks to post-application workers are not of concern.

Although the risk assessment for the agricultural scenarios identified risks of concern based on the current use pattern, the post-application risk estimates include a number of conservative (health protective) assumptions that may overestimate exposure, and therefore, risk. The application of the proposed mitigation measures reduces concern for risk from post-application activities, however, proposed protective measures to reduce worker exposure require consultation with user groups to determine their acceptability to the agricultural community. Additional data may refine the current risk assessment and would be required to reduce the proposed REIs.

Postapplication exposure is not of concern for golf course workers.

Post-application exposure is of concern for greenhouse uses. Appropriate dissipation data were not available for greenhouse uses. In the absence of suitable greenhouse dislodgeable foliar residue (DFR) studies, the default peak (day 0) DFR value of 20% of the application rate and the assumption of no dissipation were used in the occupational post-application risk assessment. As a result, agronomically feasible REIs could not be determined for greenhouse cucumbers, peppers, tomatoes, roses, gerbera, aster, chrysanthemums, hollyhock and phlox. A reduction in the number of applications from 6 to 5 for greenhouse poinsettias provided agronomically feasible REIs for this crop. Consultation with stakeholders and additional data are required to address the risk of concern identified by the PMRA for post-application exposure in greenhouses.

Environmental Considerations

What Happens When Myclobutanil is Introduced Into the Environment?

Myclobutanil poses a potential risk to birds, small wild mammals and aquatic organisms, therefore additional risk reduction measures need to be observed.

When myclobutanil is released into the environment some of it can be found in soil and surface water. Myclobutanil is very persistent, somewhat mobile in soil and very soluble in water and can therefore leach into groundwater and enter surface water in runoff. Myclobutanil residues are not expected in the air because of its low volatility. Myclobutanil has a low potential for bioaccumulation in biota.

Myclobutanil may pose a risk to birds and small wild mammals and to aquatic organisms. Small wild mammals and birds may be at chronic risk on the site of application due to consumption of contaminated food items, and the risk cannot be mitigated. In order to minimize the potential exposure to aquatic organisms, strips of land between the agricultural field and the aquatic areas (buffer zones) will be left unsprayed. The width of these buffer zones will be specified on the product label.

Value Considerations

What is the Value of Myclobutanil?

In Canada, myclobutanil is registered to control a number of fungal diseases including powdery mildew, rust and scab on several field and greenhouse vegetables, orchard, nursery and greenhouse grown ornamental crops. It is also registered for the control of a number of diseases on golf course turf grass. Important uses of myclobutanil include foliar treatments to control scab, powdery mildew and rust on apples, black rot and powdery mildew on grapes, and brown and summer patch, stem rust, grey snow mold and dollar spot on golf course turf grass. Myclobutanil is also important for the treatment of several foliar diseases, particularly powdery mildew, on ornamental crops which need good disease management for the production of high

quality plants. The ornamental industry typically lacks effective alternatives. Myclobutanil has been identified as having a medium risk for resistance development. It is important in resistance management of diseases for most uses.

Measures to Minimize Risk

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

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

Additional Key Risk-Reduction Measures

Human Health

- Consistent label requirements for personal protection equipment to protect workers mixing, loading and applying myclobutanil.
- Reduced application frequencies and increased restricted-entry intervals to protect workers entering treated sites.
- In keeping with the use information supplied by the registrant regarding golf course uses: the reduction of application rate to 0.73 kg a.i./ha; reduced application. frequencies; reduced application volumes and a restriction to ground-boom only.

Environment

- Changes to label statements, including precautionary statements and buffer zones for non-target aquatic habitats are required as a result of the environmental risk assessment.

- To reduce the potential for myclobutanil of run off to adjacent aquatic habitats and contamination of groundwater, advisory statements are required.

What Additional Scientific Information is Being Requested?

The human health risks and risks to the environment were found to be acceptable for certain uses of myclobutanil with the addition of mitigation measures. However, the following information is being requested to help refine the risk assessment.

Human Health

The following studies will be required under Section 12 of the *Pest Control Products Act* and are needed to support the continued registration of greenhouse uses, where agronomically feasible REIs could not be determined:

DACO 5.9: Greenhouse foliage - Dislodgeable/Transferable Residue data for crops and conditions that are reflective of the Canadian use pattern is needed to refine the estimation of available residue on Canadian crops treated with myclobutanil in greenhouses.

Environment

The following studies are required under Section 12 of the *Pest Control Products Act* and are needed to support the continued registration of myclobutanil:

DACO 9.4.5: Chronic toxicity to estuarine/marine invertebrates
DACO 9.5.2.4: Acute and chronic toxicity to estuarine/marine fish

Next Steps

Before making a re-evaluation decision on myclobutanil, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

Other Information

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

Science Evaluation

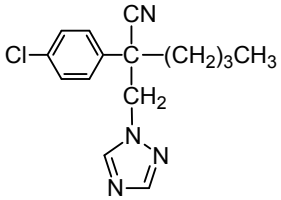
1.0 Introduction

Myclobutanil is a broad spectrum, Resistance Management Group 3 (demethylation inhibitors) fungicide, for which the mode of action is by disruption of the ergosterol biosynthesis pathway that is vital to fungal cell wall formation. It is a locally systemic fungicide with both eradicant and protectant properties.

Following the re-evaluation announcement for myclobutanil by PMRA, Dow AgroSciences Canada Inc., the registrant of the TGAI and primary data provider in Canada, indicated continued support for all uses included on the labels of myclobutanil end-use products.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name		Myclobutanil
Function		Fungicide
Chemical Family		Triazole
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	2-*p*-chlorophenyl-2-(1*H*-1,2,4-triazol-1-ylmethyl)hexanenitrile
2	**Chemical Abstracts Service (CAS)**	α-butyl- α -(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile
CAS Registry Number		88671-89-0
Molecular Formula		$C_{15}H_{17}ClN_4$
Structural Formula		
Molecular Weight		288.8
Purity of the Technical Grade Active Ingredient		95.50
Registration Number		27916

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), Section 2.13.4 of DIR98-04 and Appendix II of DIR99-03 (TSMP Track 1 substances) are not expected to be present in this product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	0.213 mPa
Ultraviolet (UV)/visible spectrum	Not expected to absorb at λ >300 nm
Solubility in water at 25°C	142 mg/L
n-Octanol–water partition coefficient at 25°C	pH: 7-8; log P: 2.94
Dissociation constant	N/A

2.3 Description of Registered Myclobutanil Uses

Appendix I, lists all myclobutanil products that are registered under the authority of the *Pest Control Products Act*. Appendix II lists all the uses for which myclobutanil is presently registered. All uses were supported by the registrant at the time of re-evaluation initiation and were therefore considered in the health and environmental risk assessments of myclobutanil. Appendix II also includes uses that were added through the PMRA Minor Use Program. While currently supported by the registrant, the data supporting the use was originally generated by a user group.

Uses of myclobutanil belong to the following use-site categories: greenhouse food crops, greenhouse non-food crops, terrestrial feed crops, terrestrial food crops, ornamentals outdoor and turf.

3.0 Impact on Human and Animal Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species. The health effects noted here were observed in animals at dose levels at least 100-fold (often much higher) above levels to which humans are normally exposed through use of products containing this chemical.

3.1 Toxicological Summary

The toxicology database supporting myclobutanil is primarily based on studies from the technical registrant. Myclobutanil is of slight acute toxicity in rats and mice by the oral route of exposure, of low acute toxicity in rabbits by the dermal route of exposure and of low acute toxicity in rats by the inhalation route of exposure. It is mildly irritating to rabbit skin, moderately irritating to rabbit eyes, and a potential skin sensitizer in Guinea pigs. Signs of acute toxicity induced by myclobutanil include ataxia, abdominal breathing, prostration, convulsions, passiveness, and salivation.

With oral exposure, myclobutanil is rapidly absorbed from the gastrointestinal tract, with peak blood levels occurring within 1.0 hour. Accumulation within tissues is minimal. Excretion is rapid and complete, with approximately equal amounts of ^{14}C-label found in the urine and in the faeces. The main metabolites are compounds which are more polar than the parent. The same metabolites are excreted by both males and females; however, in males at least 5 of the isolated metabolite fractions had greater than 10% of the ^{14}C-label, while in females there was only one major fraction, which had up to 75% of the ^{14}C-label. This fraction consisted of a sulphate conjugate of one of the main metabolites (RH-9090).

In short and long term studies, the major effect was on the liver. In subchronic mouse, rat and dog studies, effects included hepatocellular hypertrophy, vacuolation and necrosis, and increased liver weight. Other effects in the subchronic studies included decreases in body weight and food consumption, changes in haematological parameters and blood chemistry, and histological changes in organs.

In a chronic study in the mouse, in addition to the effects on the liver noted in the subchronic studies, effects included reduced body weight and body weight gain, reduced food consumption, increased WBC count and hypertrophy of the cells of the zona fasiculata area of the adrenal cortex. In chronic studies of the rat the major target organs were the liver and the testes. Effects in the liver included increased weight and increased incidence of hepatocellular enlargement and vacuolization. Effects in the testes included: reduction in testicular weight, increased testicular atrophy, reduction in the weight of the epididymides, increased bilateral aspermatogenesis, increased incidences of hypospermia and cellular debris in the epididymides, increased incidence of arteritis/periarteritis in the testes. Other effects included decreases in body weight, body weight gain and food consumption. All genotoxicity studies were negative. Myclobutanil is considered non-carcinogenic.

In a developmental study in the rat, maternal toxic effects included clinical signs (rough hair coat, desquamation, salivation, alopecia, red exudate from the mouth, and scant/soft faeces) and reduced body weight/body weight gain. Developmental effects were apparent at a lower dose, indicating fetal sensitivity; these included increased resorptions per litter, reduced viability indices and increased skeletal variations, mainly in the ribs. With the rabbit, maternal toxic effects included reduced body weight/body weight gain, increased frequencies of irregular faeces and/or bloody urine and increased abortions. Developmental effects included increased a;sldkfjasdklfj klasdjf; asdfrequencies of abortions and resorptions, decreased viability indices, reduced litter sizes and reduced fetal body weight. Both fetal and maternal effects in the rabbit

were noted at the same dose (highest), however, the fetal effects were considered to be of a more serious nature suggesting qualitative sensitivity. There was no evidence of teratogenicity in either the rabbit or the rat.

In a 2-generational study on the rat, a number of effects on reproduction were noted at the highest dose: a reduced number of females delivering litters, a reduced number of pups per litter, an increased number of stillborns, reduced fertility indices and gestation indices, reduced mean litter size, a reduced body weight gain in the pups, and effects on the male reproductive organs in the second generation (grossly small flaccid testes, multifocal or diffuse atrophy of the testes, reduced epididymal spermatozoa, necrotic spermatocytes in the epididymides, and atrophy of the prostate). Parental toxicity effects included increased liver weights, centrilobular hepatocellular hypertrophy, reduced body weight and body weight gain, and reduced food consumption

The fungicidal activity of myclobutanil is based on the inhibition of the cytochrome P450 genes CYP51 (lanosterol 14 -demethylase) which is necessary for the production of fungal cell membranes and walls. Cyp 51 is also present in plants and animals and in animals it is critical for the synthesis of cholesterol and therefore for steroid biosynthesis. The wide range of toxic endpoints noted, including reproductive and endocrinological effects, as well as effects on the liver, appear due to the fact that myclobutanil and other conazoles can alter the expression of a number of CYP enzymes.

Reference doses have been set based on the NOAEL's for the most sensitive indicators of toxicity, namely testicular effects (atrophy and decreased weight), and fetal effects (increased resorptions/litter and decreased viability index) in rats. Reference doses incorporate uncertainty factors to account for extrapolating between laboratory animals and humans, and in the case of females 13-49 years of age, a PCPA factor to account for the demonstrated fetal sensitivity and seriousness of the endpoint.

The toxicology profile of myclobutanil is summarized in Appendix III A and the toxicology endpoints used in the risk assessment of myclobutanil are summarized in Appendix III B.

3.1.1 PCPA Hazard Consideration

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

With respect to the completeness of the toxicity database as it pertains to the exposure of, and toxicity to, infants and children, extensive data were available for myclobutanil. Data of high quality included a developmental toxicity study in rats, a developmental toxicity study in rabbits and a multi-generation reproduction study in rats.

With respect to potential pre- and post- natal toxicity, a sensitivity of the young was observed in the rabbit developmental toxicity study as evidenced by increased frequencies of abortions and resorptions, decreased viability indices, reduced litter sizes and reduced fetal body weight in the presence of maternal toxicity. Sensitivity was observed in a rat developmental toxicity study in which increased resorptions and a reduced viability index occurred at maternally non-toxic dose levels. In a 2-generation rat assay, a reduced number of pups per litter, an increased number of stillborns, reduced fertility indices and gestation indices, reduced mean litter size, and a reduced body weight gain in the pups were observed in the presence of maternal toxicity.

Overall, the database is adequate for the determination of the potential sensitivity of the young. The available data demonstrates fetal sensitivity in the presence of relatively minor maternal toxicity. The fetal effects observed in the rat developmental toxicity assay, fetal death, were considered serious endpoints. Therefore, the full PCPA factor was retained for both acute and some repeat exposure scenarios where the rat developmental toxicity assay is used to establish risk for sensitive populations (females 13-49 years of age). In exposure scenarios for children, no greater susceptibility is indicated and the PCPA factor was reduced to 1-fold.

3.2 Occupational and Non-Occupational Risk Assessment

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

Dermal and inhalation exposures were combined because of a common toxicity endpoint and because dermal and inhalation exposures may occur simultaneously. A combined MOE was used to combine dermal and inhalation risk estimates since the dermal and inhalation target MOEs are identical.

3.2.1 Toxicology Endpoint Selection for Occupational Risk Assessment

3.2.1.1 Short-term dermal and inhalation risk assessment

To estimate the risk from short-term dermal and inhalation exposure, a NOAEL of 29 mg/kg bw/day from a developmental study in the rat (based on increased resorptions/litter and a decrease in viability index at 87 mg/kg bw/day) was considered. A target MOE of 1000 is based on the standard uncertainty factors of 10-fold for inter-species extrapolation and 10-fold for intra-species variability, and, in light of concerns regarding pre-natal toxicity (as outlined in the PCPA section), an additional 10-fold factor to protect for a sensitive subpopulation (namely females 13-49 years of age).

This endpoint was used for the aggregate PYO and golfer risk assessments.

3.2.1.2 Intermediate-term dermal and inhalation risk assessment

To estimate the risk from intermediate-term dermal and inhalation exposure, a NOAEL of 2.5 mg/kg bw/day from a 2-year rat study (based on decreased testicular weight and increased testicular atrophy at 9.8 mg/kg bw/day) was considered. A target MOE of 100 is based on the standard uncertainty factors of 10× for inter-species extrapolation and 10× for intra-species variability.

A cancer risk assessment was not required since the myclobutanil database did not suggest any carcinogenic potential in mice or rats.

3.2.1.3 Dermal Absorption

One dermal absorption study was submitted to the PMRA, however it was deemed inappropriate for use in this risk assessment. In the absence of adequate dermal absorption data, the default value of 100% dermal absorption was reduced to 50% based on a weight of evidence approach that considered the available dermal absorption data and the physical-chemical properties of myclobutanil.

3.2.1.4 Carcinogenic Occupational Exposure and Risk Assessment

A cancer risk assessment was not required since the myclobutanil database did not suggest any carcinogenic potential in mice or rats.

3.2.2 Occupational Exposure and Risk Assessment

3.2.2.1 Mixer, Loader and Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, applicators or other handlers. Based on typical use patterns, the major scenarios identified were:

- Mixing/loading of soluble granules in water soluble packaging;
- Applying liquids by open cab, groundboom;
- Applying liquids by open cab, airblast;
- Applying liquids by low pressure handwand;
- Applying liquids by backpack.

Generally, workers applying myclobutanil have a short- to intermediate-term duration of exposure, given that applications range from two to six per season at intervals of 7-14 days. The endpoints proposed for the risk assessments encompass both short-term and intermediate-term exposure. The PMRA has assessed all use scenarios based on the intermediate-term endpoints, thereby capturing the likelihood of exposure greater than 30 days in a growing season, which is in keeping with the use pattern of myclobutanil. Using intermediate-term endpoints as opposed to short-term endpoints does not significantly change the results of the risk assessment.

The PMRA estimated handler exposure based on the following level of personal protective equipment (PPE):

- Cotton coveralls over a single layer (long sleeved shirt and long pants) and chemical-resistant gloves.

No acceptable chemical-specific handler exposure data were submitted for myclobutanil; therefore, dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1. The PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software that facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of PPE. Wettable powder formulations were not assessed based on the technical registrant voluntarily discontinuing the wettable powder end use product.

Based on registrant response, only groundboom applications were considered in the risk assessment for turf applications (Dow AgroSciences Canada, 2008). The registrant indicates that no other application equipment is employed, and therefore label statement revisions recommended by the PMRA will include restricting turf applications to groundboom equipment only.

In some cases, PHED did not contain appropriate data sets to evaluate exposure to workers wearing PPE. This was estimated by incorporating a protection factor into the unit exposure data. Where warranted, a 75% protection factor was incorporated into the dermal unit exposure data for cotton coveralls.

It was assumed that exposure from mixing/loading and applying a liquid by low pressure handwand, high pressure handwand and backpack would be comparable for the same activities using spray solutions based on soluble granules in water soluble packaging formulations. Therefore the PHED data for mixing, loading and applying liquids via a low/high pressure handwand or backpack was used for these scenarios.

Mixer/loader/applicator exposure estimates are based on the best available data at this time. The assessment might be refined with exposure data representative of modern application equipment and engineering controls. Biological monitoring data could also further refine the assessment.

3.2.2.1.1 Occupational Exposure Risk Estimates

Occupational risk estimates associated with mixing, loading and applying product for agricultural and turf uses meet the target MOE and are not of concern. Table 1 of Appendix III C summarizes the calculated MOEs for mixers/loaders and applicators.

3.2.2.2 Post-application Worker Exposure and Risk Assessment

The post-application occupational risk assessment considered exposures to workers entering treated agricultural sites. Based on the myclobutanil use pattern, there is potential for short- to intermediate-term post-application exposure to myclobutanil residues for workers. Post-application exposure activities include (but are not limited to): hand harvesting, pinching, pruning, scouting and thinning agricultural crops.

Potential exposure to post-application workers was estimated using activity-specific transfer coefficients (TCs) and dislodgeable foliar residue (DFR) values. The TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from data generated in field exposure studies.

One dislodgeable foliar residue (DFR) study was considered acceptable for use in the risk assessment of myclobutanil. As this study was conducted following airblast applications to grapes with myclobutanil (in keeping with Canadian uses), the chemical-specific dissipation data were considered in the PMRA's risk assessment of grape uses.

As there were no other DFR studies submitted to the PMRA, the default peak (day 0) DFR value of 20% of the application rate and the default dissipation rate of 10% per day were used in the assessment of agricultural crops.

Appropriate dissipation data were not available for greenhouse uses. In the absence of suitable DFR studies, the default peak (day 0) DFR value of 20% of the application rate and the assumption of no dissipation (a default dissipation rate of 0% per day) for greenhouses were used in the occupational postapplication risk assessment.

One transferable turf residue study was submitted to the PMRA in support of the re-evaluation of myclobutanil. The study consistently indicated that the peak residue measured on the day of treatment was less than 2.5% of the application rate. However, as the dissipation rates determined by the study varied between 8-46%, it was deemed appropriate to use the default daily dissipation rate of 10% in the risk assessment. Therefore for the purposes of this risk assessment, the initial peak residue on turf was assumed to be 2.5% of the application rate with a daily dissipation rate of 10%.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely enter after application. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures above the target MOE (for example, > 100 for intermediate-term exposure scenarios).

Current REIs would need to be increased for most agricultural scenarios in order to achieve target MOEs for post-application activities, based on available data. Tables 2 and 3 of Appendix III C summarize calculated REIs for selected agricultural post-application activities, based on currently available exposure data, and the target MOE of 100.

The newly calculated REIs are largely considered agronomically feasible, given the timing of application in relation to the crop cycle. However, some of these REIs may not be practical for growers.

The assessments could be refined and uncertainties reduced with the following data:

- enhanced information on the myclobutanil use pattern, including typical rates and number of applications per season;
- survey information on critical worker activities that typically take place for each crop during the use season, and the timing of these activities with respect to crop growth and applications of myclobutanil;
- DFR data for key Canadian crops (particularly for greenhouse uses) conducted under typical Canadian use conditions;
- Passive dosimetry or biological monitoring data.

With these additional data and information, it is expected that estimated exposure and risk would decrease (for example, REIs).

3.2.3 Non-Occupational Exposure and Risk Assessment

3.2.3.1 Pick Your Own Exposure

"Pick Your Own (PYO)" farms are those that allow the public to harvest their own fruits and vegetables. As PYO fruit and vegetable operations become more and more prevalent, the PMRA recognizes the need for a means of assessing exposure to pesticides during hand-harvesting by members of the public. For the purpose of this risk assessment, "Pick Your Own" facilities are considered commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled myclobutanil products.

Although there are many PYO operations involving a wide variety of produce across Canada, only a few orchard and berry crops can be readily eaten in an appreciable quantity during the harvest. For those PYO crops that do not represent acute, commodity-specific dietary exposure, the hand harvest exposure for the public is addressed by the occupational post-application exposure assessment.

An assessment of the potential risk of exposure incurred by the public at a "Pick-Your-Own" facility was conducted for cherries, peaches and nectarines. Although the use pattern and the occupational and dietary risk assessments of myclobutanil should preclude the possibility of PYO patrons incurring acute, toxicologically significant exposure to myclobutanil, a quantitative analysis was performed to ensure that there was no risk of concern for the public. As there is potential for a person to be exposed through contact with treated foliage as well as eating the fruits that they are harvesting, both dermal and dietary exposure were aggregated in the PYO risk assessment.

Since members of the public who harvest at PYO facilities may be of any age, a number of subpopulations including adults and children were considered for this scenario. A PYO assessment was not required for children because no acute dietary endpoint was identified for this age group. An acute dietary endpoint was only identified for females aged 13-49 (See Table 1 of Appendix III D), so only adults were included in the aggregate risk assessment. Two exposure pathways were considered: ingestion of fruit and dermal exposure through contact of the fruit while harvesting. Maximum residue limits (MRLs) were used to estimate the residue of fruits consumed. The MRL represents a high end residue estimate, as could potentially occur in a PYO scenario. Dislodgeable foliar residue data were used to estimate the residue dislodged for dermal exposure during harvesting.

The PYO risk assessment for myclobutanil aggregated the dermal exposure from hand harvesting fruit, oral exposure from consumption of fresh fruit during harvest and chronic dietary exposure (to account for background exposure to myclobutanil from all routes, including food and drinking water). Results of the PYO risk assessment are presented in Table 2 (dermal exposure) and Table 4 (aggregate exposure) of Appendix III C.

The combined exposures of diet, drinking water and PYO activities exceed the target MOE and do not represent a concern for the PMRA.

3.2.3.2 Golf Exposure

A quantitative assessment of the potential risk of exposure incurred by the public at golf courses was conducted, although it is expected that the use pattern and the occupational and dietary risk assessments of myclobutanil should generally preclude the possibility of golfers incurring significant exposure to myclobutanil.

Aggregate exposure for golfers included the sum of the chronic dietary exposure (including drinking water) and the dermal exposure incurred at the golf course. Youth golfers were used to represent the potential risk to all golfers (both youth and adult) due to their lower body weight. Inhalation exposure was not considered for golf courses, as it was considered to be negligible due to low vapour pressure. Aggregating exposure estimates yielded an MOE well above the target MOE for non-occupational aggregate exposure. Results of the youth golfer risk assessment are presented in Table 3 (dermal exposure) and Table 4 (aggregate exposure) of Appendix III C.

The combined exposures of diet, drinking water and golfing activities exceeded the target MOE and do not represent a concern for the PMRA.

3.3 Dietary Risk Assessment

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

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

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

Residue estimates used in the dietary risk assessment (DRA) may be conservatively based on the MRL or the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency's National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program (PDP).

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.03), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998.

For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendix III D and V.

3.3.1 Determination of Acute Reference Dose

An acute (1 day) reference dose (ARfD) was not calculated for the general population since there was not an acute endpoint of concern. For the population subgroup females 13-49 years of age an ARfD was calculated based on a NOAEL of 29 mg/kg bw/day from a developmental toxicity study in rats. The endpoint selected was based on increased resorptions/litter and a decrease in viability index at a LOAEL of 87 mg/kg bw/day. Standard uncertainty factors of 10× for interspecies extrapolation and 10× for intraspecies variability were used. A PCPA factor of 10× was retained. The endpoint of concern was fetal death which was interpreted to possibly result from a single exposure. This endpoint occurred in the presence of relatively mild maternal effects. The PCPA factor of 10× was retained due to the demonstrated fetal sensitivity and seriousness of the endpoint. The resulting ARfD is 0.029 mg/kg bw (29 mg/kg bw/day ÷ 1000).

3.3.2 Acute Dietary Exposure and Risk Assessment

Acute dietary risk is calculated considering the highest ingestion of myclobutanil that would be likely on any one day, and using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of myclobutanil residue that might be consumed in a day. A value representing the high end (99.9^{th} percentile) of this distribution is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, then acute dietary exposure is considered to be acceptable.

A refined acute aggregate (food + drinking water) exposure assessment was performed by using CFIA and PDP monitoring data for the most consumed commodities; MRL/tolerance-level residues for all other commodities; available information on percent crop treated in Canada and in the United States; 100% crop treated for all other registered uses; DEEM default processing factors; and the drinking water estimated environmental concentration (EEC) from modelling, incorporated directly in the dietary assessment. The probabilistic assessment results show that the acute dietary exposure estimate (at the 99.9^{th} percentile) is at about 88% of the ARfD, below the PMRA's level of concern. The main contributor is water (direct and indirect, all sources), accounting for about 94% of the total exposure (83% of the ARfD). Although the acute dietary risk assessment for myclobutanil is highly refined with respect to most consumed commodities, there still is some conservatism in the assessment inherent in the use of MRL/tolerance-level residues and/or a 100% crop treated assumption for a few commodities. This did not, however, contribute significantly to the estimates of exposure.

3.3.3 Determination of Acceptable Daily Intake

The acceptable daily intake (ADI), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects, that was selected was based on a NOAEL of 2.5 mg/kg bw/day from a 2-year rat study. The endpoint selected was based on decreased testicular weight and increased testicular atrophy at a LOAEL of 9.8 mg/kg bw/day. An overall uncertainty factor of 100 was required to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold). The PCPA factor was reduced to 1× based on the completeness and quality of the database, and the lack of residual concerns related to potential effects on the young. The resulting ADI is 0.025 mg/kg bw/day (2.5 mg/kg bw/day ÷ 100). This value was considered to be protective of all populations, including infants and children, and females 13-49 years of age.

3.3.4 Chronic Non-Cancer Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated by using the average consumption of different foods and the average residue values on those foods. This expected intake of residues was then compared to the ADI. When the expected intake of residues is less than the ADI, then chronic dietary exposure is acceptable.

