

# **Proposed Re-evaluation Decision**

PRVD2019-03

# Dimethomorph and Its Associated End-use Products

Consultation Document

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# **Proposed Re-evaluation Decision**

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

Dimethomorph is a commercial fungicide registered for the management of disease in various vegetable and fruit crops, ginseng, and ornamentals grown under field and greenhouse conditions.

This document presents the proposed regulatory decision for the re-evaluation of dimethomorph including the proposed risk mitigation measures to further protect human health and the environment, as well as the science evaluation on which the proposed decision was based. All products containing dimethomorph registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period during which the public, including the pesticide manufacturers and stakeholders, may submit written comments and additional information to the <u>PMRA Publications Section</u>. The final re-evaluation decision will be published taking into consideration the comments and information received.

# **Outcome of Science Evaluation**

Dimethomorph is important for the management of potato late blight tuber rot, and sudden oak death on many high value outdoor, container and field grown ornamental plants in nurseries and landscape plantings, especially considering the limited number of registered alternatives for these diseases. Due to its protectant and antisporulant activity, and lower risk for resistance development, dimethomorph is valued as a rotational product in disease management programs.

With respect to human health, risks are considered to be acceptable for all dimethomorph uses when used according to the proposed revised label directions.

Dimethomorph enters the environment when used to control moulds on a variety of agricultural food and feed crops and outdoor ornamentals, or when it is present in water discharges from use in greenhouses. When used according to the proposed label directions, environmental risks associated with the use of dimethomorph were determined to be acceptable.

# **Proposed Regulatory Decision for Dimethomorph**

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing dimethomorph are acceptable for continued registration in Canada, provided that the required risk mitigation measures are in place.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law.

As a result of the re-evaluation of dimethomorph, further risk mitigation measures are being proposed.

#### Human Health

To protect mixer/loader/applicators, updated statements for personal protective equipment (PPE) to reflect current standards are required; a label restriction against applications as a mist or fog will also be added.

To protect workers entering treated sites, updated restricted-entry intervals (REIs) are proposed for certain agricultural uses.

To protect bystanders from spray drift, a statement is proposed to promote best management practices in order to minimize human exposure.

Residue Definition for Enforcement:

• The residue definition for the dietary risk assessment and enforcement is expressed as the parent compound, ethyl 2-[[[(4-chloro-6-methoxy-2-pyrimidinyl)amino]carbonyl]amino] sulfonyl] benzoate for all food commodities. No change to the residue definition is proposed.

#### Environment

To protect the environment:

- Hazard statements on the label to inform the user that dimethomorph is toxic to aquatic organisms,
- Buffer zones to mitigate the risk of exposure to non-target aquatic organisms,
- A label statement to inform the user to not discharge dimethomorph-contaminated effluent from greenhouses into aquatic environments,
- A label statement informing users of ways to reduce the potential for runoff; and
- A label statement indicating dimethomorph may leach to groundwater.

# **International Context**

Dimethomorph is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the European Union, the United States and Australia.

No decision by an OECD member country to prohibit all uses of dimethomorph for health or environmental reasons has been identified.

# **Next Steps**

The public, including registrants and stakeholders, are encouraged to submit comments during the 90-day public consultation period<sup>1</sup> upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document,<sup>2</sup> which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

# **Additional Scientific Information**

• None

<sup>&</sup>lt;sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>&</sup>lt;sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

# **Science Evaluation**

# 1.0 Introduction

Dimethomorph is a locally systemic fungicide with protectant and antisporulant activity. Its mode of action, classified as a Group 40 by the Fungicide Resistance Action Committee, acts by inhibiting fungal cell wall biosynthesis. Appendix I, Table 1 lists all dimethomorph products that are currently registered under the authority of the *Pest Control Products Act* as of 7 January 2019. Appendix I, Table 2 lists all commercial uses for which dimethomorph is 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 dimethomorph.