A refined chronic aggregate (food + drinking water) dietary exposure assessment was performed for the general population and all population subgroups of regulatory concern by incorporating the EEC point estimate directly in the dietary assessment and by using average residues from the same CFIA and USDA PDP monitoring data that were used in the acute analysis; Canadian MRLs or United States tolerances or Codex MRLs for some commodities; average percent crop treated in Canada and in the United States when available; 100% crop treated for all other registered uses; and DEEM default processing factors. The assessment results show that the aggregate chronic non-cancer dietary exposure is below the PMRA's level of concern (<100% of the ADI) for the general population (17% of the ADI) and all population subgroups (13%-51% of the ADI). The most exposed population subgroup is "all infants" (< 1 year old) with an exposure at about 51% of the ADI. The main contributor is water (direct and indirect, all sources), accounting for about 96% of the total exposure (49% of the ADI).

3.3.5 Cancer Potency Factor

The myclobutanil database did not suggest any carcinogenic potential in mice or rats.

3.3.6 Carcinogenic Dietary Exposure and Risk Assessment

A cancer risk assessment was not required since the myclobutanil database did not suggest any carcinogenic potential in mice or rats.

3.4 Exposure from Drinking Water

3.4.1 Concentrations in Drinking Water

Myclobutanil residues in potential drinking water sources were estimated using modelling data. The estimated environment concentrations (EECs) were calculated using PRZM/EXAMS and LEACHM models for surface and groundwater, respectively. The modelling was based on both a revised use pattern for turf grass on golf courses (two applications of 0.8 kg a.i./ha at 14-day intervals) assuming a percent cropped area (PCA) of 34% and the use pattern for apples (six applications of 0.136 kg a.i./ha at 7-day intervals) assuming 100% cropped area. The highest, most conservative, groundwater EEC value of 175 ppb for both the acute and chronic scenarios (based on the use pattern on apples) was used in the dietary risk assessment.

3.4.2 Drinking Water Exposure and Risk Assessment

Drinking water exposure estimates were not calculated separately. They were combined with food exposure estimates, with EEC point estimates incorporated directly in the dietary (food + drinking water) assessment. Please refer to Sections 3.3.2, 3.3.4 and 3.5 for details.

3.5 Aggregate Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

Aggregate risk assessment looks at the combined potential risk associated with food, drinking water and residential exposures. Acute aggregate risk assessments do not combine residential and dietary exposures, as it is unlikely that an individual would be exposed to high-end dietary and residential exposure on the same day. For myclobutanil, acute aggregate exposure is, therefore, from dietary and drinking water exposures (see Section 3.3 and Section 3.4).

As residential uses of myclobutanil are not permitted, the short-term aggregate exposure is comprised of contributions from food and drinking water. The relevant duration of exposure to assess toxicological endpoints for this assessment would be a period of up to one month. The database did not include short-term inhalation or dermal studies. The oral developmental study in the rat, with a NOAEL of 29 mg/kg bw/day based on increased resorptions/litter and a decrease in viability index at the next higher dose, was used for all exposure routes. The target MOE selected for the aggregate assessment is 1000, comprised of the standard uncertainty factors of 10-fold for interspecies extrapolation and of 10-fold for intraspecies variability, and a PCPA factor of 10-fold.

The combined exposures of diet, drinking water and golfing or PYO activities exceed the target MOE for all sub-populations and do not represent a concern for the PMRA. See Sections 3.2.3.1 and 3.2.3.2 for more details.

3.6 Incident Reports

Starting April 26, 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Incidents are classified into six major categories including effects on humans, effects on domestic animals and packaging failure. Incidents are further classified by severity, in the case of humans for instance, from minor effects such as skin rash, headache, etc., to major effects such as reproductive or developmental effects, life-threatening conditions or death.

The PMRA will examine incident reports and, where there are reasonable grounds to suggest that the health and/or environmental risks of the pesticide are no longer acceptable, appropriate measures will be taken, ranging from minor label changes to discontinuation of the product. Incident reports reflect the observations and opinion of the person reporting it and the Incident Reporting Program does not include validation of the reports. The PMRA collects incident reports in an effort to establish trends and the publishing of individual reports should not be considered as a statement of causality.

In the US, data from the California illness surveillance program showed that in the 10 years following the registration of myclobutanil on grapes, there were more than 160 cases of illnesses among California agricultural workers that could possibly be attributed to the use of myclobutanil (CalDPR, 2000). The most prevalent effects reported for a possible exposure to myclobutanil included: skin rash, allergic dermatitis and itchiness, nausea, headaches, diarrhoea, abdominal pain, vomiting, nosebleed, and eye irritation. The skin hypersensitivity is consistent with the potential for skin sensitization identified in the PMRA's toxicological review of myclobutanil. However, it should be noted that the possibility of concomitant exposure to other pesticides and formulants complicated the determination of a clear association of illnesses due to myclobutanil use.

There were no health-related incident reports submitted to the PMRA for end use products containing myclobutanil as of April 7th, 2009.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Terrestrial Environment
Myclobutanil is classified as relatively non-volatile under field conditions from the reported vapour pressure (1.29×10^{-8} mm Hg at 25ºC). The octanol–water partition coefficient (log K_{ow}) was reported to be 1.98 which indicates that myclobutanil has a low potential for bioaccumulation in biota. Phototransformation of myclobutanil is not an important route of transformation in soil. Biotransformation is a route of transformation for myclobutanil in soil under aerobic conditions although transformation is slow. Myclobutanil would be considered moderately persistent to persistent in soil under aerobic conditions. The only major (> 10%) transformation product is 1,2,4-triazole. Myclobutanil is stable in soil under anaerobic conditions.

Myclobutanil is classified as having a low to medium mobility in soil according to the classification scheme of McCall *et al.* (1981) as K_{oc} values were 226-920. Submitted soil column leaching studies also indicate that myclobutanil and its transformation products have a low potential for vertical mobility in soil. Myclobutanil satisfies all of the criteria set out by Cohen *et. al.* (1984) except K_d and K_{oc} values in some soils, therefore myclobutanil may have a high potential to leach in some soils. The Groundwater Ubiquity Score (GUS) also indicates that myclobutanil is a potential leacher. Groundwater modelling further confirms that myclobutanil has the potential to reach groundwater (See Appendix VII). Volatilization from soil and plant surfaces is expected to be minimal under field conditions.

Myclobutanil would be considered moderately persistent to persistent in soil according to the classification scheme of Goring *et al.* (1975) based on the reported DT_{50} values of 64 - > 365 days from field dissipation studies conducted in Canada. The major soil transformation product, 1,2,4-triazole did not accumulate above 10% of the parent myclobutanil at any of the sites and was not detected below 10 cm. The results of these studies indicate that myclobutanil has a significant potential for carryover to the next growing season.

Aquatic environment
The reported solubility of myclobutanil in water (142 mg/L at 25ºC), would classify it as very soluble. The Henry's Law constant (3.45×10^{-11} atm.m^3.mol^{-1}), and 1/H value of 7.1×10^8, indicates that myclobutanil is non-volatile from moist soil and water.

Available information all indicate that myclobutanil will likely persist in aquatic environments with a significant amount of residues partitioning to the sediments. Myclobutanil is stable to hydrolysis at environmentally relevant pH's (pH 5 to pH 9). Phototransformation of myclobutanil is not an important route of transformation in water. Biotransformation is extremely slow under both aerobic and anaerobic conditions in aquatic environments and would not be considered to be an important route of transformation for myclobutanil.

Environmental fate data for myclobutanil are summarized in Table 6 of Appendix VI.

4.2 Effects on Non-target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible. Data derived from monitoring studies may also be used in refining a risk assessment (Appendix VII).

4.2.1 Effects on Terrestrial Organisms

A risk assessment of myclobutanil to terrestrial organisms was based upon an evaluation of toxicity data for the following (Table 7, Appendix VI):

- one earthworm species, one bee species (acute exposure)
- two bird and two mammal species representing vertebrates (acute, dietary, reproduction exposure)
- five plant species

For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with myclobutanil. For multiple applications the cumulative application rates were calculated taking into consideration the dissipation half-life of myclobutanil in soil from the aerobic soil biotransformation study (691 days) and on foliage (10.5 days).

Terrestrial Invertebrates
The screening level risk assessment indicated that the level of concern for earthworms and bees was not exceeded for any of the application rates. Table 8 (Appendix VI) summarizes the screening level risk to earthworms and bees from myclobutanil.

Terrestrial Plants
The risk to non-target terrestrial plants is presented in Table 9 (Appendix VI). The level of concern is exceeded by a factor of 3.4 for nontarget plants inhabiting the site of application following two applications at 720 g a.i./ha to turf on golf courses. Non-target plants would, however, not be present on tees, greens, and fairways on golf courses so this identified risk is not realistic. The level of concern is also exceeded by a factor of 1.2 for non-target plants inhabiting the site of application following six airblast applications at 136 g a.i./ha (for example, orchard uses).

In addition, the risk from spray drift off the treated site was also assessed taking into consideration the spray drift deposition of spray quality of ASAE medium for field sprayer (6%), airblast early season (74%) and late season (59%) at 1 m downwind from the site of application. The LOC was not exceeded for field sprayer applications on golf courses or early or late season airblast applications (Table 9, Appendix VI).

Birds and Small Wild Mammals
Standard exposure scenarios on vegetation and other food sources based on correlations in Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher *et al.* (1994) were used to determine the concentration of pesticide (dry weight) on various food items in the diet of birds and small wild mammals, or estimated daily exposure (EDE). Exposure is dependent on the body weight of the organism and the amount and type of food consumed. In the screening level assessment a set of generic body weights was used for birds (20, 100, 1000 g) and small wild mammals (15, 35, 1000 g) to represent a range of bird and small wild mammal species. For each body weight, the food ingestion rate (FIR; equivalent to food consumption) will be based on equations from Nagy (1987). It is noted that diets of animals can be highly

variable from season to season as well as day to day. Furthermore, animals are often opportunists and if they encounter an abundant and/or desirable food source, they may consume large quantities of that food. For these reasons, the screening level assessment used relevant food categories for each size group consisting of 100% of a particular dietary item. These items included the most conservative residue values for plants, grains/seeds, insects, and fruits. A 100% diet of plants for the smallest sizes of birds and mammals was not included as this was considered unrealistic. No small birds or mammals in North America are known to eat a diet primarily of leafy plant material or grass; a small bird or mammal would need to consume unrealistically high amounts of leafy plant material or grass to meet its energy requirements.

Birds

The screening level risk to birds is presented in Table 10 (Appendix VI).

Following two field sprayer applications of myclobutanil at 720 g a.i./ha to turfgrass on golf courses, the acute oral LOC is only exceeded by a factor of 1 for 20 gram insectivores and by a factor of 1.5 for 1000 gram herbivores. The acute oral LOC is not exceeded for any of the generic body weights or feeding guilds of birds following any of the other applications of myclobutanil.

The acute dietary LOC is exceeded by a factor of 1.7 in 20 gram insectivores, by a factor of 1.3 in 100 gram insectivores and by a factor of 2.5 in 1000 gram herbivores following two field sprayer applications of myclobutanil at 720 g a.i./ha to turfgrass on golf courses. The acute dietary LOC is not exceeded for any of the generic body weights or feeding guilds of birds following any of the other applications of myclobutanil.

The chronic LOC is exceeded by a factor of 3.3 in 20 gram insectivores, by a factor of 1.7 in 20 gram frugivores, by a factor of 2.6 in 100 gram insectivores, by a factor of 1.3 in 100 gram frugivores and by a factor of 4.8 in 1000 gram herbivores following two field sprayer applications of myclobutanil at 720 g a.i./ha to turfgrass on golf courses. The identified risks to frugivores is not realistic because fruit would not be present on golf courses.

The chronic LOC is also exceeded by a factor of 1.1 in 20 gram insectivores and by a factor of 1.6 in 1000 gram herbivores following six airblast applications of myclobutanil at 136 g a.i./ha.

The chronic LOC is not exceeded for any of the generic body weights or feeding guilds of birds following five applications at 80 g a.i./ha or three applications at 45 g a.i./ha.

In addition, the risk associated with the consumption of food items contaminated from spray drift off the treated field was also assessed taking into consideration the spray drift deposition of spray quality of ASAE medium for field sprayer (6%) and airblast early season (74%) and late season (59%) at 1 m downwind from the site of application. The risk to birds inhabiting areas adjacent to the treated field from spray drift off the treated field following field sprayer and airblast applications of myclobutanil are contained in Tables 11 and 12 (Appendix VI). The analysis was only performed on the generic body weights and feeding guilds of birds that exceeded the acute oral, dietary or chronic LOC following applications on the site of myclobutanil application.

The acute oral, acute dietary and chronic levels of concern were not exceeded for any of the generic body weights and feeding guilds of birds feeding in areas immediately adjacent to the treatment site following two field sprayer applications of myclobutanil at 720 g a.i./ha to turfgrass on golf courses (Table 11, Appendix VI). The chronic level of concern is only exceeded by a factor of 1.2 for 1000 gram herbivores feeding in areas immediately adjacent to the treatment site following six early season airblast applications at 136 g a.i./ha (Table 12, Appendix VI).

The on-field assessment assumes that birds are being exposed to residues on food items at levels equivalent to those present immediately after application, that these levels remain constant over time and that birds would feed exclusively on a single food item (such as leaves and leafy crops) within the treated field. In cases where risk quotients exceed the LOC, an additional analysis was conducted to determine the amount of contaminated food, expressed as a percentage of the daily diet that must be consumed in order to reach the LOC (calculated as 1/RQ × 100).

Given the conservative nature of this assessment, an acute, dietary or chronic risk to most birds both on-field and off-field is unlikely because the LOC's were only slightly exceeded and birds would need to consume an unrealistically large proportion of a single contaminated food item over an extended time period (30-100% of their diet). The exception is chronic risk to 1000 g herbivores feeding on-field following two applications at 720 g a.i./ha to golf courses, who would only need to consume 21% of their diet to reach the LOC.

Small wild mammals

The screening level risk assessment for small wild mammals is presented in Table 10 (Appendix VI).

The acute oral LOC is only exceeded by a factor of 1 for 35 gram herbivores following two field sprayer applications of 720 g a.i./ha to turfgrass on golf courses. The acute oral LOC is not exceeded for any of the generic body weights or feeding guilds of small wild mammals following any of the other applications of myclobutanil.

The acute dietary LOC is exceeded by a factor of 3.7 in 35 gram herbivores and by a factor of 2.0 in 1000 gram herbivores following two field sprayer applications of 720 g a.i./ha to turfgrass on golf courses. The acute dietary LOC is exceeded by a factor of 1.3 in 35 gram herbivores following six airblast applications of myclobutanil at 136 g a.i./ha . The acute dietary LOC is not exceeded for any of the generic body weights or feeding guilds of mammals following five applications at 80 g a.i./ha or three applications at 45 g a.i./ha.

The chronic LOC is exceeded by factors ranging from 1.1 to 2 in 15 gram insectivores and frugivores, by factors ranging from 1.7 to 10.8 in 35 gram insectivores and herbivores and by a factor of 5.8 in 1000 gram herbivores following two field sprayer applications of 720 g a.i./ha to turfgrass on golf courses. The identified risk to frugivores is not realistic since fruit would not be present on golf courses.

The chronic LOC is exceeded by a factor of 3.7 in 35 gram herbivores and by a factor of 2.0 in 1000 gram herbivores following six airblast applications of myclobutanil at 136 g a.i./ha . The chronic LOC is not exceeded for any of the generic body weights or feeding guilds of mammals following five applications at 80 g a.i./ha or three applications at 45 g a.i./ha.

The risk associated with the consumption of food items contaminated from spray drift off the treated field was also assessed taking into consideration the spray drift deposition of spray quality of ASAE medium for field sprayer (6%) and airblast early season (74%) and late season (59%) at 1 m downwind from the site of application. The risk to small wild mammals inhabiting areas adjacent to the treated field from spray drift off the treated field following field sprayer and airblast applications of myclobutanil are contained in Tables 11 and 12 (Appendix VI). The analysis was only performed on the generic body weights and feeding guilds of mammals that exceeded the acute oral, dietary or chronic LOC following applications on the site of myclobutanil application.

The acute oral, acute dietary and chronic levels of concern were not exceeded for any of the generic body weights and feeding guilds of small wild mammals feeding in areas immediately adjacent to the treatment site following two field sprayer applications of myclobutanil at 720 g a.i./ha to turfgrass on golf courses (Table 11, Appendix VI).

The chronic level of concern is exceeded by factors of 2.7 and 2.2, respectively for 35 gram herbivores feeding in areas immediately adjacent to the treatment site following six early season and late season airblast applications at 136 g a.i./ha. The chronic level of concern is exceeded by factors of 1.5 and 1.2, respectively for 1000 gram herbivores feeding in areas immediately adjacent to the treatment site following six early season and late season airblast applications at 136 g a.i./ha (Table 12, Appendix VI).

Similar to the bird risk assessment, given the conservative nature of this assessment, an acute, dietary or chronic risk both on-field and off-field is unlikely because the LOC's were only slightly exceeded for many of the body weights and feeding guilds of small wild mammals and they would need to consume an unrealistically large proportion of a single contaminated food item over an extended time period (37-100% of their diet). The exception is chronic risk to 35 or 1000 g herbivores feeding on-field who would only need to consume 9-27 % of their diet to reach the LOC.

4.2.2 Effects on Aquatic Organisms

A risk assessment of myclobutanil to aquatic organisms was based upon an evaluation of toxicity data for the following (Table 7, Appendix VI):

- one freshwater invertebrate species (acute and chronic exposure)
- four freshwater fish species (acute and chronic exposure)
- two freshwater algae
- two estuarine/marine invertebrate species (acute exposure)

Screening Level Assessment
The initial aquatic assessment conducted is a deterministic screening level risk assessment. This approach is conservative, and primarily designed to identify the taxonomic groups which are not at risk and/or the use scenarios which do not pose an unacceptable risk. The initial conservative screening level EEC calculations for aquatic systems were based on a direct application to water depths of 15 and 80 cm . The 15 cm depth was chosen to represent a temporary body of water that could be inhabited by amphibians. The 80 cm depth was chosen to represent a typical permanent water body for applications of pest control products in agriculture.

Table 13 (Appendix VI) summarizes the screening level risk assessment of myclobutanil to aquatic organisms. The acute level of concern is exceeded by a factor of 1.3 for freshwater fish following two field sprayer applications at 720 g a.i./ha to turf on golf courses, and by factors ranging from 2 to 7 for amphibians following two field sprayer applications at 720 g a.i./ha to turf on golf courses, six airblast applications at 136 g a.i./ha and five airblast applications at 80 g a.i./ha to grapes. The acute level of concern is also exceeded by a factor of 1.5 for estuarine/marine invertebrates following two field sprayer applications at 720 g a.i./ha to turf on golf courses.

The chronic level of concern is exceeded by factors ranging from 1.4 to 5 for amphibians following two field sprayer applications at 720 g a.i./ha to turf on golf courses, six airblast applications at 136 g a.i./ha and five airblast applications at 80 g a.i./ha for use on grapes.

A refined risk assessment was conducted for those taxa that exceeded the level of concern in the screening level risk assessment.

Spray Drift Refinement
Similar to the terrestrial risk assessment, the risk to aquatic organisms from spray drift off the treated site was also assessed taking into consideration the spray drift deposition of spray quality of ASAE medium for field sprayer (6%) and airblast early season (74%) and late season (59%) at 1 m downwind from the site of application. Table 14 (Appendix VI) summarizes the refined drift risk assessment of myclobutanil to aquatic organisms.

The acute or chronic LOC is not exceeded for any of the freshwater or estuarine/marine taxa following two field sprayer applications at 720 g a.i./ha to turf on golf courses. The acute LOC for amphibians is exceeded by factors of 3 and 2.4 respectively for six early and late season airblast applications at 136 g a.i./ha. The acute LOC for amphibians is exceeded by factors of 1.5 and 1.2 respectively for five early and late season airblast applications at 80 g a.i./ha.

The chronic LOC for amphibians is exceeded by factors of 2.2 and 2.0 respectively for six early and late season airblast applications at 136 g a.i./ha. The chronic LOC for amphibians is exceeded by a factor of 1.0 for five early airblast applications at 80 g a.i./ha.

The acute LOC for estuarine/marine invertebrates is not exceeded following two field sprayer applications at 720 g a.i./ha to turf on golf courses.

Runoff Refinement
For Level 1 aquatic ecoscenario assessment, estimated environmental concentrations (EECs) of myclobutanil from runoff into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m. The EEC's from Tables 2 and 3 in Appendix VII were used for this refined assessment.

The results of the assessment are summarized in Table 15 (Appendix VI). The highest peak and 21-day values were used for the acute and chronic risk assessments, respectively, for both the apple and turfgrass application scenarios. The acute and chronic LOC's were not exceeded for any of the freshwater species using these conservative EECs. The acute LOC was also not exceeded in estuarine/marine invertebrates for the Abbotsford B.C. or Charlottetown P.E.I. turf scenarios following two applications at 720 g a.i./ha. Aquatic organisms would, therefore, be at negligible risk from residues of myclobutanil in runoff following all applications in Canada.

4.2.3 Incident Reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the US EPA Ecological Incident Information System (EIIS).

There are currently no environmental-related incident reports involving myclobutanil in Canada.

There have been 3 myclobutanil incidents involving terrestrial plants reported in EPA's Ecological Incident Information System (EIIS). Two occurred from registered use on grapes and one from an undetermined use in a nursery. The certainty of all three incidents resulting from myclobutanil was listed as "possible".

5.0 Value

5.1 Commercial Class Products

Appendix I lists all myclobutanil products that are registered in Canada as of 1 January, 2009. Appendix II lists all of the Commercial Class product uses for which myclobutanil is presently registered; the registrant continues to support these uses.

5.2 Value of Myclobutanil

Myclobutanil is used to control a number of fungal diseases on a wide variety of field and greenhouse vegetables, orchard, nursery and greenhouse grown ornamental crops and golf course turf grass. Important uses of myclobutanil include foliar applications to control fungal diseases on apples, grapes and turf grass. It is essential to the management of disease resistance by providing an alternate mode of action to fungicides from other chemical families. Myclobutanil is also important to the ornamental industry for the control of diseases, especially powdery mildew. This industry typically lacks effective alternatives. It is also an integral part of integrated pest management programs for many vegetable and orchard crops and turf grass in Canada.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, for example, CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

During the review process, myclobutanil and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[6] and evaluated against the Track 1 criteria (table 16, appendix VI). The PMRA has reached the following conclusions:

- Myclobutanil does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Table 16, Appendix VI for comparison with Track 1 criteria.

- Myclobutanil does not form any transformation products that meet all Track 1 criteria.

[6] DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical are compared against the list in the *Canada Gazette.* The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Technical grade myclobutanil does not contain any contaminants of health or environmental concern identified in the Canada Gazette.

The use of formulants in registered pest control products identified in the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern maintained in the *Canada Gazette*[9] is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[10]

7.0 Summary

7.1 Human Health and Safety

7.1.1 Occupational Risk

Risk estimates associated with mixing, loading and applying activities for the currently registered label uses are not of concern, provided personal protective equipment are used. Post-application risks for workers were not of concern for the majority of scenarios; mitigation measures that would diminish the risk are considered agronomically feasible, with the possible exception of ornamental flowers and shrubs. Agronomically feasible restricted-entry intervals could not be determined for all greenhouse uses without further mitigation. A reduction in the number of applications for some greenhouse uses result agronomically feasible restricted-entry intervals. However, it is unknown whether the reduced number of applications is agronomically feasible.

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

8 DIR2006-02, PMRA Formulants Policy.

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

10 DIR2006-02, PMRA Formulants Policy.

7.1.2 Dietary Risk from Food

No dietary concerns were found from the acute (for females 13-49 years of age) and chronic (for the general population and all population subgroups, including infants, children, teenagers, adults and seniors) dietary (food + drinking water) risk assessments.

7.1.3 Non-Occupational Risk

Given that there are no residential uses of myclobutanil, a risk assessment for this scenario was not required.

7.1.4 Aggregate Risk (Food, drinking water and non-occupational exposure events)

The combined exposures of diet, drinking water and golfing or PYO activities do not represent a concern provided mitigation measures are applied as described in Section 8.

7.2 Environmental Risk

When applied in the Canadian environment myclobutanil is expected to be persistent in both terrestrial and aquatic environments. In terrestrial environments myclobutanil has the potential to leach to groundwater in certain soil types. On treated fields a significant amount of myclobutanil is expected to carry over to the next growing season. Myclobutanil may enter aquatic environments via spray drift and run-off. Once in the aquatic environment myclobutanil is expected to be persistent with a significant portion of residues partitioning to sediments.

In the terrestrial environment, the use of myclobutanil may pose a chronic risk to herbivorous birds and small wild mammals feeding directly on the treated fields. In the aquatic environment myclobutanil may pose a risk to some non-target aquatic organisms as a result of spray-drift, however aquatic organisms are not expected to be at risk as a result of run-off into aquatic habitats. To reduce the potential effects of myclobutanil in the environment, mitigation in the form of precautionary label statements and buffer zones are required. Environmental mitigation statements are listed in Appendix VIII (Label Amendments for Commercial Class Products Containing Myclobutanil).

7.3 Value

Myclobutanil is registered to control a number of diseases on a wide variety of field and greenhouse vegetables, orchard, nursery and greenhouse grown ornamental crops and golf course turf grass. Important uses of myclobutanil include foliar applications to control fungal diseases on apples, grapes and golf course turf grass. It is an integral part of disease management on a number of crops and on turf grass. It is also an important tool for resistance management.

8.0 Proposed Regulatory Decision

After a re-evaluation of the fungicide myclobutanil, Health Canada's PMRA, under the authority of the *Pest Control Products Act,* is proposing continued registration of myclobutanil products for sale and use in Canada provided that the mitigation measures to protect health and environment described in this document are implemented. Additional data are being requested to refine the risk assessment. The proposed mitigation measures and use limitations are presented in Appendix VIII.

8.1 Proposed Regulatory Actions

8.1.1 Proposed Regulatory Action Related to Human Health

The wettable powder formulation of myclobutanil is being voluntarily discontinued by the registrant.

For agricultural uses, the PMRA has determined that most worker risks during mixing, loading and application and during post-application activities are acceptable, provided that the mitigation measures listed in Appendix VIII are implemented. The PMRA has identified a risk concern for post-application activities in greenhouses.

8.1.1.1 Toxicological Information

Appendix VIII summarizes toxicological information for the commercial class products.

8.1.1.2 Proposed Mitigation for Dietary Exposure

No mitigation measures for dietary exposure are being proposed at this time.

8.1.1.3 Proposed Mitigation for Mixer, Loader and Applicator Exposure and Post-Application Exposure

Based on the exposure assessments described in Tables 1, 2, 3 and 4 of Appendix III C, recommendations to mitigate exposure include the proposal to clarify personal protective equipment and add increased restricted-entry intervals to the product labels (See Appendix VIII for details).

Agronomically feasible restricted-entry intervals could not be determined for all greenhouse uses.

Soluble Granules in Water Soluble Packaging (WSP):
All myclobutanil products currently formulated as soluble granules must be in water soluble packaging, and label instructions should be added to clearly indicate directions for water soluble packaging.

Number of Applications and Application Intervals:
The post-application assessment was based on the maximum number of applications and minimum interval between applications as listed in Table 8.1 below. It is necessary to ensure that the labels reflect the maximum number of application per year and interval between applications as specified in this Table.

The number of applications was reduced for greenhouse poinsettias. A minimum application interval of 14 days was applied to Saskatoon berries, based on label instructions for strawberries. A minimum application interval of 14 days was applied to Kentucky bluegrass grown for seed, based on label instructions for golf course turf. A maximum of 2 applications per year was applied for golf courses, based on information from the registrant. All other application frequencies and intervals are based on end use product current label instructions. Agronomically feasible REIs, application frequencies and application intervals could not be determined for greenhouse peppers, tomatoes, cucumbers, roses, gerbera, aster, chrysanthemums, hollyhock and phlox.

All labels should be changed to specify a maximum number of applications with a minimum number of days between applications (See Appendix VIII).

Application Rates
All labels on golf course uses should be changed to specify a maximum application rate of 7.3 grams per 100 square meters (0.73 kg a.i./ha) over a maximum of 8 hectares per day for golf course turf.

Maximum Spray Volume:
For the purpose of the risk assessment, the typical maximum water volume of spray solution was assumed to be 1000 L/ha, unless otherwise stated on the label. Therefore, labels should clearly state a maximum spray volume of 1000 L per hectare for all crops unless otherwise stated on the current label.

Use Precautions:
There may be potential for exposure to bystanders from drift following pesticide application to agricultural areas. To minimize human exposure from spray drift or from spray residues resulting from drift, a standard label statement is required.

Incidental exposure to myclobutanil can be reduced by adding a precautionary statement for all products.

It is recommended that the following additional statements should be added to all myclobutanil product labels:

> "Hazardous to humans and domestic animals. Keep out of reach of children."

"Causes eye irritation. A potential skin sensitizer. May cause irritation to the nose, throat and skin. Harmful if swallowed, inhaled, or absorbed through the skin. Do not swallow, get in eyes, on skin or breathe spray mist."

"Do not apply by air."

"Use only properly calibrated groundboom, chemigation or hand held equipment as specified by the label."

"Use only properly calibrated groundboom equipment for turf applications."

"Not for use by homeowners or other uncertified users."

"Do not use in residential areas (excepting golf courses). Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, school, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed."

Personal Protective Equipment

No new label statements are being proposed regarding personal protective equipment. However, for consistency between labels, and for the purpose of mitigating the risk of exposure to myclobutanil, labels should be amended to include similar directions regarding protective equipment.

Restricted-entry Intervals

The restricted-entry intervals listed below are proposed for addition to the appropriate labels. Agronomically feasible REIs, application frequencies and application intervals could not be determined for greenhouse peppers, tomatoes, cucumbers, roses, gerbera, aster, chrysanthemums, hollyhock and phlox.

Table 8.2 Recommended Restricted-entry Intervals

Crop	Activity	REI [a] (days)
apples, cherries (sweet & sour), peaches, nectarines	thinning	12
	hand harvest	5
	hand pruning, scouting, pinching, tying, training, hand weeding, propping, animal control, mechanical harvest (cherries only)	0.5
asparagus	all	2
grapes	cane turning and girdling	14
	hand harvesting & pruning, training, thinning, tying, leaf pulling	7
	hand line irrigation, scouting, hand weeding	0.5
strawberries	hand harvest, pinching, pruning, training	2
	irrigation, mulching, scouting, hand weeding	0.5
saskatoon berries	hand harvest, hand pruning, hand thinning	3
	scouting, hedging, irrigating, hand weeding	0.5
carnations	all	17
OUTDOOR ORNAMENTAL TREES & SHRUBS: pear (flowering), crab apple,(flowering), privet, dogwood, euonymus, hawthorn, juniper (flowering & non-flowering), honeysuckle, lilac, crab-apple (flowering); nursery crops: ash, amelanchier	all	0.5
Outdoor ornamental roses	all	11
OUTDOOR ORNAMENTAL FLOWERS, SHRUBS: roses, hollyhock, phlox nursery crops: roses, (cut and potted), gerbera, aster, chrysanthemums, geraniums iris, hollyhock, phlox	all	12
nursery poinsettias	all	0.5
greenhouse poinsettias	all	0.5
Kentucky bluegrass grown for seed	harvesting/transplanting treated turf, mowing, watering, irrigation, aerating, fertilizing, hand pruning, mechanical weeding, scouting, seeding	0.5

Crop	Activity	REI [a] (days)
golf course turf	transplanting treated turf	12
	mowing, watering, irrigation, aerating, fertilizing, hand pruning, repair, mechanical weeding, scouting, seeding, cup changing, grooming	dried spray

[a] Day at which the dermal exposure results in an MOE ≥100 or the minimum label REI of 0.5 days (or until spray has dried for golf courses).

8.1.1.4 Residue Definition for Risk Assessment and Enforcement

For all registered uses, the nature of the myclobutanil residue in livestock and plant commodities is adequately understood based on acceptable metabolism studies in lactating cows, laying hens, apples and grapes. The residue of myclobutanil in all livestock and dairy commodities is expressed as the parent compound *α*-butyl-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile, including its alcohol metabolite *α*-(3-hydroxybutyl)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile, the ketone metabolite *α*-(butyl-3-one)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile and the diol metabolite α-(3,4-dihydroxybutyl)-α-(4-chlorophenyl)-lain 1*H* -1,2,4-triazole-1-propanenitrile. The residue definition in all plant commodities is expressed as the parent compound *α*-butyl-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile, including its alcohol metabolite *α*-(3-hydroxybutyl)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and conjugate) and the ketone metabolite *α*-(butyl-3-one)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile.

All triazole-based fungicides share a common metabolite resulting from the release of the triazole ring (1,2,4-triazole) from the parent compound. In animals, the triazole ring is relatively stable and is the terminal form of the metabolite. In plants, 1,2,4-triazole may become conjugated to serine. The resulting compound, triazolyl-1-alanine (TA), may be oxidized to form triazolyl-1-acetic acid (TAA). TA and TAA are the primary terminal forms of the triazole ring in plants, though some free 1,2,4-triazole may remain. Based on the fact that, for the majority of triazole-based fungicides, the degree of formation of free 1,2,4-triazole in animals and the rate of oxidation of TA to TAA in plants are relatively low, it was previously concluded that TA is the only triazole metabolite to be regulated and included in the dietary risk assessment (E93-01). A common MRL of 2.0 ppm in all plant commodities has been established. However, due to its intrinsic toxicological properties, residue chemistry and human health risks associated with this metabolite – resulting from the use of all registered triazole-based fungicides – will be assessed separately. The risk assessment will have to be updated whenever a new food/feed use is added to the existing uses of any of the registered triazole-based fungicides and/or registration of a new triazole-based fungicide is petitioned.

For more information on the residue definition for myclobutanil, see Appendix IV.

8.1.1.5 Maximum Residue Limits for Myclobutanil in Food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian maximum residue limits and to remove MRLs that are no longer supported. The PMRA recognizes, however, that interested parties may want to retain an MRL in the absence of a Canadian registration to allow legal importation of treated commodities into Canada. The PMRA requires similar chemistry and toxicology data for such import MRLs as those required to support Canadian food use registrations. In addition, the PMRA requires residue data that are representative of use conditions in exporting countries, in the same manner that representative residue data are required to support domestic use of the pesticide. These requirements are necessary so that the PMRA may determine whether the requested MRLs are needed and to ensure they would not result in unacceptable health risks.

MRLs for domestic and import uses of myclobutanil have been established on registered agricultural commodities and published in Health Canada's List of MRLs Regulated under the *Pest Control Products Act* on the Maximum Residue Limits for Pesticides webpage. No modifications of the MRLs were proposed during the course of this re-evaluation.

Where no specific MRL is established for a pest control product under the *Pest Control Products Act*, subsection B.15.002(1) of the Food and Drug Regulations applies. This requires that residues do not exceed 0.1 ppm, which is considered a general MRL for enforcement purposes. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set for the concerned commodities.

Table 8.3 Myclobutanil MRLs in Canada

Commodity	MRL (ppm[1])
Almonds	0.1
Apricots	1.4
Asparagus	0.02
Blackberries, loganberries, raspberries	1.2
Currants	3.0
Mayhaws	0.5
Plums	2.0
Prune plums	8.0
Saskatoon berries (juneberries)	0.07
Tomatoes	0.3
Tomato purée	0.5
Tomato paste	1.0
Apples	0.5
Balsam apples	0.3

Commodity	MRL (ppm[1])
Balsam pears	0.3
Bananas	2.0
Bitter melons	0.3
Cantaloupes	0.3
Casaba melons	0.3
Fat of cattle	0.05
Liver of cattle	0.3
Meat of cattle	0.05
Meat by-products of cattle	0.05
Chayotes	0.3
Cherries	1.0
Cherries, dried	4.0
Chinese cucumbers	0.3
Chinese waxgourds	0.3
Citron melons	0.3
Crenshaw melons	0.3
Cucumbers	0.3
Fat of goats	0.05
Liver of goats	0.3
Meat of goats	0.05
Meat by-products of goats	0.05
Golden pershaw melons	0.3
Gourds (edible, other than those listed in this item)	0.3
Grapes	1.0
Fat of hogs	0.05
Liver of hogs	0.3
Meat of hogs	0.05
Meat by-products of hogs	0.05
Honey balls	0.3
Honeydew melons	0.3
Fat of horses	0.05
Liver of horses	0.3
Meat of horses	0.05
Meat by-products of horses	0.05
Mango melons	0.3
Milk	0.05
Nectarines	1.0
Nectarines, dried	7.0
Peaches	1.0
Peaches, dried	7.0
Peppers	1.0
Persian melons	0.3

Commodity	MRL (ppm[1])
Pineapple melons	0.3
Eggs	0.02
Fat of poultry	0.02
Meat of poultry	0.02
Meat by-products of poultry	0.02
Pumpkins	0.3
Raisins	10.0
Santa Claus melons	0.3
Fat of sheep	0.05
Liver of sheep	0.3
Meat of sheep	0.05
Meat by-products of sheep	0.05
Snake melons	0.3
Strawberries	0.5
Summer squash	0.3
Watermelons	0.3
Winter squash	0.3

[1] ppm: parts per million, equivalent to mg/kg

For supplemental MRL information regarding the international situation and trade implications, refer to Appendix IV.

8.2 Additional Data Requirements

8.2.1 Data requirements related to Toxicology

No additional data required.

8.2.2 Data Requirements Related to Occupational Exposure Assessment

The following data requirements are needed to support the continued registration of greenhouse uses:

DACO 5.9: Greenhouse foliage - Dislodgeable/Transferable Residue data for greenhouse crops and conditions that are reflective of the Canadian use pattern

8.2.3 Data Requirements Related to the Dietary Exposure Assessment

No additional data required.

8.2.4 Data Requirements Related to Environmental Risks

The following data requirements are needed to support the continued registration of myclobutanil and will be requested under section 12 of the PCPA:

DACO 9.4.5: Chronic toxicity to estuarine/marine invertebrates
DACO 9.5.2.4: Acute and chronic toxicity to estuarine/marine fish

List of Abbreviations

μg	micrograms
μm	micrometer
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
atm	atmosphere
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BW	body weight
CAS	chemical abstracts service
cm	centimetres
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
DT_{75}	dissipation time 75% (the time required to observe a 75% decline in concentration)
DT_{90}	dissipation time 90% (the time required to observe a 90% decline in concentration)
dw	dry weight
EC_{05}	effective concentration on 5% of the population
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
EDE	estimated daily exposure
EP	End-use Product
EEC	estimated environmental exposure concentration
ER_{25}	effective rate on 25% of the population
ER_{50}	effective rate on 50% of the population
FC	food consumption
FIR	food ingestion rate
g	gram
ha	hectare(s)
HPLC	high performance liquid chromatography
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEC	lowest observed effect concentration
LOD	limit of detection
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
mg	milligram

mL	millilitre
MS	mass spectrometry
MYC	Myclobutanil
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
N/R	not required
OC	organic carbon content
OM	organic matter content
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
REI	restricted-entry interval
RSD	relative standard deviation
SG	Soluble Granules
$t_{1/2}$	half-life
TGAI	Technical Grade Active Ingredient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
URMULE	User Requested Minor Use Label Expansion
USC	Use Site Category
US EPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
WP	Wettable Powder

Appendix I Registered Myclobutanil Products as of 1 January 2009[1]

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (% active ingredient)
27916	Technical	Dow AgroSciences Canada Inc.	Myclobutanil Technical Fungicide	Solid	95.5
22399	Commercial		Nova 40W Agricultural Fungicide	Soluble Granules	40
26585			Eagle WSP Turf & Ornamental Fungicide	Soluble Granules	40

[1] excluding discontinued products or products with a submission for discontinuation

Appendix II Registered Commercial Class Canadian Uses of Myclobutanil as of 5 September 2008

Site(s)	Pest(s)	Formulation Type[1]	Application Equipment	Application Rate (g a.i./ha)[2]		Maximum Number of Applications per Year	Typical Number of Days Between Applications	Supported Use?[3]
				Maximum Single	Maximum Cumulative			
Use-Site Category 14: Terrestrial Food crops								
Asparagus	Rust	SG	Ground application equipment	136 g /ha	680 g /ha	5	7	Y, M
Sweet cherries	Brown rot, powdery mildew			136 g /ha	816 g /ha	6	10-14	Y, M
Sour cherries	Brown rot, powdery mildew, leaf spot			136 g /ha	Unable to calculate	Not available	10	Y
Peaches and nectarines	Brown rot, powdery mildew			136 g /ha	816 g /ha	6	7	Y
Strawberries	Powdery mildew			136 g /ha	816 g /ha	6		Y, M
Grapes	Black rot, powdery mildew			80 g /ha	400 g /ha	5	14	Y
Saskatoon berry	Powdery mildew			4.52 g /100L [45.2 g /ha]	[135.6 g/ha]	3	Not available	Y
Use-Site Category 13: Terrestrial Feed crops and Use-Site Category 14: Terrestrial Food crops								
Apples	Scab	SG	Ground application equipment	136 g /ha	816 g /ha	6	7 - 10	Y
	Powdery mildew							
	Cedar apple rust and quince rust							
Use-Site Category 27: Ornamental Outdoors								
Hollyhock, phlox	Powdery mildew	SG	Ground application equipment	136 g /1000L water [136 g /ha]	[816 g /ha]	6	10	Y, M
Crabapple (flowering)	Rust, powdery mildew and scab							Y, M
Azalea/rhododendron, dogwood, Euonymus, honeysuckle, lilac	Powdery mildew						14	Y, M
Privet, dogwood	Anthracnose and Septoria leaf spot							Y, M
Crabapple (flowering), hawthorn (flowering), juniper, pear (flowering)	Rust							Y, M
Carnation	Rust			216 g /1000 L water [216 g /ha]	[1296 g /ha]	6	10	Y, M
Nursery grown ornamentals: amelanchier, ash, chrysanthemum, iris, hollyhock, phlox	Rust			136 g /1000 L water [136 g /ha]	[816 g /ha]			Y, M
Roses	Powdery mildew and black spot		Hand held or pressurized sprayers.	12 g /100 L water [120 g /ha]	[480 g /ha]	4	10	Y, M
Junipers	Rust						14	Y, M

Site(s)	Pest(s)	Formulation Type[1]	Application Equipment	Application Rate (g a.i./ha)[2]		Maximum Number of Applications per Year	Typical Number of Days Between Applications	Supported Use?[3]
				Maximum Single	Maximum Cumulative			
Use-Site Category 5: Greenhouse Food Crops								
Greenhouse peppers	Powdery mildew	SG	Ground application equipment	136 g /ha	408 g /ha	3 /crop cycle	12	Y, M
Greenhouse tomatoes	Powdery mildew			136 g /ha	272 g /ha	2	7	Y
Greenhouse cucumbers	Powdery mildew and gummy stem blight			136 g /ha	816 g /ha	6	14	Y
Use-Site Categories 6: Greenhouse Non-food Crops								
Cut and potted roses, gerbera, aster and chrysanthemums	Powdery mildew (*Sphaerotheca pannosa*, *Erysiphe cichoracearum*) and rust	SG	Ground application equipment	136 g /1000 L water [136 g /ha]	[816 g /ha]	6/ year	10	Y, M
Geraniums	Rust (*Puccinia pelargonii-zonatis)*					6/ growing season		Y, M
Poinsettias	Powdery mildew			112 g /1000 L water [112 g /ha]	[672 g /ha]			Y, M
Rose	Black spot			136 g /1000 L water [136 g /ha]	[816 g /ha]	6	14	Y, M
	Powdery mildew						10	
Use-Site Category 30: Turf								
Kentucky bluegrass grown for seed	Powdery mildew (*Erysiphe graminis*)	SG	Ground application equipment	100 g /ha	200 g /ha	2	Not available	Y
Turf grass (For use on golf courses only)	Brown patch		Hand held or pressurized sprayer	7.2 g /100 m^2	14.4 g /100 m^2	2	14	Y, M
	Stem rust			7.2 g /100 m^2	14.4 g /100 m^2	2	28	
	Summer patch			7.2 g /100 m^2	Can not be calculated	Not available	30	
	Grey snow mold			12.0 g /100 m^2	12.0 g /100 m^2	1	N/A	
	Dollar spot			8.0 g /100 m^2	16.0 g /100 m^2	2	14-21	Y

N/A = Not applicable, MYC = Myclobutanil

Footnotes:

1 SG = Soluble Granules
2 The application rate per hectare in square brackets has been calculated by the PMRA assuming application in 1000 L water /ha.
3 Y = Use is supported by the registrant; M = Use was registered as a User Requested Minor Use Label Expansion (URMULE)

Appendix III A Toxicology Profile for Myclobutanil

NOTE: Effects noted below are known or assumed to occur in both sexes unless otherwise specified.

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Metabolism/Toxicokinetic Studies		
Metabolism study (absorption, distribution, metabolism and excretion) of ^{14}C- myclobutanil (radio-labeled in the chlorophenyl ring) - Crl:CD-1 (ICR) BR mice		Absorption: ^{14}C-label was rapidly absorbed with peak concentrations in the blood at 0.25 - 1 hour. Distribution: the liver had a greater affinity (4 to 11 times greater) for the ^{14}C-label than blood although the liver/blood concentration ratio decreased with increasing dose. - the blood, plasma and liver concentrations were proportional to the dose as was the area under the curve of the whole blood concentration time curve. Metabolism: ^{14}C-myclobutanil was extensively metabolized to more-polar compounds; only 1-7% of the dose was excreted unchanged. - metabolic profiles were similar between males and females. - four fractions of the 15 isolated each accounted for > 10% of the excreted ^{14}C-label. - the disposition and metabolism of ^{14}C-myclobutanil was similar over the dose range studied. Excretion: clearance from the blood was biphasic with a rapid phase t½ of 0.63 to 0.88 hours (absent in high-dose males) and a slow phase t½ of 6.0 to 30.1 hours. - excretion of the ^{14}C-label was rapid and complete; after 96 hours 81-107% of the dose was excreted (no tissue accumulation after 96 hr.); most of the dose was excreted approximately equally in the urine (with cage-wash: 41-57%) and faeces (31-52%) of both sexes, within 24-48 hours.
Metabolism study (absorption, distribution, metabolism and excretion) of ^{14}C- myclobutanil (radio-labeled at the 3 and 5 carbons of the triazole ring) - Sprague-Dawley rats		Absorption: rapid absorption (based on the rate of excretion) Distribution:- highest concentrations were in liver, kidney and intestines (residues: at 4 days - ♂1.76%/♀0.33%; at 7 days - ♂0.54%/♀0.15%) Metabolism:- extensively metabolized; unchanged parent myclobutanil was estimated to represent only 2-3% of the excreted dose - six more-polar metabolites, all with oxygen substituents on the butyl group, were equally distributed in the faeces and urine of males but in females 75% was in the form of the sulphate conjugate of RH-9090 -excretion products included RH-9090 and RH-9089, the major unconjugated phenethyl triazole-containing metabolites found in plants. Excretion: - most (99.3%) of the radioactivity was rapidly eliminated in the urine (♂43%/♀36%) and faeces (♂56%/♀64%); half-life clearance was 11 hours in females and 15 hours in males - radioactivity in CO_2 was 0.02% or less

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Metabolism study (absorption, distribution, metabolism and excretion) of ^{14}C- myclobutanil (radio-labeled in the chlorophenyl ring) - Sprague-Dawley (Crl:CD BR) rats		Absorption: practically the entire dose (89-115 %) was absorbed following oral administration with peak plasma concentrations within 1 hour Distribution: ^{14}C-label appeared rapidly in the tissues of male rats and reached a peak within one hour to 6 hours, with liver concentrations at 1 hour 2 to 8 times greater than whole blood. Residual tissue levels in orally treated rats after 96 hours were generally less than 1% of the dose, with highest concentrations present in the liver, kidneys, adrenals, whole blood, thyroids and bone marrow. Metabolism: myclobutanil was extensively metabolised in the rats; only 1.0-3.6% of the excreted dose was the parent compound - although the same metabolites were in the excreta of males and females, there were 5 major fractions (> 10% ^{14}C-label) excreted in males but only one major fraction in females (53-61% of the radio-label; probably the sulfate conjugate of RH9090) -pretreatment for 2 weeks with myclobutanil had little effect on the distribution and metabolism of a pulse oral dose Excretion: clearance from the plasma was biphasic with a rapid phase t½ of 2 to 5 hours and a slow phase t½ of 26 to 32 hours - ^{14}C-label was rapidly eliminated from the tissues in a biphasic manner similar to plasma - At 96 hours the amount of ^{14}C-label in the tissues of both sexes was < 1% of the dose - Most of the dose was eliminated, essentially evenly distributed in the urine and faeces, within 24 hours (i.v. dose) or 24-48 hours (oral dose) and 82-97% of the recovered label was eliminated by 96 hours [urine (35-48%); faeces (32-46%)]
Acute Toxicity Studies		
Acute oral toxicity—mouse		LD_{50} = 1360 mg/kg bw **SLIGHTLY TOXIC**
Acute oral toxicity—rat		LD_{50} = 1600 mg/kg bw **SLIGHTLY TOXIC**
Acute dermal toxicity—rabbit		LD_{50} >5000 mg/kg bw Scant droppings and red-stains on the anogenital area (1/6). Local skin reactions: moderate to severe erythema and very slight edema on day 1; the erythema lasted beyond 14 days and edema was clear by day 6. **LOW TOXICITY**
Acute inhalation toxicity—rat		LD_{50} >5.1 mg/L **LOW TOXICITY**
Eye irritation—rabbit		Vascularization of the cornea was observed right through day 21 in one rabbit and corneal haziness lasted as long in another rabbit; irritating to both the iris and conjunctiva. Mean scores: 22.3 (24 hr); 1 (7 days) **MODERATE EYE IRRITANT**
Dermal irritation—rabbit		**MILD DERMAL IRRITANT**

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Dermal sensitization - Guinea pig	**POTENTIAL SKIN SENSITIZER**	
Subchronic Toxicity Studies		
3-month oral (feeding) — Crl:CD-1 (ICR) BR mouse	44.2	≥147 mg/kg bw/day (1000 ppm): histological changes in the liver (hepatocytic hypertrophy, swollen-vacuolated centrilobular hepatocytes, single large hepatocyte vacuoles, centrilobular individual cell hepatocyte necrosis and centrilobular necrotic hepatitis), ↑liver weight, accentuated lobular liver architecture, ↑liver MFO (hepatic mixed function oxidase) activity (♂), ↓serum cholesterol (♂), and cytoplasmic eosinophilia of the zona fasiculata cells of the adrenal glands (♂) ≥442 mg/kg BW/day (3000 ppm): ↓BW (♂ - sig. wk 2, 3, 5, 6, 9, 10, 11 & 12), ↓glucose (♀), ↓serum cholesterol, ↑ALT(♂), swollen/enlarged livers, and increased pigmentation in the spleen and in liver Kupffer cells, cytoplasmic eosinophilia and hypertrophy of the zona fasiculata cells of the adrenal glands 1472 mg/kg bw/day (10,000 ppm): clinical signs (scant droppings), ↓BW (♂ - 19%/♀ - 8%: wk 13), ↓food consumption (wk 1), changes in haematological parameters [↓Hct, ↓Hgb (♀), ↓MCV, ↓MCH, ↓WBC (♂), ↓lymphocytes (♂), ↑MCHC, ↑segmented neutrophils (♂), ↑platelets (♀)], changes in blood biochemical parameters [↓glucose, ↑AST, ↑ALT, ↑GGT, ↑SAP, ↑BUN], ↓kidney weight (♂), immature uteri; altered histopathology of the kidney (increased pigment in cortical tubular cells), ovary (absence of corpora lutea), bone marrow (immaturity - ↑myeloid/erythroid ratio), skin (mononuclear cell infiltration), thymus and mesenteric lymph nodes (necrosis), and liver (bile duct proliferation)

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
3-month oral (feeding) — COBS-CD(SD) BR rat	49.1	14.7 mg/kg bw/day (300 ppm):↑MFO (hepatic mixed function oxidase)(♂) ≥49.1 mg/kg bw/day (1000 ppm): accentuated lobular architecture of the liver, ↑MFO, ↑rel. liver weight ≥147.2 mg/kg bw/day (3000 ppm): histological alterations in the liver (hepatocellular hypertrophy, swollen hepatocytes, and individual hepatocellular necrosis), kidneys (↑pigmentation in convoluted tubular epithelium), adrenals (↑cortical vacuolization), thyroid (↑#small follicles), ovary (congestion), thymus (congestion); ↑liver and kidney weight; gross kidney and liver lesions; ↓BW gain; ↓BW [wk 6-12 (♂); wk 9 (♀)]; and slight serum chemistry changes (↑cholesterol, ↑ globulin, ↓AST, ↓albumin/globulin ratio) 491 mg/kg bw/day (10,000 ppm): ↓food consumption(P4), ↓BW (wk 1-13); histopathological changes in the liver (swollen-vacuolated hepatocytes, increased Kupffer cell pigmentation and coagulative necrosis), spleen (increased pigmentation in red pulp) and lung (increased alveolitis);, slight haematological changes (↓Hct, ↓Hgb, ↓MCV, ↓MCH, ↑RBC, ↑platelets), and clinical chemistry changes (↑SGPT, ↑GGT, ↑BUN, ↑cholesterol, ↑SAP, ↑serum total protein and ↑serum calcium) 1472 mg/kg bw/day (30,000 ppm): all rats died during the first 9 weeks of treatment
3-month oral (feeding) — Crj:CD SD rat	18.8	192 mg/kg bw/day: slight to moderate hepatocytic hypertrophy (♂ - 10/10; ♀ - 8/10), slight vacuolar degeneration of the renal tubular epithelium (♂ - 7/10), alterations of the adrenal gland [vacuolization of the cortical cells (♂ - 7/10), atrophy of the zona fasiculata (♂ - 5/10), fine vacuolization of the zona glomerulosa (♂ - 1/10)], changes in reproductive organ (moderate atrophy of the seminiferous tubule(s) and giant cell-like changes with absence of sperm cells in the epididymis in 1/10 ♂), ↓BW, blood chemistry changes (↓bilirubin, ↓glucose, ↓triglycerides), ↑liver wt., ↑kidney wt., ↓adrenal wt., slight ↑# ♂ with round cells in the urine, ↓food consumption (1st wk - ♂)