# 2.0 Technical Grade Active Ingredient

#### 2.1 Identity

Common name	Dimethomorph
Function	Fungicide
Chemical Family	Cinnamamide

Chemical name

1	International Union of Pure and Applied Chemistry (IUPAC)	( <i>EZ</i> )-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine
2	Chemical Abstracts Service (CAS)	4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1- oxo-2-propen-1-yl]morpholine
CAS	Registry Number	110488-70-5
Molecular Formula		$C_{21}H_{22}CINO_4$
Struc	tural Formula	$H_{3}C_{0}$ $H_{3}$ $H_{3}C_{0}$ $H_{3}C_{$
Moleo	cular Weight	387.9
	y of the Technical e Active Ingredient	98%
Regis	tration Number	24545

#### 2.2 Physical and Chemical Properties

Property	Result
Vapour pressure at 25°C	(E)-isomer = 0.00097 mPa (Z)-isomer = 0.001 mPa
Ultraviolet (UV) / visible spectrum	No absorbance at $\lambda > 300$ nm
Solubility in water at 20-25°C	49.2 mg/L (pH 7)
n-Octanol/water partition coefficient	(E)-isomer: $\log K_{ow} = 2.63$ (Z)-isomer: $\log K_{ow} = 2.73$
Dissociation constant	N/A

# 3.0 Human Health Assessment

#### 3.1 Toxicology Summary

Dimethomorph is a mixture of E- and Z-isomers in the ratio of approximately 1:1. A detailed review of the toxicological database for dimethomorph was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is acceptable and the database is considered adequate to define the majority of the toxic effects that may result from exposure to dimethomorph.

Dimethomorph was well absorbed following oral gavage dosing in rats. Following a single low, single high or repeat low dose administration, radiolabelled dimethomorph was rapidly excreted, with the majority eliminated via the feces and lesser amounts via urine. No radioactivity was detected in expired air. The elimination half-life following low-dose administration was approximately 3 hours for both sexes, and following high-dose administration half-lives were 11 and 6 hours, for males and females respectively. Tissue levels were low 48 hours after administration with the highest levels found in liver and muscle. In bile-duct cannulated rats, biliary excretion declined and excretion half-life increased with increasing dose level, suggesting saturation of absorption and metabolism. The main pathways of metabolism involved demethylation of one of the methoxyl groups of the dimethoxy-phenyl ring with subsequent conjugation of the resulting metabolites before excretion in the urine and feces, and catabolism of morpholine ring. There were no sex-related differences in the metabolism of dimethomorph following single low oral dosing. Following single high-dose administration, there were minor differences in the urinary metabolite profile between the sexes. In animals given a single or repeat low dose, only an oxidative metabolite CUR 7117 (resulting from cleavage of the morpholine ring) was identified in the urine. Following a single high dose, two metabolites formed by demethylation of the dimethoxyphenyl ring (predominantly at the 4 rather than 2 position, in a ratio 9:1) were detected in the urine.

In acute studies dimethomorph was of low oral (rats and mice) and inhalation toxicity (rats), and of low dermal toxicity in the rat and rabbit. In rabbits, dimethomorph was non-irritating to the skin and minimally irritating to the eye. In guinea pigs, dimethomorph was not a dermal sensitizer. The Z- and E-isomers of dimethomorph were of similar oral acute toxicity in rats.

No treatment-related effects occurred at the limit dose of testing in a rat repeat-dose dermal toxicity study. A repeat-dose inhalation toxicity study was not available.

In short-term repeat-dose dietary toxicity studies in mice, rats and dogs, the liver was the main target organ with increased liver weights observed. Additional liver effects in rat included hyperplasia and hypertrophy of hepatocytes, liver discoloration, and clinical chemistry changes associated with liver pathology (increased serum GGT, bilirubin, decreased A/G ratio, BUN). In short-term gavage studies with pure isomers in rats, slight mid-zonal hepatocellular cytoplasmic lipid vacuolation was noted. In the dog, additional liver effects included increases in intracellular lipid and serum ALP levels. Liver effects in dogs and rats increased in incidence and or severity with increasing dose level and duration of treatment.

In supplemental rat 28-day dietary studies, digestive system effects at high dose levels included swollen abdomen, small intestine distension and acute inflammation of the ileum. These effects were not noted in other short term studies in rats at lower dose levels. Following long-term dietary exposure in rats at lower dose levels than in the 28-day studies, arteritis in abdominal/mesenteric blood vessels and dilated mesenteric blood vessels associated with arteritis were noted. In mice, dilation of villa and/or villous atrophy of the ileum were observed with longer treatment duration.

Colon inflammation was also noted in dogs following 90 days, but not 1 year, of dietary exposure at lower dose levels than in the rats. In dogs, subdued behaviour, occasional vomiting, lip licking and tremors were also noted after repeated dietary dosing. Other treatment-related effects in dogs included decreased prostate weight, prostatitis and prostate fibrosis, as well as increased testicular weight, following exposure to dimethomorph for 90days. Dogs also experienced alterations in body weight along with increased thyroid, kidney and uterine weights at higher doses.

Mild anemia occurred in rats, as indicated by decreased erythrocyte counts and hemoglobin levels, increased hepatic pallor along with increased splenic and sternal hematopoiesis, following short-term high-dose dietary exposure and in long-term studies conducted at lower dose levels.

Long-term dietary exposure to dimethomorph contributed to a decrease in body weight and reduced body weight-gain in rats and mice. Hepatic effects noted were "ground glass" foci and accumulation of pigment in hepatocytes in rats, and increased ALP and AST in mice. An increased incidence of swollen hind feet in males, and swollen hind feet and limbs in females was noted at the high dose level. Lumbar lymph node cysts in males at the high dose level, and ovarian cysts in females at mid- and high-dose levels were observed in rats. There was no evidence that dimethomorph was oncogenic. Overall, dimethomorph was considered negative for genotoxicity in a battery of in vitro and in vivo studies. Equivocal findings were noted in two in vitro chromosomal aberration studies, one in the absence of a positive control. In a 2-generation rat dietary reproductive toxicity study, a reduction in premating body weights and body weight gain was noted at the high dose level in  $F_0$  and  $F_1$  dams. Dimethomorph treatment did not affect reproductive performance, fertility, gestation, litter size, sex ratio of the offspring or pup survival. Effects in offspring included an equivocal delay in tooth eruption. There was no indication of sensitivity of the young in the reproductive toxicity study.

In a rabbit gavage developmental toxicity study, a slight increased incidence of abortions was observed at the high dose level in the presence of maternal toxicity (decreased body weight gain and food consumption). A high incidence of abortions was also noted in a range-finding study at the highest dose level, which was the limit dose of testing. In a rat gavage developmental toxicity study, an increased incidence of early resorptions (total litter loss) was noted at the high dose level along with the decrease in body weights in dams. There was no evidence of treatment-related malformations in rats or rabbits and no indication of sensitivity of the young in the developmental toxicity studies.

In a rat acute neurotoxicity study, decreased motor activity, rearing and habituation were observed at the lowest dose tested. At the next higher dose level, further gait impairment and reduced exploration were noted. At the highest dose level, which was the limit dose of testing, there was an increased incidence of clinical signs and mortality. There was no evidence of selective neurotoxicity. In a rat short-term dietary neurotoxicity study, there were no treatmentrelated effects on mortality, clinical signs of toxicity, motor activity or neuropathology. At the highest dose level, body weight, body-weight gain, food consumption and food efficiency were reduced.

No treatment-related effects on spleen or thymus weights, or on the humoral immune response, were observed in a rat 28-day dietary immunotoxicity study.

The toxicology reference values used for human health risk assessment are summarized in Appendix II, Table 1. The results of toxicology studies conducted in laboratory animals with dimethomorph are summarized in Appendix II, Table 2.

# Epidemiology

There were no epidemiological studies relevant for risk assessment purposes.

## 3.1.1 Pest Control Products Act Hazard Characterization

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 to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal 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 toxicity to infants and children, the standard complement of required studies were available, including gavage developmental toxicity studies in rats and rabbits, and a dietary multi-generation reproductive toxicity study in rats. A supplemental range-finding developmental toxicity study in rabbits was also available. With respect to potential pre- and post-natal toxicity, an increased incidence of early resorptions (total litter loss) was noted in the presence of maternal toxicity in the rat developmental toxicity study, and an increased incidence of abortions was noted in the developmental toxicity study in rabbits, also in the presence of maternal toxicity. An increased incidence of abortions was also noted in a range-finding study in rabbits at the limit dose of testing. A slight delay in tooth eruption noted in  $F_{1a}$  and  $F_{2a}$  pups in a dietary 2-generation reproductive toxicity study was considered equivocal and occurred in the presence of maternal toxicity. In all these studies, maternal toxicity consisted of effects on body weight. There was no evidence of treatment-related malformations in the developmental toxicity studies and no indication of increased susceptibility of the young compared to adult animals.