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
3-month oral (feeding) — Beagle dog	5.9	≥5.9 mg/kg bw/day: histological liver changes (centrilobular or midzonal hepatocellular hypertrophy)(3/4 ♂) ≥23.6 mg/kg bw/day: histological liver changes (centrilobular or midzonal hepatocellular hypertrophy)(8/8), ↑liver weights (♂), ↑incidence and severity of unilateral chronic nephritis (♂), ↑ALP 47.1 mg/kg bw/day): ↓BW, ↓food consumption, ↑liver weights, ↑platelets
1-year oral (feeding) — Beagle dog	3.09	≥14.3/15.7 mg/kg bw/day (400 ppm): hepatocellular hypertrophy, ↑liver weights (rel. and absol.) (♀), ↑kidney weights (rel.) (♂), ↑ALP (♀) 54.2/58.2 mg/kg bw/day (1600 ppm): increased severity of effects on the liver: ↑liver weights, ↑incidences of accentuated lobular architecture and hepatocellular hypertrophy (predominantly centrilobular but panlobular in severe cases), enlarged hepatocytes with large clear cytoplasmic spaces (4/6 ♀), ↓BW (♂ - week 1, ♀ - week 1-5), ↓food consumption (♂ - week 1, ♀ - throughout the study), changes in haematology [↓RBC (♂), ↑platelet count (♂)] and blood chemistry [↑iP, ↑ALP, ↑ALT (♂), ↑GGT (♀), ↓albumin]
2-year feeding study — Crl:CD - 1 (ICR)BR mouse	13.7	13.7/16.5 mg/kg bw/day (100 ppm): ↑MFO activity (♂ - 6 months; ♀ - 3, 6 & 12 months; no measurements were made at 24 months) 70.2/85.2 mg/kg bw/day (500 ppm): ↑MFO activity (♂&♀ - 3, 6 & 12 months; no measurements were made at 24 months), liver effects [↑ALT (♀ - 3 months), ↑liver weight (absol.. & rel.), ↑hepatocyte hypertrophy & periportal punctate hepatocyte vacuolations (3, 6 & 12 months)(♂), ↑Kupffer cell pigmentation (6 & 12 months)(♂), ↑individual hepatocellular necrosis (12 months)(♂), focal hepatocellular alterations and multifocal heptocellular vacuolation, which were not associated with any hypertrophy (24 months)] No treatment-related increases in tumour incidence were observed. **not oncogenic**

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
18-month feeding study — Crl:CD - 1 (ICR)BR mouse (Supplementary - repeat of above at higher dose)	-	393.5 mg/kg bw/day: ↓BW (sig. decreased throughout 18 months: 2-12% control), ↓BW gain (decreased 12-26% of control over 18 months), ↓ food consumption (first 2 wk, then intermittently), ↑WBC, ↑liver weight (absol. and rel.), ↑liver pathology (hepatocellular hypertrophy, necrosis of single hypertrophied hepatocytes, hepatocellular vacuolation, yellow-brown pigment in the Kupffer cells and cytoplasmic eosinophilia) and hypertrophy of the cells of the zona fasiculata area of the adrenal cortex. No treatment-related increases in tumour incidence were observed. **not oncogenic**
2-year feeding study — Sprague-Dawley rat	2.49/52.34 (♂/♀)	9.84/12.86 mg/kg bw/day (200 ppm): ↓testicular weight (absol.)(24 months), ↑testicular atrophy (24 months), ↑MFO activity (♀ - 3 months) 39.21/52.34 mg/kg bw/day (800 ppm): ↓testicular weight (absol.)(12 & 24 months), ↑testicular atrophy (12, 17 & 24 months), slight ↑liver weight [♀ - 3 months (rel.) & 6 months (absol.)], slight ↑MFO activity (♀ - 3 months; ♂ - 3 & 6 months; not measured at 17 & 24 months), slight ↓BW, slight ↓BW gain, slight ↓food consumption (♂). No treatment-related increases in tumour incidence were observed. **not oncogenic**
2-year feeding study — Sprague-Dawley rat (Supplementary - repeat of above at higher dose)	-	106.08/135.62 mg/kg bw/day (2500 ppm): ↓BW, ↑liver wts. (absol. & rel.), ↑incidences of centrilobular to midzonal hepatocellular enlargement and vacuolization in the liver, testicular atrophy, ↓testes wts., ↓epididymides wts., increases in bilateral aspermatogenesis in the testes, ↑incidence of hypospermia and cellular debris in the epididymides, ↑incidence of arterititis/periarteritis in the testes. No treatment-related increases in tumour incidence were observed. **not oncogenic**

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Reproductive and Developmental Toxicity Studies		
Two-generation reproduction feeding study — Crl: CD (SD) BR rat	Parental, Reproduction, and Offspring: 14.9	Parental:14.9 mg/kg bw/day (200 ppm): ↑liver weight (P1/P2 ♂), centrilobular hepatocellular hypertrophy (P2 ♂)(liver effects considered adaptive in the ♂ at this dose level) 74.5 mg/kg bw/day (1000 ppm): liver effects - P1/P2 [centrilobular hepatocyte hypertrophy, ↑liver weight (absol. & rel.)], ↓BW (P1 ♂ - wk 1 & 2; P2 ♂ throughout the pre-mating period.), ↓BW gain [F1a pups (selected for P2) prior to weaning], ↓ food consumption (P1 during the first few weeks of dosing & P2 ♂ throughout pre-mating, possibly due to palatability) Developmental/Reproductive: 74.5 mg/kg bw/day (1000 ppm): testicular effects (P_2 ♂ - grossly small flaccid testes, testicular and prostate atrophy, ↓epididymal spermatozoa and/or necrotic spermatocytes), ↓fertility index (n.s.) (F_{1b}, F_{2a}, F_{2b}), ↓gestation index (n.s.) (F_{1a}, F_{2b}), ↓mean litter size (F_{2a}), ↑incidence stillborn pups,↓BW gain pups during lactation (lower than controls by day 4 or 7 increasing difference up to day 21) Note: Pronounced testicular effects were noted in the P_2 animals (first generation parents) but not in the P_1's (original parents). This difference was attributed to the longer duration of the dosage over a more sensitive period of life (i.e., *in utero*, birth through to mating) in the P_2's, compared to the P_1's which received the dosage only as adult animals prior to mating. **fetal sensitivity (qualitative)**

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Developmental study (gavage) — Crl: CD (SD) BR rat	Maternal: 87 Developmental: 29	Maternal: ≥290 mg/kg bw/day: clinical signs (rough hair coat, desquamation, salivation) 435 mg/kg bw/day: clinical signs (alopecia, red exudate around mouth, scant/soft faeces), ↓BW (day 10), ↓BW gain Developmental: ≥87 mg/kg bw/day: ↑resorptions/litter, ↓# live fetuses/implantation (viability index) ≥290 mg/kg bw/day: ↑incidence of skeletal variations, mainly in the ribs (14th rudimentary and 7th cervical ribs) 435 mg/kg bw/day: hydrocephaly [2/100 fetuses (2 litters)] **fetal sensitivity (qualitative and quantitative)**
Developmental study (gavage)—New Zealand White rabbit	Maternal and Developmental: 60	Maternal: 200 mg/kg bw/day:↑frequencies of irregular faeces &/or bloody urine, ↓BW/BW gain throughout gestation Developmental: 200 mg/kg bw/day: ↑frequency of abortions, ↑# resorption/litter, ↑# litters with >2 resorptions, ↑# litters totally resorbed, ↓viable fetuses/implants (viability index), ↓litter size (viable fetuses/litter), ↓fetal BW **fetal sensitivity (qualitative)**
Genotoxicity Studies		
Ames reverse mutation test—*Salmonella typhimurium* TA1535, TA1537, TA98, TA100	**Negative**	
Ames reverse mutation test—*Salmonella typhimurium* TA1535, TA1537, TA98, TA100	**Negative**	
Ames reverse mutation test—*Salmonella typhimurium* TA1535, TA1537, TA98, TA100	**Negative**	
Ames reverse mutation test—*Salmonella typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2 uvrA	**Negative**	

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
HGPRT gene mutation assay. Point mutation (hprt) assay - Chinese hamster ovary (CHO) cells	**Negative**	
In vivo chromosome aberration assay - CR CD1 mice bone marrow	**Negative**	
In vivo chromosome aberration assay - CR CD1 (ICR) mice bone marrow	**Negative**	
In vitro chromosome aberration assay - Chinese hamster ovary (CHO) WB1 cells	**Negative**	
DNA repair - *Bacillus subtilis* H17, M45	**Negative**	
Unscheduled DNA synthesis - rat hepatocyte culture	**Negative**	
Dominant lethal test - Crl: COBS CD (SD) BR rats	**Negative**	
Mechanistic Studies		
Disruption of testosterone homeostasis as a mode of action for the reproductive toxicity of triazole fungicides in the male rat - timed pregnant Wistar Han IGS rats	6.1 (based on reduced fertility index and decreased pituitary weight) 32.9 ((based on elevated serum testosterone)	<u>6.1 mg/kg bw/day (100 ppm)</u>: ↑testis weights (absol.)(at PND1), <u>32.9 mg/kg bw/day (500 ppm)</u>: ↑testis weights (absol.)(at PND22), ↓pituitary weight (PND92), ↑ventral prostate weights (rel. & absol.)(at PND92), ↓fertility index <u>133.9 mg/kg bw/day (2000 ppm)</u>: ↑testis weights (absol.)(at PND1), ↓pituitary weight (PND92), ↑anogenital distance (AGD) (indicating hypervirilization), ↑liver weights (rel.)(at PND1, 50, & 92), hepatocellular hypertrophy (PND92), ↑serum testosterone (at PND92 & 99), ↓insemination index, ↓fertility index This study was designed to identify potential modes of action for the reproductive toxicity of three triazole fungicides: myclobutanil, propiconazole and triadimefon. It was concluded that disruption in steroid homeostasis is the key event in a common mode of action leading to abnormal reproductive development and diminished reproductive function.

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Effect of conazole fungicides on reproductive development in the female rat - timed-pregnant Wistar-Han rats	39	152.8 mg/kg bw/day (2000 ppm): ↑anogenital distance (AGD), delay in vaginal opening (VO), ↑ovary weight In this study, AGD was significantly increased, ovarian weight was significantly increased and VO was significantly delayed by the high dose of myclobutanil. These results are consistent with an androgenic effect or inhibition of estrogen production (antiestrogenic effect). It was concluded that developmental exposure to high concentrations of the triazole fungicides, propiconazole, myclobutanil and triadimefon adversely impacted reproductive development in the female rat. The antiestrogenic activities of the triazole fungicides have been attributed to their being aromatase inhibitors (i.e., inhibit conversion of testosterone to estrogen).
Gene expression profiling in the liver - CD-1 mice	5 mg/kg bw/day: ↑liver weights (rel. - 13.7%), mild centrilobular to midzonal hepatocyte hypertrophy 150 mg/kg bw/day: ↑liver weights (rel. - 10.9%), mild centrilobular to mid-zonal hepatocyte hypertrophy This study examined 3 other triazoles in addition to myclobutanil. All 4 triazoles (myclobutanil, fluconazole, propiconazole, triadimefon) caused hepatocyte hypertrophy and all except triademefon increased relative liver/body weight ratios at the middle and high doses. Cytochrome P450 enzymes (CYP) and xenobiotic metablizing enzymes (XME) were differentially expressed in response to the triazoles. While several CYP and XME genes were differentially expressed in response to all 4, or 3 of the 4 triazoles, differential expression of numerous other CYP and XME genes discriminated between the various triazoles, consistent with differences in CYP enzyme activities, indicating possible differences in the mechanism of hepatotoxicity or the dose response.	

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Gene expression profiling in liver and testis - Sprague -Dawley rats		75 mg/kg bw/day: ↑liver weights (rel. - 15.0%), mild centrilobular hepatocyte hypertrophy (2/5) 150 mg/kg bw/day: ↑liver weights (rel. - 13.4%), mild centrilobular to panlobular hepatocyte hypertrophy ↑testis weight (rel. - marginally significant), ↑serum testosterone (> 2-fold), ↓sperm motility This study examined 3 other triazoles in addition to myclobutanil. All 4 triazoles (myclobutanil, fluconazole, propiconazole, triadimefon) caused hepatocyte hypertrophy and increased relative liver/body weight ratios at the middle and high doses. Statistically significant increases in testis weight, increases in serum testosterone and reductions in sperm motility were noted only with myclobutanil (mean testosterone levels after treatment were even higher with triadimefon than with myclobutanil, but the ANOVA was not statistically significant; triadimefon also produced a downward trend in sperm motility, but again, not significant. In toxicology studies of the 4 triazoles only myclobutanil and triadimefon are reported testicular or reproductive toxicants). No treatment-related testis histopatholgy was observed.

Appendix III B Toxicology Endpoints for Health Risk Assessment for Myclobutanil

Exposure Scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE[a]
Acute dietary General Population	An acute reference dose was not calculated for the general population since there was not an endpoint of concern			
Acute dietary Females 13-49 years of age	NOAEL = 29	Increased resorptions/litter and decrease in viability index	Developmental study—rat	1000 PCPA factor of 10 was retained for fetal sensitivity and the seriousness of the endpoint (fetal death)
	ARD = 0.029 mg/kg bw/day			
Chronic dietary	NOAEL =2.5	Decreased testicular weight and increased testicular atrophy	2-year feeding study—rat	100
	ADI = 0.025 mg/kg bw/day			
Short[b]-term oral, dermal and inhalation	NOAEL = 29	Increased resorptions/litter and decrease in viability index	Developmental study—rat	1000 An additional 10-fold factor was applied to protect for a sensitive subpopulation, namely females 13-49 years of age
Intermediate[c]-term oral, dermal and inhalation[d]	NOAEL = 2.5	Decreased testicular weight and increased testicular atrophy	2-year feeding study—rat	100
Aggregate risk assessment-food and drinking water	The most relevant studies are those selected for the Acute Reference Dose, females 13-49 years of age, for acute and short term exposure scenarios and the Acceptable Daily Intake for intermediate and long term exposure scenarios			
Cancer	non-carcinogenic			

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments

[b] Duration of exposure is 1-30 days

[c] Duration of exposure is 1-6 months

[d] Because an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) should be used in route-to-route extrapolation

Appendix III C Mixer/Loader/Applicator and Post-Application Risk Assessment

Table 1 Intermediate-Term M/L/A exposure estimates and MOEs with Moderate Personal Protection Equipment (PPE) [a]

Crop	Form[b]	Application Equipment[c]	Application Rates[d] (kg a.i./ha)	Area treated per day[e] (ha or L)	Daily Exposure (µg/kg/day)		Margins of Exposure (Target of 100)		
					Dermal[f]	Inhalation[g]	Dermal[h]	Inhalation[i]	Combined[j]
Greenhouse peppers, tomatoes and cucumbers	SG	LP handwand	1.36E-04 kg a.i./L	150 L	0.11	1.32E-02	23336	189788	20781
		backpack			0.38	1.81E-02	6606	138139	6305
apples	SG	airblast	0.136	16	7.70	0.186	325	13449	317
cherries (sweet and sour), peaches, nectarines	SG	airblast	0.136	16	7.70	0.186	325	13449	317
asparagus	SG	groundboom	0.136	80	2.25	0.177	1111	14109	1030
grapes	SG	airblast	0.08	16	4.53	0.109	552	22863	539
strawberry	SG	groundboom	0.136	80	2.25	0.177	1111	14109	1030
		chemigation		140	1.08	0.049	2321	51062	2220
Saskatoon berries	SG	airblast	0.0452	16	2.56	0.062	977	40465	954
		LP handwand	4.52E-05 kg a.i./L	150 L	0.04	4.38E-03	70214	571044	62526
		backpack	4.52E-05 kg a.i./L	150 L	0.13	6.01E-03	19877	415639	18970
Ornamental trees & shrubs: crab-apple (flowering) pear (flowering), privet, dogwood, euonymus, hawthorn, juniper (flowering) nursery crops: ash, amelanchier	SG	airblast	0.136	16	7.70	0.186	325	13449	317
		HP handwand	1.36E-04 kg a.i./L	3750 L	8.94	1.10	280	2272	249
		LP handwand	1.36E-04 kg a.i./L	150 L	0.11	1.32E-02	23336	189788	20781
		backpack	1.36E-04 kg a.i./L	150 L	0.38	1.81E-02	6606	138139	6305
Outdoor roses, juniper	SG	airblast	0.12	16	6.80	0.16	368	15242	359
		LP handwand	1.2E-04	150 L	0.09	1.2E-02	26447	215093	23551
		backpack	1.2E-04	150 L	0.33	1.6E-02	7487	156558	7145

Crop	Form[b]	Application Equipment[c]	Application Rates[d] (kg a.i./ha)	Area treated per day[e] (ha or L)	Daily Exposure (µg/kg/day)		Margins of Exposure (Target of 100)		
					Dermal[f]	Inhalation[g]	Dermal[h]	Inhalation[i]	Combined[j]
Ornamental flowers, shrubs: roses, hollyhock, phlox, azalea/rhododendron, honeysuckle, lilac; nursery crops: iris, chrysanthemums, hollyhock, phlox, roses (cut and potted), gerbera, aster	SG	airblast	0.136	16	7.70	0.186	325	13449	317
		LP handwand	1.36E-04 kg a.i./L	150 L	0.11	1.32E-02	23336	189788	20781
		backpack	1.36E-04 kg a.i./L	150 L	0.38	1.81E-02	6606	138139	6305
carnations	SG	airblast	0.216	16	12.23	0.295	204	8468	200
		LP handwand	2.16E-04 kg a.i./L	150 L	0.17	0.02	14693	119496	13084
		backpack	2.16E-04 kg a.i./L	150 L	0.60	0.03	4159	86976	3970
Ornamental flowers (including greenhouse): Roses, (cut and potted), gerbera, aster, chrysanthemums, geraniums	SG	airblast	0.136	16	7.70	0.186	325	13449	317
		LP handwand	1.36E-04 kg a.i./L	150 L	0.11	0.0132	23336	189788	20781
		backpack	1.36E-04 kg a.i./L	150 L	0.38	0.0181	6606	138139	6305
poinsettias	SG	airblast	0.112	16	6.34	0.153	394	16330	385
		LP handwand	1.12E-04 kg a.i./L	150 L	0.09	0.011	28336	230457	25234
		backpack	1.12E-04 kg a.i./L	150 L	0.31	0.015	8022	167740	7656
Turf (Kentucky bluegrass grown for seed)	SG	groundboom	0.10	30	0.62	0.049	4029	51170	3735
Turf (golf course only)	SG	groundboom	0.73	8	1.21	0.095	2069	26286	1918

[a] An open mixing and loading system and open cab applications. Moderate Personal Protection Equipment (PPE) for all operators: cotton coveralls over a single layer (long pants and a long-sleeved shirt) with chemical-resistant gloves.

[b, c] SG = Soluble granules in Water Soluble Packaging; HP = high pressure; LP = low pressure

[d] Maximum listed label rate in kilograms of active ingredient per hectare (kg a.i./ha) unless otherwise specified as kilograms of active ingredient per litre (kg a.i./L). The typical maximum water volume of spray solution is assumed to be 1000 L/ha where necessary for handheld equipment.

[e] Based on default assumptions and registrant response data. (Dow AgroSciences Canada, 2008)

[f] Where dermal exposure µg/kg/day = (unit exposure × DA × area treated × rate)/70 kg bw. Dermal absorption (DA) value = 50%

[g] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw.

[h] Based on an intermediate-term oral NOAEL of 2.5 mg/kg bw/day and a target MOE of 100.

[i] Based on an intermediate-term oral NOAEL of 2.5 mg/kg bw/day and a target MOE of 100.

[j] Combined MOE = $1/(1/MOE_{dermal} + 1/MOE_{inhalation})$.

Table 2 Agricultural and Ornamental Intermediate-Term Post-Application Exposure Estimates, MOEs and REIs

Crop	Applications per Year		Rates[c] (kg a.i./ha)	Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] at REI (µg/ cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
	Number[a]	Interval[b] (days)							
Greenhouse peppers	3	12	0.136	All	1800	0.82	83.93	30	N.D.
Greenhouse tomatoes	2	7	0.136	All	1800	0.54	55.95	45	N.D.
Greenhouse cucumbers	6	14	0.136	All	1800	1.63	167.86	15	N.D.
apples	6	7	0.136	thinning	3000	0.15	24.94	100	12
				hand harvest	1500	0.30	26.07	96	5
				hand pruning, scouting, pinching, tying, training	500	0.52	14.72	170	0.5
				hand weeding, propping, animal control	100	0.52	2.94	849	0.5
cherries (sweet & sour), peaches, nectarines	6	7	0.136	thinning	3000	0.15	24.94	100	12
				hand harvest	1500	0.30	26.07	96	5
				hand pruning, scouting, pinching, tying, training	500	0.52	14.72	170	0.5
				mechanical harvest (cherries only)	200	0.52	5.89	425	0.5
				hand weeding, propping, animal control	100	0.52	2.94	849	0.5
asparagus (post-harvest)	5	7	0.136	transplanting	1000	0.41	23.53	106	2
				irrigation, scouting	500	0.51	14.52	172	0.5
				hand weeding	300	0.51	8.71	287	0.5
grapes	5	14	0.08	cane turning and girdling	19300	0.02	26.41	95	14
				hand harvesting & pruning, training, tying, thinning, leaf pulling	8500	0.06	26.71	94	7
				hand line irrigation	1100	0.13	7.94	315	0.5
				scouting, hand weeding	700	0.13	5.05	495	0.5

Crop	Applications per Year		Rates[c] (kg a.i./ha)	Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] at REI (µg/ cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
	Number[a]	Interval[b] (days)							
strawberries	6	14	0.136	hand harvest, pinching, pruning, training	1500	0.29	24.48	102	2
				irrigation, mulching, scouting, hand weeding	400	0.35	8.06	310	0.5
Saskatoon berries	3	14	0.045	hand harvest, hand pruning, hand thinning	5000	0.08	24.12	104	3
				scouting	1000	0.12	6.62	378	0.5
				hedging, irrigating, hand weeding	500	0.12	3.31	756	0.5
Carnations	6	10	0.216	all	4000	0.11	25.24	99	17
Outdoor ornamental shrubs and trees: pear (flowering), privet, dogwood, euonymus, hawthorn, juniper (flowering), honeysuckle, lilac, crab apple (flowering)	6	14	0.136	all	400	0.35	8.06	310	0.5
azalea/rhododendron	6	14	0.136	all	4000	0.11	25.29	99	11
Outdoor ornamental shrubs and trees: crab-apple (flowering); nursery crops: ash, amelanchier	6	10	0.136	all	400	0.42	9.53	262	0.5
Outdoor ornamental roses	4	10	0.12	all	4000	0.11	26.04	96	11
Outdoor ornamental juniper	4	14	0.12	all	400	0.31	7.09	352	0.5
Outdoor ornamental flowers: roses, hollyhock, phlox, nursery crops: iris, chrysanthemums, hollyhock, phlox	6	10	0.136	all	4000	0.12	26.91	93	12
Greenhouse: roses, (cut and potted), gerbera, aster, chrysanthemums, geraniums	6	10	0.136	all	4000	1.63	373.03	7	N.D
Greenhouse: roses, (cut and potted), gerbera, aster, chrysanthemums, geraniums	1	n/a	0.136	all	4000	0.27	62.17	40	N.D.

Crop	Applications per Year		Rates[c] (kg a.i./ha)	Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] at REI (µg/ cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
	Number[a]	Interval[b] (days)							
Nursery: roses, (cut and potted), gerbera, aster, chrysanthemums, geraniums	6	10	0.136	all	4000	0.12	26.91	93	12
Greenhouse poinsettias	6	10	0.112	all	400	1.34	30.72	81	0.5
Greenhouse poinsettias	5	10	0.112	all	400	1.12	25.60	98	0.5
Nursery poinsettias	6	10	0.112	all	400	0.34	7.85	319	0.5
PYO (Child) Cherries (sweet & sour), peaches, nectarines	6	7	0.136	hand harvest	639	0.30	12.96	2238	5
PYO (Adult) Cherries (sweet & sour), peaches, nectarines	6	7	0.136	hand harvest	1500	0.30	6.52	4449	5

[a] The label listed number of applications per year. Six applications per year were assumed for brown rot control in cherries based on label instructions for peaches and nectarines. No application interval was specified for Saskatoon berries; so an application interval of 14 days was assumed, based on label directions for strawberries. Number of applications refined for greenhouse uses. Greenhouse peppers, tomatoes and cucumbers were also assessed using 1 application, which resulted in an MOE of 89. This MOE failed to reach the target MOE of 100.

[b] The minimum listed label application interval described in days.

[c] Maximum listed label rates expressed in kilograms a.i./hectare.

[d] Transfer coefficients are from the Science Advisory Council for Exposure Agricultural Transfer Coefficient document and any amendments thereof. High bush blueberry TCs were used as surrogate data to evaluate Saskatoon berries. TCs were scaled accordingly for the Pick-Your-Own (PYO) assessment.

[e] Based on DFR data, at x days after application, where x is the day when an MOE ≥100 is determined or the proposed REI. Default peak (day 0) DFR value of 20% of the application rate and the default dissipation rate of 10% (or 0% for greenhouses) per day were used for all agricultural crops except grapes. For grapes a peak (day 0) DFR value of 13% of the application rate and a dissipation rate of 11% per day was used (Zogorski, 1987a).

[f] Dermal exposure = DFR or TTR × TC × 8 hr × DA / 70 kg. Dermal absorption (DA) value = 50%[g] The resulting MOE on the recommended REI day. Based on the intermediate-term oral NOAEL of 2.5 mg/kg/day and a target MOE of 100. Shaded cells indicate those calculated MOEs that failed to meet the target MOE of 100. MOEs in the range of the target MOE were considered to be acceptable due to conservatisms in the risk assessment. PYO (pick your own) assessments based on the short-term oral NOAEL of 29 mg/kg/day and a target MOE of 1000.

[h] Day at which the dermal exposure results in an MOE ≥100 or the minimum REI of 12 hours. N.D. = unable to determine. All REIs are set following the final application.