Overall, the database is adequate for determining the sensitivity of the young and effects on the young are well-characterized. Fetal death noted in the rat developmental toxicity study was considered a serious endpoint for which concern was tempered by the presence of maternal toxicity. Therefore, the 10-fold *Pest Control Products Act* factor (PCPA factor) was reduced to 3-fold for scenarios in which this endpoint was used to establish the point of departure for assessing risk. This endpoint is considered protective of the abortions in the rabbit and the equivocal developmental delays in rat offspring. For all other exposure scenarios the risk was considered well-characterized and the PCPA factor was reduced to onefold.

#### 3.2 Dietary Exposure and Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue may be ingested with the daily diet. Exposure to dimethomorph from potentially treated imported foods is also included in the assessment. Dietary exposure 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 exposure exceeds 100% of the reference dose. In its science policy note, SPN2003-03 *Assessing Exposure from Pesticides: A User's Guide*, the PMRA presents detailed acute, chronic and cancer risk assessment procedures.

Sufficient information was available to adequately assess the dietary risk from exposure to dimethomorph. Acute and chronic dietary exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database<sup>TM</sup> (DEEM-FCID<sup>TM</sup>, Version 4.02, 05-10-c) program, which incorporates consumption data from the National Health and Nutrition Examination Survey, What We Eat in America 2005-2010 available through the Centers for Disease Control and Prevention's National Center for Health Statistics. Further details on the consumption data are available in the Science Policy Note, SPN2014-01 *General Exposure Factor Inputs for Dietary, Occupational and Residential Exposure Assessments*. For more information on dietary risk estimates and the residue chemistry information used in the dietary assessment, see Appendix III.

#### 3.2.1 Determination of Acute Reference Dose

#### Females 13-49 Years of Age

To estimate acute dietary risk for females 13–49 years of age, the developmental toxicity study in rats with a NOAEL of 60 mg/kg bw/day was selected. At the LOAEL of 160 mg/kg bw/day, an increased incidence of early resorptions (total litter loss) was observed. As this serious effect could result from a single dose during development, it is considered relevant to the selection of an acute reference dose (ARfD) for this sub-population. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization Section, the PCPA factor was reduced to 3-fold for this scenario, thus, the composite assessment factor (CAF) is 300.

The ARfD is calculated according to the following formula:

ARfD (females 13–49 years of age) =  $\frac{\text{NOAEL}}{\text{CAF}} = \frac{60 \text{ mg/kg bw}}{300} = 0.2 \text{ mg/kg bw of dimethomorph}$ 

The ARfD provides a margin of 1500 to the NOAEL of 300 mg/kg bw/day for abortions in the rabbit developmental toxicity study.

#### General Population (excluding females 13–49 years of age)

To estimate acute dietary risk for the general population, the acute neurotoxicity study in rats with a LOAEL of 250 mg/kg bw was selected. No NOAEL was determined, as this was the lowest dose level tested. At the LOAEL, decreased motor activity, habituation and rearing were observed. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, and an additional 3-fold factor for the lack of NOAEL were applied. The PCPA factor was reduced to onefold as discussed in the *Pest Control Products Act* Hazard Characterization Section. Thus, the CAF is 300.

The ARfD is calculated according to the following formula:

ARfD (general population) =  $\frac{\text{NOAEL}}{\text{CAF}} = \frac{250 \text{ mg/kg bw}}{300} = 0.8 \text{ mg/kg bw of dimethomorph}$ 

#### 3.2.2 Acute Dietary Exposure and Risk Assessment

The acute dietary risk was calculated considering the highest ingestion of dimethomorph that would be likely on any one day, and using food and drinking water consumption and food and drinking water residue values. The expected intake of residues is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, the acute dietary exposure has been shown to be acceptable.

The acute analysis was conducted assuming food residue values at Canadian MRLs or American tolerances. The percent crop treated was assumed to be 100. Drinking water contribution to the exposure was accounted for by direct incorporation of the appropriate estimated environmental

concentration (EEC), obtained from water modelling (see Section 3.3), into DEEM. DEEM default processing factors were applied. Experimental processing factors were used when values were higher than default DEEM processing factors.