Table 3 Turf Intermediate-Term Post-Application Exposure Estimates, MOEs and REIs

Crop	Applications per Year		Rates [c] (kg a.i./ha)	Activity	Transfer Coefficient [d] (cm^2/hr)	DFR [e] at REI (µg/ cm^2)	Dermal Exposure [f] (µg/kg bw/day)	MOE [g]	REI [h] (days)
	Number [a]	Interval [b] (days)							
Turf (Kentucky bluegrass grown for seed)	2	14	0.10	harvesting, transplanting treated turf	6800	0.03	11.94	209	0.5
				mowing, watering, irrigation	3500	0.03	6.14	407	0.5
				aerating, fertilizing, hand pruning, mechanical weeding,	500	0.03	0.88	2848	0.5
Turf (golf courses)	2	14	0.73	harvesting, transplanting treated turf	6800	0.06	24.61	102	12
				mowing, watering, irrigation	3500	0.22	16.82	149	dried spray
				aerating, fertilizing, hand pruning, mechanical weeding, scouting, seeding	500	0.22	6.41	390	dried spray
Youth Golfing	2	14	0.73	golfing	345	0.22	3.97	7309	dried spray

[a] The label listed number of applications per year. Two applications per year were assumed for golf courses based on registrant response data (Dow AgroSciences, 2008).

[b] The minimum listed label application interval described in days. A minimum interval of fourteen days between applications was assumed in the risk assessment for Kentucky bluegrass grown for seed on sod farms, based on label instructions for golf course turf.

[c] Maximum listed label rates expressed in kilograms a.i./hectare. The rate for golf course turf was assumed to be 0.73 kg a.i./ha based on registrant response data (Dow AgroSciences, 2008).

[d] Transfer coefficients are from the Science Advisory Council for Exposure Agricultural Transfer Coefficient document and any amendments thereof. TCs were scaled accordingly for the assessment of youth golfers.

[e] Based on TTR data, at x days after application, where x is the day when an MOE ≥100 is determined or the proposed REI. A peak (day 0) DFR value of 2.5% of the application rate and the default dissipation rate of 10% per day were used (Meyer, 1999).

[f] Dermal exposure = TTR × TC × 8 hr × DA/70 kg (A duration of 3 hrs was used for the "mowing" activity group for golf courses, based on information from the registrant (Dow AgroSciences, 2008; Dow AgroSciences, 2009)). Dermal absorption (DA) value = 50%

[g] The resulting MOE on the recommended REI day. Based on the intermediate-term oral NOAEL of 2.5 mg/kg/day and a target MOE of 100.

[h] Day at which the dermal exposure results in an MOE ≥100 or the minimum REI of dried spray (or until spray dries). All REIs are set following the final application.

Table 4 Aggregate Exposure for PYO Operations and Golf Course Turf

Crop[a]	Sub-Population[e]	Dermal Exposure[b]	Dietary Exposure	Aggregate Exposure[c]	Aggregate MOE[d]
PYO [cherries (sweet & sour), peaches, nectarines]	Adult	6.52	1.59	8.11	3577
Turf (golfing)	Youth	3.97	3.29	7.17	4046

[a] Cherries (sweet & sour), peaches and nectarines are considered to be representative of all PYO orchard crops for the purposes of assessing exposure.

[b] Dermal exposure and MOE values based on the values calculated in Tables 2 & 3 of Appendix II.

[c] Aggregate exposure = dermal exposure + dietary exposure

[d] The resulting aggregate MOE on the recommended REI day. Aggregate MOEs were calculated by summing the route-specific exposures and comparing to the short-term oral NOAEL of 29 mg/kg/day and a target MOE of 1000.

[e] An aggregate PYO assessment was not required for children because no acute dietary endpoint was identified for this subpopulation. An acute dietary endpoint was only identified for females aged 13-49. Youth golfers were used to represent the potential risk to all golfers (both youth and adult) due to their lower body weight.

Appendix III D Dietary Exposure and Risk Estimates for Myclobutanil

Table 1 Dietary Exposure and Risk Estimates of Myclobutanil

Population Subgroup	Acute Dietary[1] (99.9th Percentile)		Chronic Dietary[2]	
	Exposure (mg/kg/day)	%ARfD	Exposure (mg/kg/day)	%ADI
General Population (total)	N/A		0.0043	17
All Infants (<1 year old)			0.0127	51
Children 1-2 years old			0.0068	27
Children 3-5 years old			0.0063	25
Children 6-12 years old			0.0043	17
Youth 13-19 years old			0.0032	13
Adults 20-49 years old			0.004	16
Adults 50+ years old			0.0041	16
Females 13-49 years old	0.0255	88	0.004	16

[1] Acute Reference Dose (ARfD) of 0.029 mg/kg/day for females 13-49 years old. No acute dietary endpoint was chosen for the general population, including infants and children.

[2] Acceptable Daily Intake (ADI) of 0.025 mg/kg/day applies to the general population and all population subgroups.

Appendix IV A Food Residue Chemistry Summary

1.1 Metabolism

The residue chemistry database for myclobutanil is complete for the currently registered uses. Nature and magnitude of the residue in plant and livestock commodities are adequately understood based on acceptable metabolism studies in lactating cows, laying hens, apples and grapes. However, an acceptable study in a third diverse crop may be needed to support additional uses or MRLs.

1.1.1 Plant Metabolism

Plant metabolism studies on file for apples and grapes were reviewed with past petitions and found adequate to characterize the nature of the residue in plants.

A greenhouse ^{14}C RH-3866 (myclobutanil ^{14}C radiolabelled in the phenyl or triazole ring) study to assess the translocation indicates no significant amount of ^{14}C residues was translocated from the treated leaf to the roots or foliage in grape and apple seedlings. However RH-3866 was easily absorbed from a nutrient solution by the roots and translocated in wheat and grape seedlings.

Metabolism was studied in the field on apples using ^{14}C RH-3866 labelled in the phenyl or triazole ring. Trees were treated 10 times at 240g a.i./ha (registered maximum rate = 136g a.i./ha, maximum number of applications/season = 6), sampled at harvest and radioassayed. Residues levels, calculated as RH-3866 equivalents for apples were 0.48 ppm (phenyl label) and 0.32 ppm (triazole label). Grapes were similarly treated in the field with 5 applications at 50g a.i./ha (registered maximum rate = 80g a.i./ha, maximum number of applications/season = 5). Residues levels calculated as RH-3866 equivalents for grapes were 0.32 ppm (phenyl label) and 0.24 ppm (triazole label).

In a laboratory grape seedling study, grape seedlings grown in a nutrient solution containing 3.5 ppm ^{14}C RH-3866 (triazole label) or 4.6 ppm ^{14}C RH-3866 (phenyl label) had plants extracted and characterized for metabolites content following 7 and 16 days uptake. The predominant metabolites were found to be the alcohol RH-9090 (*α*-(3-hydroxybutyl)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile), its oxidation product (ketone) RH-9089 (*α*-(butyl-3-one)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile) and glycoside conjugates.

1.1.2 Livestock Metabolism

Animal metabolism studies in lactating cows and laying hens were previously reviewed and deemed adequate.

In the cow metabolism study, two cows received daily doses of ^{14}C RH-3866 (triazole or phenyl label) at levels of 10 ppm for 5 days. Results indicated over 98% of the recovered dose were in the faeces (~34%) and urine (~64%), <0.5% of the dose was in the milk and 1% in tissues.

Of the recovered radioactivity from the urine, a lactone derivative of the alcohol metabolite RH-9090 comprised 31%, RH-9090 comprised 23%, a compound similar to RH-9090 (nitrile moiety oxidized to the methyl ester of the carboxylic acid) comprised 19% and a polar metabolite containing the chlorinated phenyl ring, 4 nitrogens and a molecular weight of 334 comprised 13%. The diol metabolite RH-294 (α-(3,4-dihydroxybutyl)-α-(4-chlorophenyl)-1*H* -1,2,4-triazole-1-propanenitrile) was also detected but not further quantified. The parent RH-3866 was not detected in the urine.

Radiolabelled milk aliquots from days 2, 3 and 4 were analysed for present metabolites. On the three days examined, no RH-3866 was detected. RH-294 was the predominant metabolite observed, accounting for 71% of the recovered radioactivity on day 2 and 61% on day 3. By day 4 there was a decrease in RH-294 to 21% and a corresponding increase in polar metabolites. Identification of the polar metabolites was not possible due to their very low concentrations. A small amount of RH-9090 was observed on days 2 and 3 but none was detected on day 4.

In the hen metabolism study, 4 groups of 10 hens received oral doses of ^{14}C RH-3866/RH-9090/RH-9089 at a ratio of 45:45:10 for 28 days. The ^{14}C label was incorporated at positions 3 and 5 of the triazole ring. Dosing levels were 1 ppm, 3 ppm, 10 ppm and 30 ppm. For the 30 ppm dose level, residues in tissues ranged from non-detectable to 0.047 ppm while egg residues ranged from 0.059 ppm to 0.126 ppm.

Two groups of 3 hens received oral doses of ^{14}C RH-3866 (group 1) or ^{14}C RH-9090/RH-9089 (82:18) (group 2) for 7 days at a dose level of 110 ppm for metabolite characterization. Radioanalysis indicated over 95% of the total dose was found in excreta. Characterization of residues accounting for the remaining radioactivity (~5%) showed that RH-9090 is the major metabolite in eggs (group 1: 47%-55%, group 2: 58%-67%), organs and tissues of hens with smaller amounts of the ketone RH-9089 (group 1: ~21%, group 2: ~10%), the diol RH-294 (~15%), the hydroxy-lactone and more polar metabolites also present.

1.1.3 Triazole metabolites

All triazole-based fungicides share a common metabolite resulting from the release of the triazole ring (1,2,4-triazole) from the parent compound. In animals, the triazole ring is relatively stable and is the terminal form of the metabolite. In plants, 1,2,4-triazole may become conjugated to serine. The resulting compound, triazolyl-1-alanine (TA), may be oxidized to form triazolyl-1-acetic acid (TAA). TA and TAA are the primary terminal forms of the triazole ring in plants, though some free 1,2,4-triazole may remain. Based on the fact that, for the majority of triazole-based fungicides, the degree of formation of free 1,2,4-triazole in animals and the rate of oxidation of TA to TAA in plants are relatively low, Health Canada had previously concluded that TA is the only triazole metabolite to be regulated and included in the dietary risk assessment. A common MRL of 2 ppm in all plant commodities has been established. However, due to its intrinsic toxicological properties, residue chemistry and human health risks associated with this metabolite – resulting from the use of all registered triazole-based fungicides – will be assessed separately. The risk assessment will have to be updated whenever a new food/feed use is added to the existing uses of any of the registered triazole-based fungicides and/or registration of a new triazole-based fungicide is petitioned. This approach is consistent with the USEPA position on the matter.

1.1.4 Residue Definition

Based on the apple and grape metabolism studies, the residue for enforcement and risk assessment purposes in plant commodities is defined as the combined residue of the parent compound RH-3866 (*α*-butyl-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile), the free and conjugated forms of the alcohol metabolite RH-9090 (*α*-(3-hydroxylbutyl)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile) and the ketone metabolite RH-9089 (*α*-(butyl-3-one)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile).

The residue in animal products has been defined as the combined residue of the parent compound RH-3866 (*α*-butyl-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile), the alcohol metabolite RH-9090 (*α*-(3-hydroxylbutyl)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile), the ketone metabolite RH-9089 (*α*-(butyl-3-one)-*α*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile) and a third metabolite named α-(4-chlorophenyl)-α-(2-formylethyl)-1*H*-1,2,4-triazole-1-propanenitrile. However, according to the supporting studies the third metabolite should be the diol RH-294 with the CAS name α-(3,4-dihydroxybutyl)-α-(4-chlorophenyl)-1*H* -1,2,4-triazole-1-propanenitrile. The supporting metabolism studies indicate that the diol appeared to be a stable compound and analytical methods have been developed for its quantitation for both risk assessment and enforcement. This residue definition (with the diol instead of the aldehyde) is in accordance with that of the USEPA though the US Agency does not include the ketone metabolite in its residue definition. Thus, it is recommended that the compound α-(4-chlorophenyl)-α-(2-formylethyl)-1*H*-1,2,4-triazole-1-propanenitrile be replaced by the metabolite α-(3,4-dihydroxybutyl)-α-(4-chlorophenyl)-1*H* -1,2,4-triazole-1-propanenitrile in Health Canada's Table of Residue Definitions for Chemicals with MRLs Regulated under the *Pest Control Products Act* on the Maximum Residue Limits for Pesticides webpage.

1.2 Analytical Methods

1.2.1 Supervised Residue Trial Analytical Methodology

Plants - Several analytical methods have been developed. The analytical methods on file have been previously reviewed. Quantitation of the residues of myclobutanil (RH-3866) and its metabolites (RH-9089 and RH-9090) in plants is performed by gas chromatography (GC) or liquid chromatography (LC) or high performance liquid chromatography (HPLC) coupled with an electron capture detector (ECD) or a nitrogen/phosphorus detector (NPD) also known as thermionic specific detector (TSD) or a mass selective detector (MSD) or a mass spectrometer (MS). The methods 310-83-23 (GC-ECD), 310-84-13 (GC-ECD), 310-84-27 (GLC-ECD or NPD a.k.a. TSD), 34S-88-10 (GC-ECD or NPD), E4-10-230 (GC-MSD), E4-10-671 (GC-MSD), E3-03-171 (GC-MS or LC-MS), E6-03-061B (HPLC-MSD) and GRM 03.01 (LC-MS/MS) have been found adequate for data collection in support of the establishment of MRLs in/on various crops and processed fractions thereof. Method 34S-88-10 measures the total residues of myclobutanil in plant matrices. Briefly, the method involves extraction of samples with acidified methanol. Present RH-9090 conjugates are hydrolysed during extraction to the alcohol RH-9090. The extract is made basic by addition of sodium hydroxide. Present RH-9089 (ketone) residues are converted to RH-9090 (alcohol) by sodium borohydride reduction. The obtained mixture is washed and partitioned into methylene chloride twice. The sample is then cleaned up by Chelex 100-Fe^{+++} affinity chromatography, followed by a second methylene chloride partitioning. Additional sample clean up is facilitated by Bio-Sil A column chromatography. RH-3866 and

RH-9090 residues are determined by GC with nitrogen/phosphorus detection (NPD) and electron capture detection (ECD), respectively. Previous reviews of the residue data, fortification and control data and submitted chromatograms show the method to have sensitivity in the range 0.01-0.03 ppm for myclobutanil and its alcohol metabolite in various crops.

Animals - The analytical methods on file have been previously reviewed. The GC-ECD methods 310-84-13 and 31S-87-02 were found adequate for determining residues of the parent RH-3866 and the metabolites RH-9090 and RH-294 (milk only) in various animal matrices. In addition, methods 34S-88-22, 34S-88-15, 31S-87-02 and 34S-88-21 have been reviewed by the USEPA and submitted for publication in Pesticide Analytical Methods Volume II (PAM Vol. II).

1.2.2 Enforcement Analytical Methodology

Plants - Method 34S-88-10 on file has been reviewed and accepted as the enforcement method in plant matrices. As already mentioned, this GC method measures the parent RH-3866 and the metabolites RH-9090 (free and bound) and RH-9089 (converted to RH-9090) with a limit of quantitation (LOQ) in the 0.01-0.03 ppm range. This method has undergone a successful method validation by the USEPA HED and has been forwarded to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Methods Volume II (PAM Vol. II). In addition, the Rohm and Haas method 310-84-27 is listed in the Residue Analytical Methods (RAM) repertory, pending compilation in PAM Vol. II. This method measures the residues of the parent RH-3866 and its alcohol metabolite RH-9090 in apples with an estimated LOQ of 0.5 ppm.

Animals - Methods Rohm and Haas 310-84-13 and 31S-87-02 have been reviewed and deemed adequate as enforcement analytical methods for animal matrices. In addition, the Rohm and Haas methods 31S-87-02, 34S-88-15 and 31S-87-09 are listed in the Residue Analytical Methods (RAM) repertory, pending compilation in PAM Vol. II. Method 31S-87-02 measures the parent RH-3866 and the diol metabolite RH-294 in milk with an LOQ of 0.05 ppm. The alcohol metabolite RH-9090 (including the ketone metabolite RH-9089 after conversion to alcohol) in milk and beef liver is measured by methods 34S-88-15 (milk only) and 310-87-09.

1.2.3 Inter-Laboratory Analytical Methodology Validation (ILV)

Plants - GC-ECD or GC-NPD method 310-84-13 and LC-MS/MS method GRM 03.01 submitted for analysis of plant commodities and processed fractions have been previously reviewed and deemed adequately inter-laboratory validated. Method 34S-88-10 has been successfully validated by the USEPA (see Enforcement Analytical Methodology in Section 1.2.2 above).

Animals - Since methods 31S-87-02, 34S-88-15 and 31S-87-09 are listed in the Residue Analytical Methods (RAM) repertory, they can be considered as independently validated. Method 31S-87-02 measures the parent RH-3866 and the diol metabolite RH-294 in milk with an LOQ of 0.05 ppm. The alcohol metabolite RH-9090 (including the ketone metabolite RH-9089 after conversion to alcohol) in milk and beef liver is measured by methods 34S-88-15 (milk only) and 310-87-09.

1.2.4 Multi-Residue Analytical Methodology Evaluation

Three multi-residue methods on file (GC-MS method MRM-1, GC-ECD method DFG_S19 and GC-ECD method 34S-88-21) have been previously reviewed and deemed adequate for enforcement. In addition, the 10/99 US FDA PESTDATA database (PAM Volume I, Appendix I) indicates that residues of the parent myclobutanil are adequately recovered (>80%) using Multi-Residue Method Section 302 (Luke Method; Protocol D), but are not recovered using Multi-Residue Method Sections 303 (Mills, Onley, Gaither Method; Protocol E, non-fatty foods) or 304 (Mills Method; Protocol E, fatty foods). Residues of the metabolite RH-9090 are poorly recovered (30-55%) using Multi-Residue Method Section 302 (Luke Method; Protocol D); the metabolite is not recovered using Multi-Residue Method Sections 303 (Mills, Onley, Gaither Method; Protocol E, non-fatty foods) and 304 (Mills Method; Protocol E, fatty foods).

1.2.5 Storage Stability of Working Solutions

There is no data on storage stability of working solutions on file. The registrant addressed the deficiency by presenting a rationale for a waiver stating that "the support for the stability of myclobutanil and the metabolite RH-9090 is by virtue of the calibration standards and fortification solutions which were used in numerous method validation studies and indicated that there was no change in response observed for either myclobutanil or the alcohol metabolite RH-9090 over the course of any study. Typically, sample extracts were analysed within 24 hours of extraction, so no data on the storage stability of samples in extraction solvents is provided. Additionally, the chemical nature of myclobutanil makes it highly unlikely that it would be unstable in the solvents used during the analysis of residues". Since the daily standard curves, spiked samples and spiked aged samples indicated that the residues of myclobutanil and the metabolite RH-9090 were stable, the PMRA accepted the rationale and concluded that the stability of the parent myclobutanil and the metabolite RH-9090 in working solutions is adequate.

1.3 Food Residues

1.3.1 Freezer Storage Stability

Freezer storage stability tests on file have been previously reviewed for apples, grapes, asparagus, peppers, almond and livestock commodities. These were deemed adequate and sufficiently representative to cover all treated commodities. It was found, for example, that residues of myclobutanil and its metabolites remain stable in apples and grapes for up to 2 years in frozen conditions. Freezer storage stability tests conducted for post harvest use of myclobutanil on imported bananas were found adequate to support the storage stability requirement. Concurrent freezer storage stability studies submitted as part of the supervised crop field trials on apricots, caneberries, currants, mayhaw, plums/prunes and tomatoes were deemed acceptable.

1.3.2 Residue Decline Study

Residue decline studies on file were previously reviewed for apple, cantaloupe, cherry, cucumber, grape, peach, pepper, strawberry, Saskatoon berries, summer squash, caneberry crop subgroup 13A (blackberry and raspberry), currant and tomatoes. The studies showed that the residues declined with time and were found adequate to support the established PHIs as specified on the labels.

1.3.3 Confined Crop Rotation Trial Study

A confined outdoor rotational crop study submitted to and reviewed by the USEPA is on file. The study was conducted to determine the nature and amount of uptake of ^{14}C RH-3866-derived residues in rotational crops planted at various time intervals in soil treated with ^{14}C-RH-3866. The ^{14}C RH-3866 used was uniformly labelled with ^{14}C in the aromatic ring of the molecule. The soil was treated 3 times at a rate approximating 224g a.i./ha for a total seasonal rate of 672g a.i./ha. The use pattern of myclobutanil (in single formulation) in Canada is typically 136g a.i./ha (except for grapes: 80g a.i./ha), the number of applications per season ranging from 2 to 6. A leafy crop (lettuce or mustard), a root crop (white radish or turnip) and a small grain crop (grain sorghum or wheat) were planted in soil at nominal timings of 30, 120, 210 and 365 days after last application (DALA). Soybean, an additional crop that is widely rotated, was also planted at the 30, 210 and 365 day intervals. All crop and soil samples were analysed by combustion analysis to determine the level of total radioactive residue (TRR). Crops containing significant levels of TRR (≥0.010 ppm ^{14}C RH-3866 equivalents) were extracted. Extractable residues with TRR levels ≥0.010 ppm were assayed by reversed-phase high performance liquid chromatography (RP-HPLC) in conjunction with liquid scintillation counting (LSC) to determine their product composition. In general, the average TRR found in mature and immature crop samples grown in ^{14}C RH-3866-treated soil decreased significantly with increasing plant-back interval (PBI). Results showed the presence of a number of products including parent chemical (RH-3866), an alcohol metabolite (RH-9090), trace amounts of a ketone metabolite (RH-9089), and polar, early eluting, metabolites. A number of minor miscellaneous components were also found in some but not all crop extracts. RH-3866 was a significant contributor to the TRR at 30 days after last application but its content declined by 120 DALA and was <0.010 ppm by 210 DALA.

Additional samples of 30 DALA soybean straw and forage, which contained the highest levels of TRR, were extracted and the nature of residue in the extracts characterized and identified in detail. RH-3866, RH-9090, and unknown polar metabolites were isolated and purified by RP-HPLC and NP-TLC (normal phase thin-layer chromatography). The identities of RH-3866 and RH-9090 were confirmed by LC/MS analysis in comparison to known reference standards. The identity of the major polar fraction in soybean forage was shown by LC/MS and LC/MS/MS to be a mixture of one major and one minor glucose conjugate of RH-9090. An additional minor soybean straw metabolite (7.74% of TRR, 0.018 ppm) was tentatively identified as a carboxylic acid metabolite of RH-3866. Attempts to release bound residues from 30 DALA soybean straw post extraction solids (PES) using enzymes (cellulase and protease) resulted in solubilization of only a modest amount of the TRR. Sequential acid (1N and 6N HCl) hydrolysis followed by base (6N NaOH) hydrolysis was successful. RP-HPLC analysis of acid-released residues indicated the presence of predominantly polar residues along with trace levels of RH-3866.

A number of plant samples were analysed using the Rohm and Haas total residue analytical method 34S-88-10 (see Analytical Methodology in section 1.2) with an LOQ of 0.010 ppm.

Results obtained using the method correlated well with the radiochromatography results obtained for RH-3866 while the method only worked on a limited number of crops for RH-9090 metabolite. The method should be acceptable as a rotational crop residues enforcement method for RH-3866 over a wide range of crops but not for RH-9090. The nature of the residues in rotational crops is essentially the same as those found in previous plant metabolism studies and is adequately understood. The study is adequate to satisfy data requirement for DACO 7.4.3 (Confined Crop Rotation Trial Study). These data show that residues of myclobutanil and its alcohol metabolite are <0.01 ppm in lettuce with a 120-day PBI, radishes with a 210-day PBI, wheat with a 120-day PBI and soybeans with a 210-day PBI. Therefore, according to the Residue Chemistry Guideline, the results of this study support the establishment of PBIs for myclobutanil as follows:

Table 1 Plant Back Intervals (PBIs)

Crop	PBI / days after last application (DALA)
leafy vegetables	120
root vegetables	210
small grains	120
all other crops	210

1.3.4 Field Crop Rotation Trial Study

In the confined rotation trial studies, the combined residues of myclobutanil and its metabolites were <0.01 ppm in/on all tested commodities at plant-back intervals (PBIs) of 210 and 365 days. Thus, limited field trials are not required and rotational commodity MRLs need not be established. Based on the data, a 120-day PBI for leafy vegetables or grain crops and a 210-day PBI for root vegetables or all other crops are recommended.

1.3.5 Processed Food/Feed

Processing studies on file were previously reviewed for apple, grape and plums/prunes. Processing factors and MRLs on the processed commodities have been established. Processing data from JMPR (1997) and USEPA were used to estimate processing factors and MRLs on tomato paste and purée. There was no concentration of the residue in tomato juice, canned tomatoes or preserve.

1.3.6 Residue Data for Crops used as Livestock Feed

Among the registered domestic crop uses in Canada, only apples can be used both as food (fruit) and livestock feed (pomace). Residue data for the apple RAC have been reviewed under DACO 7.4.1 and processed food/feed thereof under DACO 7.4.5. Among import commodities, almond (hulls) and cotton (undelinted seed, cotton gin byproducts, meals and hulls) can be used as feedstuffs. The USEPA reports a tolerance of 2.0 ppm for almond hulls and 0.02 ppm for undelinted cottonseed.

1.3.7 Livestock, Poultry, Egg and Milk Residue Data

Livestock feeding studies have been previously reviewed for lactating cows and laying hens. The studies were deemed adequate to determine levels of myclobutanil and its metabolites in livestock commodities. MRLs are currently established for animal matrices.

Appendix IV B Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

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

In the US, myclobutanil is registered for use on (and import of) a large variety of crops including root and tuber vegetables (group 1), leaves of root and tuber vegetables (group 2), leafy vegetables (group 4), brassica leafy vegetables (group 5), legume vegetables (group 6), foliage of legume vegetables (group 7), fruiting vegetables (group 8), cucurbit vegetables (group 9), stone fruits (group 12), caneberry (subgroup 13A), cereal grains (group 15), forage, fodder and straw of cereal grains (group 16), almond, apple, artichoke, asparagus, banana, cotton, currant, gooseberry, grape, hops, peppermint, spearmint, strawberry, mayhaw, papaya, cilantro, black sapote, canistel, mamey sapote, mango, sapodilla, star apple, ornamentals and turf. The use pattern ranges from 33.6 g a.i./ha (caneberry, 4 applications/season, 10-14 days between applications and a 0-day PHI) to 280 g a.i./ha (papaya, 8 applications/season, 13-15 days between applications and a 0-day PHI).

No revisions of the myclobutanil MRLs established under the *Pest Control Products Act* are required as a result of this re-evaluation process.

Table 1 Canadian MRLs, United States Tolerances and Codex MRLs for Myclobutanil

Commodity	Canadian Current MRLs (ppm)	US Current /Reassessed Tolerances (ppm)	Codex MRLs (ppm)
Almond	0.1	0.1	-
Almond, hulls	-	2.0	-
[2]Animal feed, nongrass, group 18*	-	0.03	-
Apple	0.5	0.5	0.5
Apple, dry pomace	-	5.0	-
Apple, wet pomace	-	5.0	-
Apricot	1.4	2.0	2.0
Artichoke, globe	-	0.9	-
Asparagus	0.02	0.02	-
Banana	2.0	4.0	2.0
Bean, snap, succulent	-	1.0	-
[2]Caneberry crop subgroup 13A (blackberry and raspberry)	1.2	2.0	-
Canistel	-	3.0	-
Cattle, fat	0.05	0.05	-
Cattle, liver	0.3	1.0	-
Cattle, meat	0.05	0.1	0.01**
Cattle, meat byproducts, except liver	0.05	0.2	0.01**
Cherry	1.0	5.0	2.0
Cherry, dried	4.0	-	-
Cilantro, leaves	-	9.0	-
Cotton, undelinted seed	-	0.02	-
Crabapple	-	-	0.5
Currant	3.0	3.0	0.5
Egg	0.02	0.02	0.01**
[2]Fruit, stone, group 12	-	2.0 (except cherry)	2.0 (except plums)

Commodity	Canadian Current MRLs (ppm)	US Current /Reassessed Tolerances (ppm)	Codex MRLs (ppm)
Goat, fat	0.05	0.05	-
Goat, liver	0.3	1.0	-
Goat, meat	0.05	0.1	-
Goat, meat byproducts, except liver	0.05	0.2	-
Gooseberry	-	2.0	-
Grain, aspirated fractions	-	35	-
[2]Grain, cereal, forage, fodder and straw, group 16*	-	0.03	-
[2]Grain, cereal, group 15*	-	0.03	-
Grape	1.0	1.0	1.0
Grape, pomace, dried	-	10.0	-
Grape, pomace, wet	-	10.0	-
Grape, raisin	10.0	10.0	-
Grape, raisin, waste	-	25.0	-
Hog, fat	0.05	0.05	-
Hog, liver	0.3	1.0	-
Hog, meat	0.05	0.1	-
Hog, meat byproducts, except liver	0.05	0.2	-
Hop, dried cones*	-	10.0	2.0
Horse, fat	0.05	0.05	-
Horse, liver	0.3	1.0	-
Horse, meat	0.05	0.1	-
Horse, meat byproducts, except liver	0.05	0.2	-
[2]Leafy greens, subgroup 4A, except spinach	-	9.0	-
Loquat	-	-	0.5
Mango	-	3.0	-
Mayhaw	0.5	0.7	0.5
Milk	0.05	0.2	0.01**
Nectarine	1.0	2.0	2.0
Nectarine, dried	7.0	-	-
Okra	-	4.0	-
Papaya	-	3.0	-
Peach	1.0	2.0	2.0
Peach, dried	7.0	-	-
Pear	-	-	0.5
Pepper	1.0	4.0	-
Peppermint tops	-	3.0	-
Plum	2.0	2.0	0.2
Plum, prune, dried	8.0	8.0	-
Poultry, fat	0.02	0.02	0.01**
Poultry, meat	0.02	0.02	0.01**
Poultry, meat byproducts	0.02	0.02	0.01**
Prune	-	-	0.5
Quince	-	-	0.5
Sapodilla	-	3.0	-
Sapote, black	-	3.0	-
Sapote, mamey	-	3.0	-
Saskatoon berry	0.07	-	-
Sheep, fat	0.05	0.05	-
Sheep, liver	0.3	1.0	-
Sheep, meat	0.05	0.1	-
Sheep, meat byproducts, except liver	0.05	0.2	-
Soybean, forage	-	3.5	-
Soybean, hay	-	15.0	-
Soybean, refined oil	-	0.4	-
Soybean, seed	-	0.25	-
Spearmint tops	-	3.0	-

Commodity	Canadian Current MRLs (ppm)	US Current /Reassessed Tolerances (ppm)	Codex MRLs (ppm)
Star apple	-	3.0	-
Strawberry	0.5	0.5	1.0
Tomato	0.3	0.3	0.3
Tomato Purée	0.5	0.5	-
Tomato Paste	1.0	1.0	-
[2]Vegetable, brassica, leafy, group 5*	-	0.03	-
[2]Vegetable, cucurbit, group 9: cucumber, balsam apple, balsam pear, bitter melon, cantaloupe, casaba melon, Chinese cucumber, Chinese waxgourd, citron melon, crenshaw melon, chayote (fruit), golden pershaw melon, gourd (edible), honey balls, honeydew melon, mango melon, persian melon, pineapples melon, pumpkin, santa claus melon, summer squash, watermelon, winter squash, nake melon	0.3	0.2	-
[2]Vegetable, foliage of legume, group 7*	-	1.0 (Expiration 12/31/09)	-
[2]Vegetable, fruiting, group 8, except tomato	-	4.0	-
[2]Vegetable, leafy, except brassica, group 4*	-	0.03	-
[2]Vegetable, leaves of root and tuber, group 2*	-	0.03	-
[2]Vegetable, legume, group 6*	-	1.0 (Expiration 12/31/09)	-
[2]Vegetable, root and tuber, group 1*	-	0.03	-

[1] ppm: parts per million, equivalent to mg/kg
[2] Group MRL/Tolerance
* U.S. tolerances based on parent only
** At or about the limit of determination

Canadian MRLs are available from the Maximum Residue Limits for Pesticides webpage;
USA tolerances are available from the following web site: http://ecfr.gpoaccess.gov (Title 40, Part 180)
Codex MRLs are available from the following web site: http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp

There is a difference in residue definition between Canada, US and Codex. In the US, the residue definition for plants and livestock commodities except milk comprises the parent RH-3866 and the free and bound alcohol metabolite RH-9090. In milk, the residue is expressed as the parent RH-3866, the alcohol RH-9090 (free and bound) and the diol RH-294. Thus in the US, the ketone metabolite RH-9089 is not comprised in the residue definition. However, residue levels determined in Canada and the US should be comparable, due to the use of the same "total residue" analytical methods which convert ketones to alcohols during workup prior to quantitation. The RD for Codex is parent only.

Table 2 Enforcement Residue Definition in Canada and Other Jurisdictions

Jurisdiction	Enforcement Residue Definition	
	Plant	Animal
Canada	Parent and its alcohol (free and bound) and ketone metabolites	Parent and its alcohol, ketone and diol (in milk) metabolites
US	Parent and its alcohol (free and bound) metabolite	Parent and its alcohol and diol (in milk) metabolites
Codex	Parent only	Parent only

Appendix V Monitoring Data

The refined dietary risk assessments were performed by using:

- CFIA monitoring data for most consumed commodities including apple (fresh), apricot, artichoke, asparagus, banana, bean, beet, broccoli, Brussels sprouts, cabbage, carrot, cauliflower, celery, cherry, corn, cucumber, eggplant, endive (translated from lettuce, leaf), grape, lettuce, mango, nectarine, okra (translated from tomato), papaya, parsley, pea, peach, pepper, plum, potato, radish, radicchio (translated from lettuce, head), raspberry, spinach, squash, strawberry, sweet potato, tomatillo (translated from tomato), tomato, watermelon and yam;
- PDP anticipated residue data for milk, apple sauce and wheat (grain);
- Estimated % crop treated (PCT) in Canada for apple, grape, strawberry, cherry, peach, nectarine, tomato, cucumber and pepper; PCT = 100% for commodities for which no PCT information could be found, blended commodities and commodities imported from countries other than US;
- Estimated PCT in the US for almond, apple, apricot, artichoke, asparagus, beans, blackberry, broccoli, cantaloupe, cauliflower, cherry, cucumber, grape, nectarine, peach, pear, pepper, pistachio, plum (prune), pumpkin, raspberry, soybean, squash, strawberry, sugar beet, tomato, walnut and watermelon [USEPA Memos: DP Num. 348041, A. Grube, 2/28/08; DP Num. 341689, W. Cutchin, 10/1/07; DP Num. 341690, W. Cutchin, 10/2/07]; PCT = 100% for commodities for which no PCT information could be found, blended commodities and commodities imported from countries other than US;
- Import statistics from Statistics Canada (2007) and Industry Canada: Trade by Product (2007).

Table 1 Summary of the CFIA/PDP Monitoring data used in the dietary assessments

Commodity	B[a]/ PB/ NB	Proc. Factor	CAN Use? Y/N	Source of Data	PCT[b]		Year Span	Number Samples	Number Detected Samples	Range Detected Residues (ppm)	Range LOD[c] (ppm)	% Domestic/ Import[d]	Acute Residue (ppm)		Chronic Aver. Residue (ppm)
					C	A							Tier 1/2	Tier 3[f]	
Apple, fresh	NB	1	Y	CFIA, domestic	51	51	2003-2007	665	0	N/A[e]	0.017	70	0.5	RDF#1	0.0043
				CFIA, import	56	60	2003-2007	1695	1	0.021	0.017	30	0.5	RDF#2	0.0048
Apple, dried	B	8	Y	CFIA, import	100	100	2003-2007	1695	1	0.021	0.017	100	0.5	RDF#3	0.0085
Apple, juice	PB	1.3	Y	CFIA, domestic	51	51	2003-2007	665	0	N/A	0.017	49	0.5	RDF#4	0.0043
				CFIA, import	80	81	2003-2007	1695	1	0.021	0.017	51	0.5	RDF#5	0.0068
Apple, sauce	PB	1.3	Y	CFIA, domestic	51	51	2003-2007	665	0	N/A	0.017	49	0.5	RDF#6	0.0043
				USDA PDP	80	81	2005-2007	744	5	0.002-0.02	0.001-0.02	51	0.5	RDF#7	0.0026
Apricot, fresh	NB	1	N	CFIA, domestic	28	41	2003-2007	N/A	N/A	N/A	0.017	22	0	RDF#8	0.0037
				CFIA, import			2003-2007	197	4	0.012-0.165	0.017	78	2		
Apricot, dried	B	6	N	CFIA, import	100	100	2003-2007	197	4	0.012-0.165	0.017	100	2	RDF#9	0.0097
Artichoke, fresh	NB	1	N	CFIA, import	58	91	2003-2007	154	6	0.011-0.19	0.017	100	0.9	RDF#10	0.0068
Asparagus, fresh	NB	1	Y	CFIA, domestic	26	34	2003-2007	N/A	N/A	N/A	0.017	19	0.02	RDF#11	0.0022
				CFIA, import			2003-2007	395	0	N/A	0.017	81	0.02		
Banana, fresh (incl. plantain)	NB	1	N	CFIA, import	100	100	2003-2007	818	0	N/A	0.017	100	4.0	RDF#12	0.0085

Commodity	B[a]/ PB/ NB	Proc. Factor	CAN Use? Y/N	Source of Data	PCT[b]		Year Span	Number Samples	Number Detected Samples	Range Detected Residues (ppm)	Range LOD[c] (ppm)	% Domestic/ Import[d]	Acute Residue (ppm)		Chronic Aver. Residue (ppm)
					C	A							Tier 1/2	Tier 3[f]	
Bean, fresh	PB	1	N	CFIA, domestic	6	7	2003-2007	N/A	N/A	N/A	0.017	65	0	RDF#13	0.0021
				CFIA, import			2003-2007	390	3	0.094-0.343	0.017	35	1.0		
Bean, seed, flour	B	1	1	CFIA, domestic	35	35	2003-2007	N/A	N/A	N/A	0.017	65	0	RDF#14	0.0045
				CFIA, import			2003-2007	390	3	0.094-0.343	0.017	35	1.0		
Beet, root	NB	1	N	CFIA, domestic	10	10	2003-2007	N/A	N/A	N/A	0.017	90	0	RDF#15	0.0009
				CFIA, import			2003-2007	128	0	N/A	0.017	10	0.03		
Broccoli, fresh	NB	1	N	CFIA, domestic	7	7	2003-2007	N/A	N/A	N/A	0.017	33	0	RDF#16	0.0006
				CFIA, import			2003-2007	590	0	N/A	0.017	67	0.03		
Brussels sprouts	NB	1	N	CFIA, domestic	46	46	2003-2007	N/A	N/A	N/A	0.017	54	0	RDF#17	0.0039
				CFIA, import			2003-2007	231	0	N/A	0.017	46	0.03		
Cabbage, fresh	NB	1	N	CFIA, domestic	0	0	2003-2007	196	0	N/A	0.017	25	0	RDF#18	0
				CFIA, import	100	100	2003-2007	425	0	N/A	0.017	75	0.03	RDF#19	0.0085
Cabbage, fresh, Chinese	NB	1	N	CFIA, import	100	100	2003-2007	109	0	N/A	0.017	100	0.03	RDF#20	0.0085
Carrot, fresh	NB	1	N	CFIA, domestic	0	0	2003-2007	215	0	N/A	0.017	70	0	RDF#21	0
				CFIA, import	100	100	2003-2007	823	6	0.026-0.15	0.017	30	0.03	RDF#22	0.0089

Commodity	B[a]/ PB/ NB	Proc. Factor	CAN Use? Y/N	Source of Data	PCT[b]		Year Span	Number Samples	Number Detected Samples	Range Detected Residues (ppm)	Range LOD[c] (ppm)	% Domestic/ Import[d]	Acute Residue (ppm)		Chronic Aver. Residue (ppm)
					C	A							Tier 1/2	Tier 3[f]	
Cauliflower, fresh	NB	1	N	CFIA, domestic	4	4	2003-2007	N/A	N/A	N/A	0.017	37	0	RDF#23	0.0003
				CFIA, import			2003-2007	470	0	N/A	0.017	63	0.03		
Celery, fresh	NB	1	N	CFIA, domestic	72	72	2003-2007	N/A	N/A	N/A	0.017	28	0	RDF#24	0.0061
				CFIA, import			2003-2007	662	0	N/A	0.017	72	0.03		
Cherry, fresh	PB	1	Y	CFIA, domestic	76	76	2003-2007	68	17	0.024-0.323	0.017	48	5.0	RDF#25	0.03
				CFIA, import	40	49	2003-2007	262	13	0.02-0.184	0.017	52	5.0	RDF#26	0.0054
Corn, fresh sweet	NB	1	N	CFIA, domestic	16	16	2003-2007	N/A	N/A	N/A	0.017	84	0	RDF#27	0.0014
				CFIA, import			2003-2007	198	0	N/A	0.017	16	0.03		
Cucumber (GH)	NB	1	Y	CFIA, domestic	50	50	2003-2007	100	19	0.014-0.208	0.017	81	0.3	RDF#28	0.0131
				CFIA, import	69	70	2003-2007	654	0	N/A	0.017	19	0.3	RDF#29	0.0059
Eggplant, fresh	NB	1	N	CFIA, domestic	61	61	2003-2007	N/A	N/A	N/A	0.017	39.0	0	RDF#30	0.0052
				CFIA, import			2003-2007	433	0	N/A	0.017	61.0	4		
Grape, fresh	PB	1	Y	CFIA, domestic	49	49	2003-2007	42	8	0.017-0.202	0.017	27	1.0	RDF#31	0.018
				CFIA, import	65	69	2003-2007	1502	85	0.017-0.48	0.017	73	1.0	RDF#32	0.0088

Commodity	B[a]/ PB/ NB	Proc. Factor	CAN Use? Y/N	Source of Data	PCT[b]		Year Span	Number Samples	Number Detected Samples	Range Detected Residues (ppm)	Range LOD[c] (ppm)	% Domestic/ Import[d]	Acute Residue (ppm)		Chronic Aver. Residue (ppm)
					C	A							Tier 1/2	Tier 3[f]	
Grape, juice	PB	1.2	Y	CFIA, domestic	49	49	2003-2007	42	8	0.017-0.202	0.017	3	1.0	RDF#33	0.018
				CFIA, import	58	64	2003-2007	1502	85	0.017-0.48	0.017	97	1.0	RDF#34	0.0082
Grape, leaves	PB	1	Y	CFIA, domestic	49	49	2003-2007	42	8	0.017-0.202	0.017	3	1.0	RDF#35	0.018
				CFIA, import	58	64	2003-2007	1502	85	0.017-0.48	0.017	97	1.0	RDF#36	0.0082
Grape, wine	PB	1	Y	CFIA, domestic	49	49	2003-2007	42	8	0.017-0.202	0.017	25	1.0	RDF#37	0.018
				CFIA, import	91	92	2003-2007	1502	85	0.017-0.48	0.017	75	1.0	RDF#38	0.011
Grape, raisin	B	10	Y	CFIA, import	100	100	2003-2007	1502	85	0.017-0.48	0.017	100	1.0	RDF#39	0.0118
Lettuce, fresh	NB	1	N	CFIA, domestic	0	0	2003-2007	118	0	N/A	0.017	22	0	RDF#40	0
				CFIA, import	100	100	2003-2007	980	0	N/A	0.017	78	9.0	RDF#41	0.0085
Lettuce, leaf fresh	PB	1	N	CFIA, domestic	0	0	2003-2007	194	0	N/A	0.017	22	0	RDF#42	0
				CFIA, import	100	100	2003-2007	597	0	N/A	0.017	78	9.0	RDF#43	0.0085
Mango, fresh	NB	1	N	CFIA, import	100	100	2003-2007	489	0	N/A	0.017	100	3.0	RDF#44	0.0085
Milk	B	N/A	N/A	USDA PDP	100	100	2004-2006	746	0	N/A	0.00015	100 (domestic)	0.2	RDF#77	0.0001
Nectarine, fresh	NB	1	Y	CFIA, domestic	29	33	2003-2007	N/A	N/A	N/A	0.017	11	2.0	RDF#45	0.0025
				CFIA, import			2003-2007	410	1	<0.017	0.017	89	2.0		
Papaya, fresh	NB	1	N	CFIA, import	100	100	2003-2007	419	0	N/A	0.017	100	3.0	RDF#46	0.0085

Commodity	B[a]/ PB/ NB	Proc. Factor	CAN Use? Y/N	Source of Data	PCT[b]		Year Span	Number Samples	Number Detected Samples	Range Detected Residues (ppm)	Range LOD[c] (ppm)	% Domestic/ Import[d]	Acute Residue (ppm)		Chronic Aver. Residue (ppm)
					C	A							Tier 1/2	Tier 3[f]	
Parsley, fresh	B	1	N	CFIA, domestic	0	0	2003-2007	116	0	N/A	0.017	15	0	RDF#47	0
				CFIA, import	100	100	2003-2007	132	0	N/A	0.017	85	9	RDF#48	0.0085
Pea, fresh	PB	1	N	CFIA, domestic	12	12	2003-2007	N/A	N/A	N/A	0.017	88	0	RDF#49	0.0011
				CFIA, import			2003-2007	245	1	0.03	0.017	12	1.0		
Pea, dried	B	1	N	CFIA, domestic	2	2	2003-2007	N/A	N/A	N/A	0.017	98	0	RDF#50	0.0003
				CFIA, import			2003-2007	245	1	0.03	0.017	2	1.0		
Peach, fresh	NB	1	Y	CFIA, domestic	31	31	2003-2007	147	3	0.017-0.234	0.017	47	2.0	RDF#51	0.005
				CFIA, import	25	29	2003-2007	386	0	N/A	0.017	53	2.0	RDF#52	0.0021
Peach, dried	B	7	Y	CFIA, domestic	100	100	2003-2007	147	3	0.017-0.234	0.017	47	2.0	RDF#53	0.011
				CFIA, import	100	100	2003-2007	386	0	N/A	0.017	53	2.0	RDF#54	0.0085
Pepper, fresh	PB	1	Y	CFIA, domestic	20	20	2003-2007	214	6	0.021-0.501	0.017	44	4.0	RDF#55	0.0071
				CFIA, import	72	75	2003-2007	632	5	0.011-0.104	0.017	56	4.0	RDF#56	0.0064
Pepper, dried	B	1	Y	CFIA, domestic	100	100	2003-2007	214	6	0.021-0.501	0.017	44	4.0	RDF#57	0.0139
				CFIA, import	100	100	2003-2007	632	5	0.011-0.104	0.017	56	4.0	RDF#58	0.0088

Commodity	B[a]/ PB/ NB	Proc. Factor	CAN Use? Y/N	Source of Data	PCT[b]		Year Span	Number Samples	Number Detected Samples	Range Detected Residues (ppm)	Range LOD[c] (ppm)	% Domestic/ Import[d]	Acute Residue (ppm)		Chronic Aver. Residue (ppm)
					C	A							Tier 1/2	Tier 3[f]	
Plum, fresh	NB	1	N	CFIA, domestic	29	29	2003-2007	N/A	N/A	N/A	0.017	11	0	RDF#59	0.0025
				CFIA, import			2003-2007	335	0	N/A	0.017	89	2.0		
Plum, dried	B	4	N	CFIA, domestic	89	89	2003-2007	N/A	N/A	N/A	0.017	11	0	RDF#60	0.0076
				CFIA, import			2003-2007	335	0	N/A	0.017	89	2.0		
Potato, fresh	NB	1	N	CFIA, domestic	0	0	2003-2007	709	0	N/A	0.017	96	0	RDF#61	0
				CFIA, import	100	100	2003-2007	636	0	N/A	0.017	4	0.03	RDF#62	0.0085
Radish, root fresh	NB	1	N	CFIA, domestic	61	61	2003-2007	N/A	N/A	N/A	0.017	39	0	RDF#63	0.0052
				CFIA, import			2003-2007	156	0	N/A	0.017	61	0.03		
Raspberry, fresh	PB	1	N	CFIA, domestic	21	22	2003-2007	N/A	N/A	N/A	0.017	58	0	RDF#64	0.0020
				CFIA, import			2003-2007	178	1	0.042	0.017	42	2.0		
Spinach, fresh	PB	1	N	CFIA, domestic	86	86	2003-2007	N/A	N/A	N/A	0.017	14	0	RDF#65	0.0073
				CFIA, import			2003-2007	231	0	N/A	0.017	86	0.03		
Squash, fresh	NB	1	Y	CFIA, domestic	45	47	2003-2007	N/A	N/A	N/A	0.017	64	0.3	RDF#66	0.0039
				CFIA, import			2003-2007	294	1	0.019	0.017	36	0.3		

Commodity	B[a]/ PB/ NB	Proc. Factor	CAN Use? Y/N	Source of Data	PCT[b]		Year Span	Number Samples	Number Detected Samples	Range Detected Residues (ppm)	Range LOD[c] (ppm)	% Domestic/ Import[d]	Acute Residue (ppm)		Chronic Aver. Residue (ppm)
					C	A							Tier 1/2	Tier 3[f]	
Strawberry, fresh	PB	1	Y	CFIA, domestic	11	11	2003-2007	99	4	0.01-0.121	0.017	26	1.0	RDF#67	0.0033
				CFIA, import	37	47	2003-2007	335	20	0.011-0.38	0.017	74	1.0	RDF#68	0.0089
Sweet potato, fresh	NB	1	N	CFIA, import	100	100	2003-2007	143	0	N/A	0.017	100	0.03	RDF#69	0.0085
Tomato (GH), fresh	NB	1	Y	CFIA, domestic	50	50	2003-2007	132	8	0.03-0.146	0.017	82	0.3	RDF#70	0.0076
				CFIA, import	38	42	2003-2007	1070	0	N/A	0.017	18	0.3	RDF#71	0.0032
Tomato (GH), dried	B	14.3	Y	CFIA, domestic	100	100	2003-2007	132	8	0.03-0.146	0.017	82	0.3	RDF#72	0.0118
				CFIA, import	100	100	2003-2007	1070	0	N/A	0.017	18	0.3	RDF#73	0.0085
Watermelon, fresh	NB	1	Y	CFIA, domestic	26	30	2003-2007	N/A	N/A	N/A	0.017	0	0.3	RDF#74	0.0022
				CFIA, import			2003-2007	291	0	N/A	0.017	100	0.3		
Wheat, grain	B	1	N	CFIA, domestic	1	1	2003-2007	N/A	N/A	N/A	0.017	99	0.03	RDF#75	0.0001
				USDA PDP			2005-2007	687	0	N/A	0.013	1	0.03		
Yam, fresh	NB	1	N	CFIA, import	100	100	2003-2007	126	0	N/A	0.017	100	0.03	RDF#76	0.0085

[a] Blended (B)/Partially Blended (PB)/Not Blended (NB);
[b] Percent Crop Treated: C = Chronic, A = Acute;
[c] Limit of Detection;
[d] Data from Statistics Canada: Food Consumption in Canada (2007) and Industry Canada: Trade by Product (2007).
[e] Not available
[f] Residue Distribution File (RDF) index number.

Appendix VI Environmental Fate and Toxicity of Myclobutanil

Environmental Fate and behaviour of Myclobutanil

Table 6 Fate and Behaviour of myclobutanil in the Environment

Property	Test Material	Value	Comments	References
Abiotic Transformation				
Hydrolysis	^{14}C-myclobutanil	Myclobutanil did not transform in sterile aqueous buffer solutions (pH 5, 7, and 9)	Stable under both acidic and alkaline conditions	PMRA # 1218445
Phototransformation - soil	^{14}C-myclobutanil	Half-life 144 d	Not an important route of transformation	PMRA# 1218447
Phototransformation - water	^{14}C-myclobutanil	Half-life 24.6 days in natural (pond) water and 222 days in sterile distilled water	Not an important route of transformation	PMRA# 1218446
Biotransformation				
Soil - aerobic	^{14}C-myclobutanil	DT_{50} - 691 d. DT_{90} - 2290 d.	Persistent in soil[1]	PMRA # 1218434, 1218421
Soil - anaerobic			Stable in soil	Agriculture Canada Decision Document (E93-01)
Water/sediment aerobic	^{14}C-myclobutanil	Myclobutanil decreased by approximately 3% over the duration of the study (238 d)	Not an important route of transformation	PMRA# 1139204
Mobility				
Soil Column leaching	^{14}C-myclobutanil	81 % of the residues were located in the upper 8 cm of the columns and the eluate contained 5-6% of the residues.	Low potential for vertical mobility in soil of myclobutanil and the transformation products	PMRA# 1218422
Adsorption/ desorption	myclobutanil	K_{oc} Clay Loam 225.7 Sand 266.1 Silty Loam 596.2 Sandy Loam 581.6 Clay 920.0	Low to medium mobility in soil[2]	PMRA# 1218424
Volatility	myclobutanil	Volatilization from soil and plant surfaces is not significant (up to 2.6% applied) under the conditions of a wind tunnel study (24 hours in an air-flow at 1 meter/second.		

Property	Test Material	Value	Comments	References
Field Studies				
Field dissipation (Orchard study)	Nova 40W fungicide	DT_{50} values from field dissipation studies conducted in Osoyoos B.C., Millgrove Ont., and North Berwick Nova Scotia of 114, 136, and >365 days, respectively.	Moderately persistent to persistent in soil[1]	PMRA# 1139208, 1139209, 1139210
Field dissipation (Turf study)	myclobutanil	DT_{50} - 64 days DT_{90} - >246 days	Moderately persistent in soil[1] Carry-over of 16% of the initial concentration into the following growing season	

1 classified according to the classification of Goring et al (1975)
2 classified according to the classification of McCall et al (1981)

McCall, J.P., D.A. Laskowski, R.L. Swann and J.J. Dishburger. (1981). Measurement of sorption coefficients of organic chemicals and their use in environmental fate analysis. Pages 89 - 109 IN Test protocols for environmental fate and movement of toxicants. Proceedings of a symposium. Association of Official Analytical Chemists. 94th Annual Meeting, October 21 - 22, 1980 Washington, DC.
Goring, C.A.I., D.A. Laskowski, J.H. Hamaker, and R.W. Meikle. (1975) Principles of pesticide degradation in soil. Pages 135-172 in (R. Haque and V.H. Freed, eds.) Environmental dynamics of pesticides. Plenum Press, New York.