The acute dietary (food and drinking water) exposure estimates at the 95<sup>th</sup> percentile were shown to be acceptable at less than or equal to 40% of the ARfD for all population subgroups.

# 3.2.3 Determination of Acceptable Daily Intake

To estimate risk for the general population from repeat dietary exposure, the NOAEL of 15 mg/kg bw/day from a 1-year dietary toxicity study in dogs was selected. At the LOAEL of 45 mg/kg bw/day, increased liver and testis weights, as well as decreased prostate weights were noted. The selection of this end point is supported by a NOAEL of 13 mg/kg bw/day (females) selected from the rat 2-year carcinogenicity study. At the LOAEL of 52 mg/kg bw/day (females) effects included decreased body weight and body weight gains in addition to liver toxicity. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. The PCPA factor was reduced to onefold as discussed in the *Pest Control Products Act* Hazard Characterization Section. Thus, the CAF is 100.

The ADI is calculated according to the following formula:

$$ADI = \frac{NOAEL}{CAF} = \frac{15 \text{ mg/kg bw/day}}{100} = 0.2 \text{ mg/kg bw/day of dimethomorph}$$

The ADI provides a margin of 300 to the NOAEL of 60 mg/kg bw/day for increased early resorptions (litter loss) in the rat developmental toxicity study and a margin of 1500 to the NOAEL of 300 mg/kg bw/day for abortions in the rabbit developmental toxicity study.

# 3.2.4 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated using the average consumption of different foods and drinking water and the average residue values on those foods and in drinking water. The estimated exposure was then compared to the ADI. When the estimated exposure is less than the ADI, the chronic dietary exposure has been shown to be acceptable.

The chronic assessment was conducted assuming food residue values at Canadian MRLs or American Tolerances. The percent crop treated was assumed to be 100. Drinking water contribution to the exposure was accounted for by direct incorporation of the appropriate EEC, obtained from water modelling [see Section 3.3], into DEEM. DEEM default processing factors were applied. Experimental processing factors were used when values were higher than default DEEM processing factors.

The chronic dietary exposure estimate from food and drinking water for the general population represents 17% of the ADI. Chronic exposure estimates for the various subpopulations range from 12% for youth 13–19 years of age to 31% of the ADI for children 1–2 years of age. Thus, chronic exposure to dimethomorph residues in food and drinking water were shown to be acceptable.

#### 3.2.5 Cancer Assessment

There was no evidence of oncogenicity in mice or rats.

#### 3.3 Exposure from Drinking Water

Residues of dimethomorph in potential drinking water sources were estimated from modelling.

#### **3.3.1** Concentrations in Drinking Water

Monitoring data and modelling estimates provide different types of information and, therefore, are not directly comparable. Pesticide concentrations in water are highly variable in time and location, and Canadian monitoring data usually are sparse. When possible, monitoring data from the United States are used together with Canadian data to provide a more robust analysis. These two types of data are complementary and are considered in conjunction with each other when estimating the potential exposure of aquatic organisms or humans.

#### **Modelling Estimates**

#### **Application Information and Model Inputs**

Dimethomorph is a fungicide registered for use on various crops. The use pattern modelled was 5 applications per year of 225 g a.i./ha with a 5 day interval. Modelling used initial application dates between May 1 and July 20. The major input parameters were calculated from data available at the time of modelling, but do not include some studies.

#### **Estimated Concentrations in Drinking Water Sources: Level 1 Modelling**

EECs of dimethomorph in potential drinking water sources (groundwater and surface water) were generated using a computer simulation model. Modelling for surface water used a standard Level 1 scenario: a small reservoir adjacent to an agricultural field. EECs in groundwater were calculated by selecting the highest EEC from several selected scenarios representing different regions of Canada. All scenarios were run for 50 years.

The EECs resulting from this Level 1 assessment were calculated using conservative inputs with respect to application rate and timing, and geographic scenario. These EECs should therefore allow for future use expansion into other crops at this application rate and method. EECs of dimethomorph in potential drinking water sources are given in the following table:

#### Level 1 EECs of dimethomorph in Potential Sources of Drinking Water.

Crop/use pattern	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
Crop/use pattern	Daily <sup>1</sup>	Yearly <sup>2</sup>	Daily <sup>3</sup>	Yearly <sup>4</sup>
Single application of 225 g a.i./ha	201	201	44	11

<sup>1</sup> 90<sup>th</sup> percentile of daily average concentrations

<sup>2</sup> 90<sup>th</sup> percentile of 365-day moving average concentrations

<sup>3</sup> 90<sup>th</sup> percentile of the peak concentrations from each year

<sup>&</sup>lt;sup>4</sup>90<sup>th</sup> percentile of yearly average concentrations

The daily and yearly ground water EEC of 201  $\mu$ g a.i./L was used in the acute and chronic exposure assessment.

#### Water Monitoring Data

#### Background and sources of data

Monitoring data collected from the year 2000 onward were considered relevant for this assessment; older data were deemed unlikely to represent current Canadian use conditions. Water monitoring information was available for dimethomorph from Quebec, New Brunswick and the United States.

Water monitoring data, particularly for surface water, may miss peak concentrations, as sampling is typically sporadic and peak concentrations can be flushed through a system in a short amount of time after a runoff event. Based on available monitoring data, dimethomorph is seldom detected in water, with the maximum concentration detected in potential drinking water sources being 1.1  $\mu$ g/L, from a surface water sample collected in Quebec. Acute and chronic drinking water EEC values based on Canadian water monitoring data could not be determined due to the relatively small number of samples and low detection frequencies.

#### 3.3.2 Drinking Water Exposure and Risk Assessment

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

#### 3.4 Occupational and Non-Occupational Exposure and Risk Assessment

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

#### 3.4.1 Toxicology Endpoint Selection for Residential and Occupational Exposure

#### 3.4.1.1 Short-, Intermediate-term dermal and inhalation routes

For short- and intermediate-term occupational exposures via the dermal and inhalation routes, there were no suitable repeat-dose dermal or inhalation toxicity studies upon which to base the risk assessment. The 21-day dermal toxicity study in rats was not selected for this endpoint as it did not assess the endpoint of concern, namely developmental effects in pups following pre-natal exposure. In the absence of suitable studies, the oral developmental toxicity study in rats was deemed appropriate for these scenarios. A NOAEL of 60 mg/kg bw/day from this toxicity study was selected for risk assessment based on the increased early resorptions (total litter loss) noted at the next dose level. Worker populations could include pregnant or lactating women and

therefore this endpoint was considered appropriate for the occupational risk assessment. The target MOE for these scenarios is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, as well as an additional 3-fold factor for the reasons outlined in the *Pest Control Products Act* Hazard Characterization Section. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

#### 3.4.1.2 Long-term Dermal and Inhalation

For long-term occupational exposures via the dermal and inhalation routes, there were no suitable repeat-dose dermal or inhalation toxicity studies upon which to base the risk assessment. In the absence of suitable studies, the 1-year dietary toxicity study in dogs was deemed appropriate for these scenarios. In this dog study, the NOAEL of 15 mg/kg bw/day was selected for risk assessment based on increased liver and testis weights, and decreased prostate weights observed at the LOAEL of 45 mg/kg bw/day. The target MOE for these scenarios is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability and onefold factor for the reasons outlined in the *Pest Control Products Act* Hazard Characterization Section. The selection of this study and MOE is considered to be protective of all populations.

## 3.4.1.3 Dermal Absorption

Various in vivo and in vitro studies were submitted to the PMRA or available in the literature for the re-evaluation of dimethomorph. A dermal absorption value of 23% was chosen, based on results from a rat in vivo study.

#### 3.4.2 Non-Occupational Exposure and Risk Assessment

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

Since there are no domestic-class products containing dimethomorph registered, a residential handler assessment was not required. Also, postapplication exposure to residents/bystanders was assumed not to occur, since products used for outdoor ornamentals are prohibited from being used in residential, commercial or industrial landscapes.

## 3.4.3 Occupational Exposure and Risk Assessment

There is potential for exposure to dimethomorph in occupational scenarios to/for workers handling dimethomorph during the application process and potential for postapplication exposure to workers entering areas previously treated with dimethomorph.