Environmental Toxicity of Myclobutanil

Table 7 Environmental Toxicity of myclobutanil

Organism	Study Type	Species	Test material	Endpoint	Value	References
Terrestrial Species						
Invertebrates	Acute	Earthworm (*Lumbricus terrestris*)	myclobutanil technical	14-day LC_{50}	**250 mg a.i./kg substrate**	PMRA#1228617
	Acute	Honey bee (*Apis mellifera*)	myclobutanil technical	48-h LD_{50}	**> 100 µg a.i./bee**	PMRA#1219066
Birds	Acute oral	Bobwhite quail (*Colinus virginianus*)	myclobutanil technical	LD_{50}	**510 mg a.i./kg bw**	PMRA#1218444
	Dietary	Bobwhite quail (*Colinus virginianus*)	myclobutanil technical	LC_{50}	**> 5000 mg a.i./kg diet**	PMRA#1218981
		mallard duck (*Anas platyrhynchos*)	myclobutanil technical	LC_{50}	**> 5000 mg a.i./kg diet**	PMRA#1218970
	Chronic (repro)	Bobwhite quail (*Colinus virginianus*)	myclobutanil technical	22 week NOEC	**> 260 mg a.i./kg diet**	PMRA#1139221 PMRA#1218993
		Mallard duck (*Anas platyrhynchos*)	myclobutanil technical	22 week NOEC	**> 260 mg a.i./kg diet**	PMRA#1139226 PMRA#1219008

Organism	Study Type	Species	Test material	Endpoint	Value	References
Mammals	Acute oral	Rat (*Rattus norvegicus*)	myclobutanil technical	LD_{50}	**1600 mg a.i./kg bw**	
	Dietary	Mouse (*Mus musculus*)	myclobutanil technical	90 day NOAEL	**44.2 mg a.i./kg bw/day**	
	Chronic (repro)	Rat (*Rattus norvegicus*)	myclobutanil technical	2 generation NOAEL	**14.9 mg a.i./kg bw/day**	
Nontarget Plants	Seedling Emergence	Ryegrass	myclobutanil technical	EC25	**300 g a.i./ha**	
	Vegetative Vigour	Cucumber Onion	myclobutanil technical	EC25	300 g a.i./ha	
		Ryegrass Cabbage Soybean	myclobutanil technical	EC25	900 g a.i./ha	
Freshwater Organisms						
Invertebrates	Acute	waterflea (*Daphnia magna*)	myclobutanil technical	48-h LC50	**11.0 mg a.i./L**	PMRA#1219044
	Chronic	waterflea (*Daphnia magna*)	myclobutanil technical	21-d NOEC	**1 mg a.i./L**	
Fish	Acute	Rainbow trout *(Oncorhynchus mykiss)*	myclobutanil technical	96-h LC50	4.2 mg a.i./L	PMRA#1219020
		Sheepshead minnow (*Cyprinodon variegates*)	myclobutanil technical	96-h LC50	4.7 mg a.i./L	PMRA#1577453
		Bluegill sunfish (*Lepomis macrochirus*)	myclobutanil technical	96-h LC50	2.4 mg a.i./L	PMRA#1219031
		Fathead minnow (*Pimphales promelas*)	myclobutanil technical	96-h LC50	**1.4 mg a.i./L**	
	Chronic	Rainbow trout *(Oncorhynchus mykiss)*	myclobutanil technical	21-d NOEC	**0.2 mg a.i./L**	
		Fathead minnow *(Pimephales promelas*)	myclobutanil technical	35-d NOEC	0.98 mg a.i./L	PMRA#1219055
Algae		Green algae (*Scenedesmus subspicatus*)	myclobutanil technical	NOEC	**0.6 mg a.i./L**	PMRA#1128862
	Chronic	Green algae (*Selenastrum capricornutum*)	myclobutanil technical	NOEC	**0.6 mg a.i./L**	PMRA#1577467
Amphibians[1]	Acute		myclobutanil technical	96-h LC50	1.4 mg a.i./L	
	Chronic		myclobutanil technical	21-d NOEC	0.2 mg a.i./L	

Organism	Study Type	Species	Test material	Endpoint	Value	References
Marine/Estuarine Organisms						
Invertebrates	Acute	Mysid shrimp *(Mysidopsis bahia)*	myclobutanil technical	96-h LC50	**0.24 mg a.i./L**	PMRA#1577449
		Eastern oyster (embryo-larvae) *(Crassostrea virginica)*	myclobutanil technical	96-h LC50	0.72 mg a.i./L	PMRA#1577448

[1] Endpoints from fish used as surrogate

Table 8 Screening Level Risk Assessment for Terrestrial Invertebrates

Organisms	Exposure	Endpoint Value	Application Rate	EEC[1]	RQ[2]	LOC[3] exeeded
Invertebrates						
Earthworm	Acute	14-day $LC_{50} \div 2$ 125 mg a.i./kg soil	720 g a.i./ha × 2	0.64 mg a.i./kg	0.005	No
			136 g a.i./ha × 6	0.36 mg a.i./kg	0.003	No
			80 g a.i./ha × 5	0.18 mg a.i./kg	0.001	No
			45.2 g a.i./ha × 3	0.06 mg a.i./kg	0.0005	No
Bee	Acute	48-h LD_{50} > 100 µg a.i./bee	720 g a.i./ha × 2	1440 g a.i./ha	0.01	No
			136 g a.i./ha × 6	816 g a.i./ha	0.007	No
			80 g a.i./ha × 5	400 g a.i./ha	0.004	No
			45.2 g a.i./ha × 3	136 g a.i./ha	0.001	No

[1] Environmental Exposure Concentration (Soil: calculated based on a soil density of 1.5 g/cm3, soil depth of 15 cm and the label rates taking into consideration dissipation between applications; Bee: maximum application rate (application rate × no. of applications).
[2] Risk Quotient (RQ) = exposure/toxicity
[3] Level of Concern (LOC) = RQ = 1; a calculated RQ > 1 exceeds the LOC
[4] Toxicity in µg/bee converted to the equivalent kg a.i./ha using a conversion factor of 1.12 (Atkins et al., 1981)

Atkins EL; Kellum D; Atkins KW. 1981. Reducing pesticide hazards to honey bees: mortality prediction techniques and integrated management techniques. Univ Calif, Div Agric Sci, Leaflet 2883. 22 pp

Table 9 Risk to non-target terrestrial plants following field sprayer and airblast applications of myclobutanil

Endpoint	Application rate	EEC[1]	RQ[2]			
			100%	6%	74%	59%
EC_{25} = 300 g a.i./ha	720 g a.i./ha × 2	1006 g a.i./ha	**3.4**	0.2		
	136 g a.i./ha × 6	345 g a.i./ha	**1.2**		0.9	0.7

1 The cumulative EEC is estimated by adjusting the sum of the applications for dissipation between applications using a half-life on plants of 10.5 days.
2 Risk Quotient (RQ) = exposure/toxicity
3 Level of Concern (LOC) = RQ = 1; a calculated RQ > 1 exceeds the LOC
Note: values in bold exceed LOC

Table 10 Screening Level Risk Assessment for Birds and Mammals

Organism		Endpoint Value[1]	Feeding Guilds	Exposure[2]		RQ[3]	LOC exceeded
				EEC (mg a.i./kg dry weight)	EDE[4] (mg a.i./kg bw/day)		
Application Rate 720 g a.i./ha × 2							
Birds							
Bird: 20 g	Acute	51 mg a.i./kg bw/day	Insectivore	199	51.7	**1.0**	Yes
			Granivore	34	8.8	0.2	No
			Frugivore	102	27	0.5	No
	Dietary	30 mg a.i./kg bw/day	Insectivore	199	51.7	**1.7**	Yes
			Granivore	34	8.8	0.3	No
			Frugivore	102	27	0.9	No
	Reproduction	15.6 mg a.i./kg bw/day	Insectivore	199	51.7	**3.3**	Yes
			Granivore	34	8.8	0.6	No
			Frugivore	102	27	**1.7**	Yes
Bird: 100 g	Acute	51 mg a.i./kg bw/day	Insectivore	199	39.8	0.8	No
			Granivore	34	6.8	0.1	No
			Frugivore	102	20.4	0.4	No
	Dietary	30 mg a.i./kg bw/day	Insectivore	199	39.8	**1.3**	Yes
			Granivore	34	6.8	0.2	No
			Frugivore	102	20.4	0.7	No
	Reproduction	15.6 mg a.i./kg bw/day	Insectivore	199	39.8	**2.6**	Yes
			Granivore	34	6.8	0.4	No
			Frugivore	102	20.4	**1.3**	Yes

Organism		Endpoint Value[1]	Feeding Guilds	Exposure[2]		RQ[3]	LOC exceeded
				EEC (mg a.i./kg dry weight)	EDE[4] (mg a.i./kg bw/day)		
Bird: 1000 g	Acute	51 mg a.i./kg bw/day	Insectivore	199	11.9	0.2	No
			Granivore	34	2.0	0.04	No
			Frugivore	102	6.1	0.1	No
			Herbivore	1239	74.3	**1.5**	Yes
	Dietary	30 mg a.i./kg bw/day	Insectivore	199	11.9	0.4	No
			Granivore	34	2.0	0.06	No
			Frugivore	102	6.1	0.2	No
			Herbivore	1239	74.3	**2.5**	Yes
	Reproduction	15.6 mg a.i./kg bw/day	Insectivore	199	11.9	0.8	No
			Granivore	34	2.0	0.1	No
			Frugivore	102	6.1	0.4	No
			Herbivore	1239	74.3	**4.8**	Yes
Mammals							
Mammal: 15 g	Acute	160 mg a.i./kg bw/day	Insectivore	199	29.9	0.2	No
			Granivore	34	5.1	0.03	No
			Frugivore	102	15.3	0.1	No
	Dietary	44.2 mg a.i./kg bw/day	Insectivore	199	29.9	0.7	No
			Granivore	34	5.1	0.1	No
			Frugivore	102	15.3	0.3	No
	Reproduction	14.9 mg a.i./kg bw/day	Insectivore	199	29.9	**2**	Yes
			Granivore	34	5.1	0.3	No
			Frugivore	102	15.3	**1.1**	Yes

Organism		Endpoint Value[1]	Feeding Guilds	Exposure[2]		RQ[3]	LOC exceeded
				EEC (mg a.i./kg dry weight)	EDE[4] (mg a.i./kg bw/day)		
Mammal: 35 g	Acute	160 mg a.i./kg bw/day	Insectivore	199	25.9	0.2	No
			Granivore	34	4.4	0.03	No
			Frugivore	102	13.3	0.08	No
			Herbivore	1239	161.1	**1.0**	Yes
	Dietary	44.2 mg a.i./kg bw/day	Insectivore	199	25.9	0.6	No
			Granivore	34	4.4	0.1	No
			Frugivore	102	13.3	0.3	No
			Herbivore	1239	161.1	**3.7**	Yes
	Reproduction	14.9 mg a.i./kg bw/day	Insectivore	199	25.9	**1.7**	Yes
			Granivore	34	4.4	0.3	No
			Frugivore	102	13.3	0.9	No
			Herbivore	1239	161.1	**10.8**	Yes
Mammal: 1000g	Acute	160 mg a.i./kg bw/day	Insectivore	199	13.9	0.09	No
			Granivore	34	2.4	0.02	No
			Frugivore	102	7.1	0.04	No
			Herbivore	1239	86.7	0.5	No
	Dietary	44.2 mg a.i./kg bw/day	Insectivore	199	13.9	0.3	No
			Granivore	34	2.4	0.05	No
			Frugivore	102	7.1	0.2	No
			Herbivore	1239	86.7	**2.0**	Yes
	Reproduction	14.9 mg a.i./kg bw/day	Insectivore	199	13.9	0.9	No
			Granivore	34	2.4	0.2	No
			Frugivore	102	7.1	0.5	No
			Herbivore	1239	86.7	**5.8**	Yes
Application Rate 136 g a.i./ha × 6							
Birds							
Bird: 20 g	Acute	51 mg a.i./kg bw/day	Insectivore	68	17.7	0.3	No
			Granivore	12	3.1	0.06	No
			Frugivore	35	9.1	0.2	No
	Dietary	30 mg a.i./kg bw/day	Insectivore	68	17.7	0.6	No
			Granivore	12	3.1	0.1	No
			Frugivore	35	9.1	0.3	No
	Reproduction	15.6 mg a.i./kg bw/day	Insectivore	68	17.7	**1.1**	Yes
			Granivore	12	3.1	0.2	No
			Frugivore	35	9.1	0.6	No

Organism		Endpoint Value[1]	Feeding Guilds	Exposure[2]		RQ[3]	LOC exceeded
				EEC (mg a.i./kg dry weight)	EDE[4] (mg a.i./kg bw/day)		
Bird: 100 g	Acute	51 mg a.i./kg bw/day	Insectivore	68	13.6	0.3	No
			Granivore	12	2.4	0.05	No
			Frugivore	35	7.0	0.1	No
	Dietary	30 mg a.i./kg bw/day	Insectivore	68	13.6	0.5	No
			Granivore	12	2.4	0.08	No
			Frugivore	35	7.0	0.2	No
	Reproduction	15.6 mg a.i./kg bw/day	Insectivore	68	13.6	0.9	No
			Granivore	12	2.4	0.2	No
			Frugivore	35	7.0	0.5	No
Bird: 1000 g	Acute	51 mg a.i./kg bw/day	Insectivore	68	4.1	0.08	No
			Granivore	12	0.7	0.01	No
			Frugivore	35	2.1	0.04	No
			Herbivore	425	25.5	0.5	No
	Dietary	30 mg a.i./kg bw/day	Insectivore	68	4.1	0.1	No
			Granivore	12	0.7	0.02	No
			Frugivore	35	2.1	0.07	No
			Herbivore	425	25.5	0.9	No
	Reproduction	15.6 mg a.i./kg bw/day	Insectivore	68	4.1	0.3	No
			Granivore	12	0.7	0.04	No
			Frugivore	35	2.1	0.1	No
			Herbivore	425	25.5	**1.6**	Yes
Mammals							
Mammal: 15 g	Acute	160 mg a.i./kg bw/day	Insectivore	68	10.2	0.06	No
			Granivore	12	1.8	0.01	No
			Frugivore	35	5.3	0.03	No
	Dietary	44.2 mg a.i./kg bw/day	Insectivore	68	10.2	0.2	No
			Granivore	12	1.8	0.04	No
			Frugivore	35	5.3	0.1	No
	Reproduction	14.9 mg a.i./kg bw/day	Insectivore	68	10.2	0.7	No
			Granivore	12	1.8	0.1	No
			Frugivore	35	5.3	0.4	No

Organism		Endpoint Value[1]	Feeding Guilds	Exposure[2]		RQ[3]	LOC exceeded
				EEC (mg a.i./kg dry weight)	EDE[4] (mg a.i./kg bw/day)		
Mammal: 35 g	Acute	160 mg a.i./kg bw/day	Insectivore	68	8.8	0.06	No
			Granivore	12	1.6	0.01	No
			Frugivore	35	4.6	0.03	No
			Herbivore	425	55.3	0.3	No
	Dietary	44.2 mg a.i./kg bw/day	Insectivore	68	8.8	0.2	No
			Granivore	12	1.6	0.03	No
			Frugivore	35	4.6	0.1	No
			Herbivore	425	55.3	**1.3**	Yes
	Reproduction	14.9 mg a.i./kg bw/day	Insectivore	68	8.8	0.6	No
			Granivore	12	1.6	0.07	No
			Frugivore	35	4.6	0.3	No
			Herbivore	425	55.3	**3.7**	Yes
Mammal: 1000g	Acute	160 mg a.i./kg bw/day	Insectivore	68	4.8	0.005	No
			Granivore	12	0.8	0.005	No
			Frugivore	35	2.5	0.02	No
			Herbivore	425	29.8	0.2	No
	Dietary	44.2 mg a.i./kg bw/day	Insectivore	68	4.8	0.1	No
			Granivore	12	0.8	0.02	No
			Frugivore	35	2.5	0.06	No
			Herbivore	425	29.8	0.7	No
	Reproduction	14.9 mg a.i./kg bw/day	Insectivore	68	4.8	0.3	No
			Granivore	12	0.8	0.05	No
			Frugivore	35	2.5	0.2	No
			Herbivore	425	29.8	**2.0**	Yes

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e., protection at the community, population, or individual level)

[2] EEC: For birds and mammals, the EEC takes into account the maximum seasonal cumulative rate on vegetation and is calculated using PMRA standard methods based on the Hoerger and Kenaga nomogram as modified by Fletcher (1994)
EDE = Estimated dietary exposure; calculated for each bird or mammal size based on the EEC on appropriate food item for each food guild (at the screening level, the most conservative EEC for each food guild was used). The EDE was calculated using the following formula: (FIR/BW) × EEC. For each body weight (BW), the food ingestion rate (FIR) was based on equations from Nagy (1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used; for mammals, the "all mammals" equation was used:
Passerine Equation (body weight ≤200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All Birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$
All Mammals Equation: FIR (g dry weight/day) = 0.235(BW in g) 0.822

[3] RQ = exposure/toxicity; RQs < 0.1 were not calculated to show all decimal points

[4] Conversion from a concentration (EEC) to a dose (EDE): [EDE (mg a.i./kg bw) = EEC (mg a.i./kg diet)/BW (g) × FIR (g diet/day)]

Nagy, K.A. 1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecological Monographs 57:111-128

Table 11 Risk to birds and small wild mammals from spray drift (6%) 1 meter downwind following field sprayer applications

Organism		Endpoint Value	Feeding Guilds	RQ	LOC exceeded
Application rate 720 g a.i./ha × 2					
Birds					
Bird: 20 g	Acute	51 mg a.i./kg bw/day	Insectivore	0.06	No
	Dietary	30 mg a.i./kg bw/day	Insectivore	0.1	No
	Chronic	15.6 mg a.i./kg bw/day	Insectivore	0.2	No
			Frugivore	0.1	No
Bird: 100 g	Dietary	30 mg a.i./kg bw/day	Insectivore	0.08	No
	Chronic	15.6 mg a.i./kg bw/day	Insectivore	0.2	No
			Frugivore	0.08	No
Bird: 1000 g	Acute	51 mg a.i./kg bw/day	Herbivore	0.09	No
	Dietary	30 mg a.i./kg bw/day	Herbivore	0.2	No
	Chronic	15.6 mg a.i./kg bw/day	Herbivore	0.3	No
Mammals					
Mammal: 15 g	Chronic	14.9 mg a.i./kg bw/day	Insectivore	0.1	No
			Frugivore	0.07	No
Mammal: 35 g	Acute	160 mg a.i./kg bw/day	Herbivore	0.06	No
	Dietary	44.2 mg a.i./kg bw/day	Herbivore	0.2	No
	Chronic	14.9 mg a.i./kg bw/day	Insectivore	0.1	No
			Herbivore	0.6	No
Mammal: 1000 g	Dietary	44.2 mg a.i./kg bw/day	Herbivore	0.1	No
	Chronic	14.9 mg a.i./kg bw/day	Herbivore	0.3	No

Table 12 Risk to birds and small wild mammals from spray drift 1 meter downwind following airblast applications

Organism	Exposure	Endpoint Value	Feeding Guilds	RQ		LOC Exceeded	
				74%	59%	74%	59%
Application rate 136 g a.i./ha × 6							
Birds							
Bird: 20 g	Chronic	15.6 mg a.i./kg bw/day	Insectivore	0.8	0.6	No	No
Bird: 1000 g	Chronic	15.6 mg a.i./kg bw/day	Herbivore	**1.2**	0.9	Yes	No
Mammals							
Mammal: 35 g	Dietary	44.2 mg a.i./kg bw/day	Herbivore	0.9	0.8	No	No
	Chronic	14.9 mg a.i./kg bw/day	Herbivore	**2.7**	**2.2**	Yes	Yes
Mammal: 1000 g	Chronic	14.9 mg a.i./kg bw/day	Herbivore	**1.5**	**1.2**	Yes	Yes

Table 13 Screening Level Risk Assessment for Aquatic Organisms

Organism	Exposure	Endpoint value[1]	Use Rate	EEC[2] (mg a.i./L)	RQ	LOC exceeded
Freshwater Species						
waterflea (*Daphnia magna*)	Acute	48-h LC_{50} ÷ 2 (5.5 mg a.i./L)	720 g a.i./ha × 2	0.18	0.03	No
			136 g a.i./ha × 6	0.1	0.02	No
waterflea (*Daphnia magna*)	Chronic	21-d NOEC (1.0 mg a.i./L)	720 g a.i./ha × 2	0.18	0.2	No
			136 g a.i./ha × 6	0.1	0.1	No
Fathead minnow (*Pimphales promelas*)	Acute	96-h LC_{50} ÷ 10 (0.14 mg a.i./L)	720 g a.i./ha × 2	0.18	**1.3**	Yes
			136 g a.i./ha × 6	0.1	0.7	No
Rainbow trout (*Oncorhynchus mykiss*)	Chronic	21-d NOEC (0.2 mg a.i./L)	720 g a.i./ha × 2	0.18	0.9	No
			136 g a.i./ha × 6	0.1	0.5	No
Green algae (*Selenastrum capricornutum*)	Chronic	NOEC (0.6 mg a.i./L)	720 g a.i./ha × 2	0.18	0.3	No
			136 g a.i./ha × 6	0.1	0.2	No
Amphibians[3]	Acute	96-h LC_{50} ÷ 10 (0.14 mg a.i./L)	720 g a.i./ha × 2	0.96	**7.0**	Yes
			136 g a.i./ha × 6	0.54	**4.0**	Yes
			80 g a.i./ha × 5	0.27	**2.0**	Yes
			45.2 g a.i./ha × 3	0.09	0.6	No

Organism	Exposure	Endpoint value[1]	Use Rate	EEC[2] (mg a.i./L)	RQ	LOC exceeded
Amphibians[3]	Chronic	21-d NOEC (0.2 mg a.i./L)	720 g a.i./ha × 2	0.96	**5.0**	Yes
			136 g a.i./ha × 6	0.54	**3.0**	Yes
			80 g a.i./ha × 5	0.27	**1.4**	Yes
			45.2 g a.i./ha × 3	0.09	0.5	No
Marine/Estuarine Species						
Mysid shrimp (*Mysidopsis bahia*)	Acute	96-h LC_{50} ÷ 2 (0.12 mg a.i./L)	720 g a.i./ha × 2	0.18	**1.5**	Yes
			136 g a.i./ha × 6	0.1	0.8	No
			80 g a.i./ha × 5	0.05	0.4	No
			45.2 g a.i./ha × 3	0.007	0.06	No

1 Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e., protection at the community, population, or individual level)
2 EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.
3 Endpoints from fish used as surrogate

Table 14 Refined Risk Assessment for Aquatic Organisms (Off-field, spray drift)

Organism	Exposure	Endpoint Value[1]	Use Rate	RQ		
				6%	74%	59%
Freshwater Species						
Fathead minnow (*Pimphales promelas*)	Acute	96-h LC_{50} ÷ 10 (0.14 mg a.i./L)	720 g a.i./ha × 2	0.08		
Amphibians[2]	Acute	96-h LC_{50} ÷ 10 (0.14 mg a.i./L)	720 g a.i./ha × 2	0.4		
			136 g a.i./ha × 6		**3.0**	**2.4**
			80 g a.i./ha × 5		**1.5**	**1.2**
Amphibians[2]	Chronic	21-d NOEC (0.2 mg a.i./L)	720 g a.i./ha × 2	0.3		
			136 g a.i./ha × 6		**2.2**	**2.0**
			80 g a.i./ha × 5		**1.0**	0.8
Estuarine/Marine Species						
Mysid shrimp (*Mysidopsis bahia*)	Acute	96-h LC_{50} ÷ 2 (0.02 mg a.i./L)	720 g a.i./ha × 2	0.1		

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

Table 15 Refined Risk Assessment for Aquatic Organisms (Runoff)

Organism	Endpoint value[1]	Scenario	EEC (µg a.i./L)[2]	RQ	LOC Exceeded
Freshwater Species					
Apple, 6 × 0.136 kg a.i./ha at a 7-day interval					
waterflea (*Daphnia magna*)	Acute 48-h $LC_{50} \div 2$ (5,500 µg a.i./L)	Nova Scotia	31.7	0.006	No
waterflea (*Daphnia magna*)	Chronic 21-d NOEC (1,000 µg a.i./L)	Nova Scotia	30.8	0.03	No
Fathead minnow (*Pimphales promelas*)	Acute 96-h $LC_{50} \div 10$ (140 µg a.i./L)	Nova Scotia	31.7	0.2	No
Rainbow trout (*Oncorhynchus mykiss*)	Chronic 21-d NOEC (200 µg a.i./L)	Nova Scotia	30.8	0.2	No
Green algae (*Selenastrum capricornutum*)	Chronic NOEC (600 µg a.i./L)	Nova Scotia	30.8	0.05	No
Amphibians[3]	Acute 96-h $LC_{50} \div 10$ (140 µg a.i./L)	Nova Scotia	58.0	0.4	No
Amphibians[3]	Chronic 21-d NOEC (200 µg a.i./L)	Nova Scotia	39.8	0.2	No
Turfgrass 2 × 0.720 kg a.i./ha at a 14-day interval					
waterflea (*Daphnia magna*)	Acute 48-h $LC_{50} \div 2$ (5,500 µg a.i./L)	Charlottetown P.E.I.	24.5	0.004	No
waterflea (*Daphnia magna*)	Chronic 21-d NOEC (1,000 µg a.i./L)	Charlottetown P.E.I.	23.9	0.02	No

Organism	Endpoint value[1]	Scenario	EEC (µg a.i./L)[2]	RQ	LOC Exceeded
Fathead minnow (*Pimphales promelas*)	Acute 96-h LC_{50} ÷ 10 (140 µg a.i./L)	Charlottetown P.E.I.	24.5	0.2	No
Rainbow trout (*Oncorhynchus mykiss*)	Chronic 21-d NOEC (200 µg a.i./L)	Charlottetown P.E.I.	23.9	0.1	No
Green algae (*Selenastrum capricornutum*)	Chronic NOEC (600 µg a.i./L)	Charlottetown P.E.I.	24.5	0.04	No
Amphibians[3]	Acute 96-h LC_{50} ÷ 10 (140 µg a.i./L)	Charlottetown P.E.I.	55.7	0.4	No
Amphibians[3]	Chronic 21-d NOEC (200 µg a.i./L)	Charlottetown P.E.I.	32.2	0.2	No
Estuarine/Marine Species					
Turfgrass , 2 × 0.720 kg a.i./ha at a 14-day interval					
Mysid shrimp (*Mysidopsis bahia*)	Acute 96-h LC_{50} ÷ 2 (120 µg a.i./L)	Abbotsford - B.C.	13.4	0.1	No
Mysid shrimp (*Mysidopsis bahia*)	Acute 96-h LC_{50} ÷ 2 (120 µg a.i./L)	Charlottetown – P.E.I.	24.5	0.2	No

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

2 EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.

3 Endpoints from fish used as surrogate

Table 16 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes			
Predominantly anthropogenic[2]	Yes			
Persistence[3]:	Soil Yes	Half-life ≥182 days	Half-life 691 days	
	Water	Half-life ≥182 days	Half-life	
	Sediment	Half-life ≥365 days	Half-life	
	Air No	Half-life ≥2 days or evidence of long range transport	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (1.29×10^{-8} mm Hg at 25ºC) and Henry's Law Constant (3.45×10^{-11} $atm.m^3.mol^-$).	
Bioaccumulation[4]	Log K_{ow} ≥5		Value 1.98	
	BCF ≥5000		not available	
	BAF ≥5000		not available	
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	

1 All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).

2 The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

3 If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

4 Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K_{ow}).