#### 3.4.3.1 Mixer, Loader, and Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, and applicators. The following scenarios were assessed:

- Open mix/load of liquids;
- Open mix/load of wettable powders;
- Open mix/load/apply of liquids with backpack sprayer;
- Open mix/load/apply of liquids with manually-pressurised hand wand (MPHW);
- Open mix/load/apply of liquids with mechanically-pressurised hand gun (MPHG);
- Open mix/load/apply of wettable powders with MPHW;
- Open mix/load/apply of wettable powders with MPHG;
- Open mix/load/apply of wettable powders with backpack sprayer;
- Open cab groundboom application of liquids;
- Open cab airblast application of liquids; and
- Open cockpit aerial application of liquids.

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

Exposure was estimated for baseline PPE: long pants, long-sleeved shirt and chemical-resistant gloves.

No appropriate chemical-specific handler exposure data were available for dimethomorph. Therefore, dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database Version 1.1 (PHED) and the Agricultural Handlers Exposure Task Force (AHETF) studies. The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of PPE. The AHETF was formed in 2001 with the objective of providing more up-to-date generic exposure studies compared to the PHED studies. When available, the more modern AHETF studies were used, which meet current standards of acceptability.

For handheld equipment, including backpack sprayer, only PHED data were available. The data were considered to be limited in terms of number of replicates (less than 15 per body part) or study quality (for example, low or missing field recovery). Furthermore, since exposure studies were not available for mixing/loading and applying wettable powders by backpack sprayer or by mechanically-pressurised hand gun, an estimate for these scenarios was made by using unit exposure values for open mix/load for wettable powders plus open mix/load/apply of liquids by backpack sprayer or mechanically-pressurised hand gun, respectively. This would result in an overestimate of exposure; however, it is the best available data at this time.

Route specific MOEs for mixer/loader and applicators for agricultural crops are outlined in Appendix V, Table 1. Calculated dermal, inhalation, and combined (total exposure from dermal and inhalation routes) MOEs for mixer/loaders and applicators of dimethomorph exceeded target MOEs for all scenarios and were therefore shown to be acceptable.

#### 3.4.3.2 Postapplication Worker Exposure and Risk Assessment

The postapplication occupational risk assessment considered exposures to workers who enter treated sites to conduct agronomic activities involving foliar contact (for example, hand harvesting). Based on the use pattern, there is potential for short to intermediate-term (<6 months) and long term (>6 months) postapplication exposure to dimethomorph residues for workers outdoors and indoors, respectively.

Potential exposure to postapplication workers was estimated using updated activity-specific transfer coefficients (TCs), and default dislodgeable foliar residue (DFR) values, since chemical-specific DFR data were not available (see below). The DFR refers to the amount of residue that can be dislodged or transferred from a surface, such as leaves of a plant. 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. The TCs are specific to a given crop and activity combination, and reflect standard agricultural work clothing worn by adult workers. Activity-specific TCs from the Agricultural Re-Entry Task Force (ARTF) were used. Post application exposure activities for agricultural crops include (but are not limited to): harvesting, weeding and scouting. For more information about estimating worker postapplication exposure, refer to the PMRA's regulatory proposal, PRO2014-02 Updated Agricultural Transfer *Coefficients for Assessing Occupational Postapplication Exposure to Pesticides*.

Since no acceptable chemical-specific DFR studies were available for dimethomorph, default values were used (peak DFR of 25% of the application rate for all crops, with 10% dissipation per day for outdoor crops and 2.3% dissipation per day for ornamental greenhouse crops). For further information on these default values, refer to the PMRA's Science Policy Note, SPN2014-02 *Estimating Dislodgeable Foliar Residues and Turf Transferrable Residues in Occupational and Residential Postapplication Exposure Assessments*.

For workers entering a treated site, 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.

Postapplication exposure would be primarily via the dermal route. Based on the vapour pressure of dimethomorph, inhalation exposure would be low, provided that the minimum 12-hour REI is followed.

For some crops, the updated risk assessment resulted in shorter REIs than those on the current labels. Provided that the REIs are followed, postapplication risks to workers performing activities such as thinning, pruning, and harvesting, were shown to be acceptable. Updated REIs are proposed to be added to the labels. The postapplication exposure assessment is outlined in Appendix V, Tables 2–7.

#### 3.5 Aggregate Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Since residential exposure is not expected, the aggregate assessment for dimethomorph consisted of combining food and water exposure only (see Sections 3.2.2 and 3.2.4).