Appendix VII Myclobutanil Aquatic Ecoscenario Assessment

1.0 Introduction

The following sections provide a review of the estimated environmental concentrations (EECs) of myclobutanil resulting from water modelling and the available water monitoring data with respect to environmental exposure.

Monitoring data and modelling estimates provide different types of information, therefore are not directly comparable. Pesticide concentrations in water are highly variable in time and location, and Canadian monitoring data usually are sparse, so comparing monitoring results to modelling is not straightforward. Despite this, these two types of data are complementary and should be considered in conjunction with each other when considering the potential exposure of aquatic organisms or to humans through drinking water.

2.0 Modelling Estimates

2.1 Aquatic Ecoscenario Assessment: Level 1 Modelling

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

Myclobutanil is a fungicide used on a variety of fruits and vegetables grown outdoors and in greenhouses, as well as on outdoor ornamentals, Kentucky bluegrass and turfgrass on golf courses. The maximum annual application rate is for use on turfgrass on golfcourses, 2 applications of 0.72 kg a.i./ha at a 14 day interval. Unlike the drinking water assessment, the tee, green and fairway percent cropped area (PCA) was not applied because of the smaller drainage area of the ecoscenario water body. The use on apples (6 applications of 0.136 kg a.i./ha at a 7 day interval) was also modelled. Application information and the main environmental fate characteristics used in the models are summarized in Table 1.

Table 1 Major groundwater and surface water model inputs for Level 1 assessment of myclobutanil

Type of Input	Parameter	Value
Application Information	Crops to be treated	Turfgrass on golf courses Apples
	Maximum allowable application rate per year (g a.i./ha)	Turf: Level 1: 3200; Level 2 (drinking water): 1600; Level 1 (ecoscenario): 1440
	Maximum rate each application (g a.i./ha)	Turf (drinking water): 800; Turf (ecoscenario): 720 Apples: 136
	Maximum number of applications per year	Turf: Level 1: 4; Level 2: 2 for turfgrass, 6 for apples
	Minimum interval between applications (days)	Turf: 14 Apples: 7
	Method of application	Ground application for turf Airblast application for apples
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	Stable
	Photolysis half-life in water (days)	24.6
	Adsorption K_{oc} (mL/g)	258 (20^{th} percentile of five K_{foc} values)
	Aerobic soil biotransformation half-life (days)	691 (half-life from the slow rate of a single biotransformation study with biphasic dissipation kinetics)
	Aerobic aquatic biotransformation half-life (days)	Stable (single study; DT_{50} not reached)
	Anaerobic aquatic biotransformation half-life (days)	Stable (single study; DT_{50} not reached)

Ten standard scenarios were used to represent different regions of Canada. A total of fourteen application dates between March and June were modelled. The EECs in water bodies for application dates producing the largest EEC for each regional scenario are reported in Table 2 for a water body of 80 cm deep and in Table 3 for a water body of 15 cm deep, respectively. Deposition from spray drift was not included in the simulations, so these EECs are for the portion of the pesticide that enters the water body via runoff only. The model was run for 50 years for all scenarios. For each year of the simulation, PRZM/EXAMS calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day, and 1 year). The 90^{th} percentiles over each averaging period are reported as the EECs for that period.

Table 2 Level 1 aquatic ecoscenario modelling results (μg a.i./L) for myclobutanil in a water body 0.8 m deep, excluding spray drift.

Region	EEC (μg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Apple, 6 × 0.136 kg a.i./ha at a 7-day interval						
Okanagan-BC	3.3	3.3	3.3	3.3	3.3	3.1
Nova Scotia	31.7	31.3	30.8	30.3	30.3	28.6
Toronto-ON	24.7	24.5	24.2	23.8	23.7	22.8
Montreal-QC	21.6	21.4	21.1	20.7	20.6	19.7
Turfgrass, 2 × 0.720 kg a.i./ha at a 14-day interval (no application of PCA)						
Abbotsford-BC	13.4	13.3	13.3	13.2	13.1	12.2
Charlottetown-PEI	24.5	24.4	23.9	22.9	22.6	21.7
Grandeprairie-AB	21.0	20.9	20.9	20.6	20.2	18.7
Okanagan-BC	0.9	0.8	0.8	0.8	0.8	0.7
Toronto-ON	19.0	18.9	18.6	18.5	18.4	17.1
Winnipeg-MB	24.4	24.1	23.5	22.8	22.6	21.6

Table 3 Level 1 aquatic ecoscenario modelling results (μg a.i./L) for myclobutanil in a water body 0.15 m deep, excluding spray drift.

Region	EEC (μg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Apple, 6 × 0.136 kg a.i./ha at a 7-day interval						
Okanagan-BC	8.9	7.3	4.6	4.0	4.0	3.6
Nova Scotia	58.0	50.8	39.8	35.8	35.0	31.9
Toronto-ON	42.7	36.6	29.3	27.3	26.8	24.8
Montreal-QC	35.7	32.1	26.2	23.2	22.9	20.8
Turfgrass, 2 × 0.720 kg a.i./ha at a 14-day interval (no application of PCA)						
Abbotsford-BC	30.2	24.5	17.8	15.0	14.6	12.8
Charlottetown-PEI	55.7	46.0	32.2	28.3	27.8	24.8
Grandeprairie-AB	40.3	33.7	30.6	28.5	28.5	26.3
Okanagan-BC	1.4	1.4	1.4	1.0	0.9	0.9
Toronto-ON	37.9	30.7	24.8	22.2	22.0	19.2
Winnipeg-MB	47.9	39.3	30.7	26.6	26.4	24.4

3.0 Water Monitoring data

3.1 Sources of Data

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

US databases were searched for detections of myclobutanil. Data on residues present in water samples taken in the US are important to consider in the Canadian drinking water assessment given the extensive monitoring programs that exist in the US. Runoff events, local use patterns, site specific hydrogeology as well as testing and reporting methods are probably more important influences on residue data rather than Northern versus Southern climate. As for the climate, if temperatures are cooler, residues may break down more slowly, on the other hand if temperatures are warmer, growing seasons may be longer and applications may be more numerous and frequent.

Data were available from the US Geological Survey National Water Quality Assessment program (NAWQA) for both groundwater and surface water, and from the Six Year Review of National Drinking Water Regulations, as part of the US National Contaminant Occurrence Database (NCOD).

3.2 Approach for Evaluation

Data from Canadian and US water monitoring studies in which myclobutanil was quantified are summarized in Table 4.

For both the ecoscenario assessment and the drinking water assessment, information was extracted from the available sources, tabulated and sorted into categories as follows:

1. Residues in known drinking water sources (both surface and groundwater)
2. Residues in ambient water that may serve as a drinking water source (both surface and groundwater)
3. Residues in ambient water that are unlikely to serve as a drinking water source

An important limitation of the monitoring data set is that, in many cases, the data were not accompanied with use data for myclobutanil. For instance, the application rate applied, when the application occurred and weather conditions prior to sampling were not known or reported. Without this information, it is difficult to conclude if non-detects were a result of non-transport or more simply a result of inappropriate timing of sampling. In addition, because the data are sparse and concentrations vary in time and space, the maximum concentration reported is unlikely to be the absolute maximum concentration that would be observed in Canada. Factors that may result in higher concentrations being detected include application at higher rates,

precipitation and some areas/soils are simply more prone to leaching and/or run off. Sampling at intervals immediately following application would increase the likelihood that the maximum concentration would be detected.

Thus, it is likely myclobutanil was not used in some of the areas monitored, and that higher concentrations of myclobutanil may occur in other areas not monitored. The myclobutanil monitoring data likely underestimate the peak exposure because of the following limitations:

1. In general, the data are sparse in both time and location. In some of the studies available, myclobutanil was analyzed in samples that were taken from non-myclobutanil use areas. Myclobutanil use information from the areas surrounding where the samples were collected is often not available.

2. Sampling in some of the studies was conducted during periods when myclobutanil is not applied in Canada (for example, October through March).

3. The concentrations of pesticides in surface water are directly related to the frequency and timing of monitoring in relation to pesticide application and runoff events. Therefore, timing and frequency of sampling is likely to be the most important factor influencing the concentration detected and the frequency of detections. Samples are often taken at arbitrary time intervals (for example, once a month, once a week) and are unlikely to capture the absolute maximum concentration of myclobutanil.

The following statistics are used to interpret the information available in each dataset and are summarized in Table 5-19.

- The detection frequency provides an indication of how often positive detections occur within the given data set. Detection frequency is primarily determined by the limits of detection and is influenced by pesticide use patterns and application rates. Consequently, a wide range of detection frequencies is likely to be expected.

- The 95th percentile concentration is calculated and reported. Maximum values should also be considered, especially when the 95th percentile is not available which occurs when there are insufficient detections to calculate a 95th percentile.

- The maximum concentration is reported and is used to determine the 95th percentile concentration to estimate an acute exposure value.

- The arithmetic mean with non-detects considered at ½ LOD is used to determine the 95th percentile concentration to estimate a chronic exposure value.

Table 4 Summary of the Monitoring Studies Available

Data Source	DETECTION FREQUENCY						CONCENTRATION PERCENTILES (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
Myclobutanil Residues in Municipal drinking water sources and ground water											
PMRA 1307578	Apple growing region of Quebec 1994			0.03	42	2	4.8	–	–	0.25	0.02
PMRA 1650531	Groundwater USA - NAWQA			0.008 – 0.033	2773	6	0.22	0.01	0.02	0.02	0.009
Myclobutanil residues in ambient water that may serve as a drinking water source											
PMRA 1650541	USA - NAWQA			0.002 – 0.25	3629	396	10.9	0.04	0.19	0.51	0.012
PMRA 1307571	Corn and Soya bean region of Quebec	Chibouet	1999	0.02	45	0	0.0	–	–	–	0.01
			2000	0.04	40	0	0.0	–	–	–	0.02
			2001	0.04	46	0	0.0	–	–	–	0.020
		Hurons	1999	0.02	45	3	6.7	0.02	0.03	0.03	0.01
			2000	0.04	42	0	0.0	–	–	–	0.02
			2001	0.04	44	4	9.1	0.05	0.06	0.06	0.02
		Saint-Regis	1999	0.02	45	0	0.0	–	–	–	0.01
			2000	0.04	43	0	0.0	–	–	–	0.02
			2001	0.04	45	0	0.0	–	–	–	0.020
		Saint-Zephirin	1999	0.02	45	0	0.0	–	–	–	0.01
			2000	0.04	43	0	0.0	–	–	–	0.02
			2001	0.04	46	0	0.0	–	–	–	0.020
		Yamaska	1999	0.02	45	0	0.0	–	–	–	0.01
			2000	0.04	43	0	0.0	–	–	–	0.02

Data Source	DETECTION FREQUENCY							CONCENTRATION PERCENTILES (μg/L)			
	Location			Min detection or detection limit (μg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1398451, 1398452, 1398453	Corn and Soya bean region of Quebec	Chibouet	2002	0.02	43	0	0.0	–	–	–	0.01
			2003	0.02	41	0	0.0	–	–	–	0.01
			2004	0.02	41	0	0.0	–	–	–	0.01
		Hurons	2002	0.02	42	3	7.1	0.09	0.13	0.13	0.020
			2003	0.02	41	2	4.9	0.039	0.03	0.03	0.01
			2004	0.02	41	1	2.4	0.03	0.03	0.03	0.01
		Saint-Regis	2002	0.02	40	0	0	–	–	–	0.01
			2003	0.02	39	2	5.1	0.03	0.03	0.03	0.01
			2004	0.02	39	0	0	–	–	–	0.01
		Saint-Zephirin	2002	0.02	42	0	0.0	–	–	–	0.01
			2003	0.02	39	0	0.0	–	–	–	0.01
			2004	0.02	39	0	0.0	–	–	–	0.01
PMRA 1307568	Corn and Soya bean region of Quebec	Chibouet	1996	0.05	40	0	0.0	–	–	–	0.030
			1997	0.04	37	0	0.0	–	–	–	0.020
			1998	0.04	42	0	0.0	–	–	–	0.020
		Hurons	1996	0.05	41	13	31.7	0.05	0.05	0.05	0.03
			1997	0.04	39	2	5.1	0.04	0.04	0.04	0.02
			1998	0.04	45	5	11	0.05	0.05	0.05	0.02
		Saint-Regis	1996	0.05	41	1	2.4	0.05	0.05	0.05	0.03
			1997	0.04	40	0	0	–	–	–	0.020
			1998	0.04	51	0	0.0	–	–	–	0.020
		Saint-Zephirin	1996	0.05	39	0	0.0	–	–	–	0.030
			1997	0.04	39	0	0.0	–	–	–	0.020
			1998	0.04	48	0	0.0	–	–	–	0.020

Data Source	DETECTION FREQUENCY							CONCENTRATION PERCENTILES (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1307569	Corn and Soya bean region of Quebec	St. Zephirin	1995	0.002	38	0	0.0	–	–	–	0.01
		Chibouet	1995	0.002	38	0	0.0	–	–	–	0.01
		des Hurons	1995	0.002	34	0	0.0	–	–	–	0.01
		St. Regis	1995	0.002	35	1	2.9	0.02	0.02	0.02	0.01
		St. Esprit	1995	0.002	6	0	0.0	–	–	–	0.01
		des Anges	1995	0.002	2	0	0.0	–	–	–	0.01
		Yamaska	1995	0.002	2	0	0.0	–	–	–	0.01
PMRA 1307578	Apple Growing Region of Quebec	Deversant	1995	0.02	15	5	33.3	0.13	0.31	0.35	0.05
			1996	0.05	23	12	52.2	0.14	0.53	1.20	0.1
		Boffin	1995	0.02	13	0	0	–	–	–	0.01
			1996	0.05	24	12	50	0.05	0.05	0.06	0.04

4.0 Discussion and Conclusions

4.1 Discussion of Exposure Estimates for Ecoscenario

The limited amount of monitoring data available to the PMRA did not allow for an estimation of the residues of myclobutanil in wetlands based on monitoring data.

The concentrations of myclobutanil detected in water were obtained from studies conducted in Quebec and do not represent detections that may have occurred in other regions of Canada. Except for one sample location the detection frequency of myclobutanil was generally below 10% at levels less than 0.5 µg/L.

The EECs available for use in the ecological risk assessment are listed in Tables 2 and 3.

4.2 Drinking Water

The limited amount of monitoring data available to the PMRA did not allow for an estimation of the residues of myclobutanil in drinking water. The concentrations of myclobutanil in drinking water that should be considered in the risk assessment are the Level 2 EECs estimated for drinking water sources (Table 6). These estimates are considered to be reasonable upper bound values and are representative of the highest concentration of myclobutanil that may be detected in drinking water.

4.3 Estimated Concentrations in Drinking Water Sources: Level 1 Modelling

Level 1 Modelling

Estimated environmental concentrations (EECs) of myclobutanil in potential drinking water sources (groundwater and surface water) were estimated using computer simulation models. An overview of how the EECs are estimated is provided in the PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*. EECs of myclobutanil in groundwater were calculated using the LEACHM model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using LEACHM are estimates of the flux, or movement, of pesticide into shallow groundwater (2 m or 5 m depth) with time. EECs of myclobutanil in surface water were calculated using the PRZM/EXAMS models, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in one type of vulnerable drinking water source, a small reservoir.

Myclobutanil is a fungicide used on a variety of fruits and vegetables grown outdoors and in greenhouses, as well as on outdoor ornamentals, Kentucky bluegrass and turfgrass on golf courses. The maximum annual application rate is 3.2 kg a.i./ha, for use on turfgrass on golfcourses (four applications of 0.8 kg a.i./ha at 14-day intervals). The next highest rate of application is for apples, six applications of 0.136 kg a.i./ha at 7-day intervals, for a total yearly rate of 0.816 kg a.i./ha. Only the use on turfgrass was modelled at Level 1.

It was assumed that the use with the highest rate of myclobutanil, turfgrass on golfcourses, would not affect dugouts used for drinking water. A dugout used for drinking water would not likely be placed in a golf course. EECs in surface water were thus only generated for the reservoir. Application information and the main environmental fate characteristics used in the models are summarized in Table 1.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. The Level 1 EEC estimate is expected to allow for future use expansion into other crops at this application rate. Table 1 lists the application information and main environmental fate characteristics used in the models. Table 5 below provides the Level 1 EECs for potential sources of drinking water.

Table 5 Level 1 estimated environmental concentrations of myclobutanil in potential drinking water sources

Compound	Groundwater EEC (μg a.i./L)		Surface Water EEC[1] (μg a.i./L)	
			Reservoir	
	Daily[2]	Yearly[3]	Daily[4]	Yearly[5]
myclobutanil	**803**	**794**	**99**	**32**

1 EECs provided for the reservoir only, as use on golf course turfgrass is not likely to affect dugouts used for drinking water.
2 90th percentile of daily average concentrations
3 90th percentile of yearly average concentrations
4 90th percentile of yearly peak concentrations
5 90th percentile of yearly average concentrations

Level 2 modelling

A Level 2 drinking water assessment was requested as the dietary assessment did not pass using EECs from Level 1 modelling.

For surface water modelling at Level 2, a revised use pattern for turfgrass (two applications of 0.8 kg a.i./ha at 14-day intervals), was modelled using a turf scenario and weather files for six locations across Canada. Given the turf use is on golf courses only and additionally only on tees and greens, the EECs for the turf use were modified by assuming a percent cropped area (PCA) of 34% (US EPA). The use pattern for apples (six applications of 0.136 kg a.i./ha at 7-day intervals) was modelled using apple scenarios and weather files for four regions across Canada.

For groundwater, the main environmental fate characteristics used in the models were the same as those for Level 1 (Table 1). Similar to surface water, the EECs for the turf use were modified by assuming a percent cropped area of 34%. In addition, at level 2, the LEACHM model was run using the application schedule for apples (for which no PCA was used). Table 6 below provides the Level 2 EECs for potential sources of drinking water for both turf and apple uses.

Table 6 Level 2 estimated environmental concentrations of myclobutanil in potential drinking water sources

Use	Groundwater EEC (μg a.i./L)		Surface Water EEC[1] (μg a.i./L)	
			Reservoir	
	Daily[2]	Yearly[3]	Daily[4]	Yearly[5]
Turf (2 × 0.8 kg a.i./ha, 14-d intervals)[6]	137	135	11	11
Apple (6 × 0.136 kg a.i./ha, 7-d intervals)	175	175	19	19

Notes:
1 EECs provided for the reservoir only, as use on golf course turfgrass is not likely to affect dugouts used for drinking water.
2 90th percentile of daily average concentrations
3 90th percentile of yearly average concentrations
4 90th percentile of yearly peak concentrations
5 90th percentile of yearly average concentrations
6 Revised use pattern for turf (two applications per year instead of four).

Appendix VIII Proposed Label Amendments for Commercial Class Products Containing Myclobutanil

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

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

Application Rates

All labels must be changed to specify a maximum application rate for golf course turf of 7.3 grams per 100 square meters (0.73 kg a.i./ha) over a maximum of 8 hectares per day for golf course turf.

Soluble Granules in Water Soluble Packaging (WSP):

All myclobutanil products currently formulated as soluble granules must be in water soluble packaging. The following label instructions should be added to clearly indicate directions for water soluble packaging:

> Product "X" is a soluble granule sealed within a water soluble bag. **DO NOT** open or puncture water soluble bag for any reason. **DO NOT** use opened or punctured water soluble bag for any reason. If broken water soluble bags are found when container is opened, avoid contact with, and inhalation of the product. Wear chemical resistant coveralls, chemical resistant gloves and a respirator to dispose of broken water soluble bags according to **DISPOSAL** section.

Application Intervals

All labels must be changed to specify: "Limit the number of applications to a maximum of (value from Table 1) with a minimum of (value from Table 1) days between applications."

Table 1 Recommended Application Intervals

Crop	Applications per Year	
	Number	Interval (days)
apples	6	7
cherries (sweet & sour), peaches, nectarines	6	7
asparagus (post-harvest)	5	7
grapes	5	14
strawberries	6	14
Saskatoon berries	3	14
carnations	6	10
OUTDOOR ORNAMENTAL TREES & SHRUBS: pear (flowering), privet, dogwood, euonymus, hawthorn, juniper (flowering), azalea/rhododendron, honeysuckle, lilac	6	14
OUTDOOR ORNAMENTAL TREES & SHRUBS: crab-apple (flowering); nursery crops: ash, amelanchier	6	10
outdoor ornamental roses	4	10
outdoor ornamental juniper	4	14
OUTDOOR ORNAMENTAL FLOWERS, SHRUBS: roses, hollyhock, phlox, nursery crops: iris, chrysanthemums, hollyhock, phlox	6	10
Nursery poinsettias	5	10
Greenhouse poinsettias	5	10
Turf (Kentucky bluegrass grown for seed)	2	14
Turf (golf courses)	2	14

Maximum Spray Volume

Where maximum spray volume is not currently specified the following statement should be added:

> Apply at the recommended rate using a maximum spray volume of 1000L per hectare, unless otherwise stated.

Use Precautions

To reduce bystander exposure, the following statements must be added to all 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.

Keep the following personal protective equipment immediately available for use in case of emergency (i.e., a broken package, spill, or equipment breakdown): chemical-resistant coveralls, chemical-resistant gloves, chemical-resistant foot wear, chemical-resistant head gear and a respirator.

Hazardous to humans and domestic animals. Keep out of reach of children.
Causes eye irritation. A potential skin sensitizer. May cause irritation to the nose, throat and skin. Harmful if swallowed, inhaled, or absorbed through the skin. **DO NOT** get in eyes, on skin or breathe spray mist.

DO NOT apply by air.

Use only properly calibrated groundboom, chemigation or hand held equipment as specified by the label"

Use only properly calibrated groundboom equipment for turf applications.

Not for use by homeowners or other uncertified users.

DO NOT use in residential areas (excepting golf courses). Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, school, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed.

Personal Protective Equipment

For consistency between labels, and for the purpose mitigating the risk of exposure to myclobutanil, the following directions must be included on all labels:

Wear goggles, mid-forearm to elbow-length chemical- resistant gloves, chemical-resistant footwear, a wide brimmed hat, chemical-resistant coveralls over long pants and a long-sleeved shirt and an appropriate respirator when mixing, loading, and applying this product. Pants or coveralls should be worn outside footwear to prevent pooling within boots.

Remove protective equipment immediately after handling this product. Wash outside of gloves and footwear before removing. As soon as possible, wash thoroughly and change into clean clothing. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this products concentrate. **DO NOT** reuse them. Contaminated clothing must be laundered

separately in hot water before reusing. Wash hands and face thoroughly after handling and before eating, drinking, chewing gum, smoking, or using toilet.

DO NOT enter treated areas for a minimum of 12 hours for all crops (unless a longer REI is specified) or until sprays have dried for golf courses. Wear gloves, long sleeved shirts, long pants, a hat and work boots when entering treated areas, including greenhouses, for harvesting, pruning, thinning, suckering or for any other agricultural practice in the treated area. **DO NOT** apply this product in such a manner as to directly or through drift expose workers or other persons. Unprotected persons must be vacated from the area being treated. Only protected handlers may be in the area during application.

Restricted-entry Intervals

Where deemed necessary, REIs are subdivided according to re-entry activities. Any REI calculated to be less than 24 hours will be listed as 0.5 days (or until the spray has dried for golf courses) in order to be consistent with current label recommendations. REIs could not be determined for most greenhouse uses. All REIs are set following the final application of myclobutanil.

These restricted-entry intervals must be added to the appropriate labels as listed below:

Table 2 Recommended Restricted-entry Intervals

Crop	Activity	REI[a] (days)
apples, cherries (sweet & sour), peaches, nectarines	thinning	12
	hand harvest	5
	hand pruning, scouting, pinching, tying, training, hand weeding, propping, animal control, mechanical harvest (cherries only)	0.5
asparagus	All	2
grapes	cane turning and girdling	14
	hand harvesting & pruning, training, thinning, tying, leaf pulling	7
	hand line irrigation, scouting, hand weeding	0.5
strawberries	hand harvest, pinching, pruning, training	2
	irrigation, mulching, scouting, hand weeding	0.5
Saskatoon berries	hand harvest, hand pruning, hand thinning	3
	scouting, hedging, irrigating, hand weeding	0.5
carnations	all	17

Crop	Activity	REI[a] (days)
OUTDOOR ORNAMENTAL TREES & SHRUBS: pear (flowering), crab apple,(flowering), privet, dogwood, euonymus, hawthorn, juniper (flowering & non-flowering), honeysuckle, lilac, crab-apple (flowering); nursery crops: ash, amelanchier	all	0.5
Outdoor ornamental roses	all	11
OUTDOOR ORNAMENTAL FLOWERS, SHRUBS: roses, hollyhock, phlox nursery crops: roses, (cut and potted), gerbera, aster, chrysanthemums, geraniums iris, hollyhock, phlox	all	12
Nursery poinsettias	all	0.5
Greenhouse poinsettias	all	0.5
Kentucky bluegrass grown for seed	harvesting/transplanting treated turf, mowing, watering, irrigation, aerating, fertilizing, hand pruning, mechanical weeding, scouting, seeding	0.5
Golf course turf	transplanting treated turf	12
	mowing, watering, irrigation, aerating, fertilizing, hand pruning, repair, mechanical weeding, scouting, seeding, cup changing, grooming	dried spray

[a] Day at which the dermal exposure results in an MOE ≥100 or the minimum label REI of 0.5 days (or until spray has dried for golf courses).

ENVIRONMENTAL HAZARDS

All environmental statements under "**PRECAUTIONS**" and "**ENVIRONMENTAL HAZARDS**" on the labels for NOVA 40W and EAGLE WSP fungicides should be replaced by the following statements.

ENVIRONMENTAL HAZARDS

TOXIC to birds and small wild mammals

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

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

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.

DIRECTIONS FOR USE

As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply by air.

Buffer zones:

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

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Turfgrass (golf courses), carnations, grapes, asparagus, azalea, dogwood, euonymus, honeysuckle, lilac, privet, hawthorn, juniper, pear		1	0	1	1	1
Airblast	Grapes	Early growth stage	2	0	1	0	1
		Late growth stage	1	0	1	0	1
	Cherries, hollyhock, crabapple, nursery ornamentals, rose, peaches, apples, azalea, dogwood, euonymus, honeysuckle, lilac, privet, hawthorn, juniper, pear, Saskatoon berries	Early growth stage	4	0	2	0	2
		Late growth stage	2	0	1	0	1

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