#### 3.6 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current evaluation, the PMRA did not identify information indicating that dimethomorph shares a mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

#### 3.7 Incident Reports

As of 27 June 2018, no human, domestic animal or environmental incident reports involving dimethomorph had been submitted to the PMRA.

# 4.0 Environmental Assessment

## 4.1 Fate and Behaviour in the Environment

A summary of environmental fate data for dimethomorph is presented in Appendix VI.

Dimethomorph is soluble in water and is not expected to volatilize from water or moist soil. Dimethomorph is unlikely to persist in the atmosphere and is not expected to undergo long-range transport. Hydrolysis and phototransformation on soil are not important routes of dimethomorph transformation.

No major transformation products were observed in terrestrial studies. Laboratory studies suggest dimethomorph is moderately persistent in aerobic soils ( $DT_{50}=115$  days) and slightly persistent in anaerobic soils ( $DT_{50}=16.4$  days). Dimethomorph is not expected to bioaccumulate in organisms in aquatic environments.

Some evidence (adsorption/desorption, Cohen criteria and GUS score) suggests dimethomorph has the potential to leach and move through soils. This is further supported by groundwater modelling which predicts some residues in groundwater. Evidence from leaching and terrestrial field dissipation studies indicate dimethomorph has a relatively short to moderate half-life in soil (43 to 112 days) and very limited downward movement into lower soil horizons, with residues being limited to the upper soil horizons (0–10 cm). Although dimethomorph was not detected in the available Canadian groundwater data (305 samples), American groundwater monitoring indicates that dimethomorph is detected (7.5% of 366 samples), with a maximum detection of  $0.427\mu$ g/L. Considering the available evidence, it is concluded that dimethomorph has the potential to leach to groundwater and an advisory statement is required on product labels. Dimethomorph is also not expected to carry-over into the next growing season. In aquatic environments, hydrolysis is not expected to be an important transformation pathway. Photolysis is also not expected to be an important transformation pathway in aquatic systems except in clear shallow water, where transformation is expected to be rapid. In aerobic water/sediment systems, dimethomorph is slightly persistent, with a 90<sup>th</sup> percentile DT<sub>50</sub> value of 42 days. It partitions rapidly to sediment where non-extracted residues (NER) are expected to accumulate over time. Results also indicate that NER are not residues of concern. In anaerobic systems, dimethomorph is non-persistent to slightly persistent, with DT<sub>50</sub> values ranging from 0.9 to 18.7 days. Bisdesmethyl dimethomorph was the only major transformation product in anaerobic water systems (>13.2% applied radioactivity at study termination of 103 days).

#### 4.2 Environmental Risk Characterization

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 EECs with concentrations that are known to cause significant effects on non-target organisms. EECs are pesticide concentrations within environmental compartments, including food, water, soil and air that are estimated using standard models. These models account for the application rate(s) and associated treatment intervals, as well as the chemical and environmental fate properties for the pesticide, including dissipation of the pesticide between multiple applications and potential to leach or sorb to organic matter. The EEC values for dimethomorph (soil and aquatic) are presented in Appendix VIII. Ecotoxicological information that is used includes acute and chronic toxicity data for various groups of organisms from both aquatic and terrestrial habitats including invertebrates, vertebrates and plants. Toxicological endpoints in this assessment were obtained from registrant submitted data, open literature, and foreign reviews previously conducted for dimethomorph. The endpoints for each taxa that were considered to be appropriate for use in the assessment are presented in Appendix VII.

To account for potential differences in species sensitivity, as well as varying protection goals (i.e., protection at the community, population, or individual level), toxicity endpoints that are used in the risk assessment may be adjusted by applicable uncertainty factors.

Initially, a screening-level risk assessment is conducted to identify those pesticide uses that do not pose potential risks to non-target organisms and to identify those groups of organisms for which there may be a potential risk. The screening-level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application using the maximum cumulative rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated in the risk assessment by dividing the EEC associated with a particular pesticide use by the selected toxicological endpoint (uncertainty factor if applicable) for the taxonomical group of interest. The resulting RQ is then compared to the level of concern (LOC). The uncertainty factors and applicable LOCs used in the screening-level risk assessment are presented in the table below.

Risk Category	Risk Quotient	Uncertainty Factor	Level Of Concern (LOC) if Risk Quotient Exceeds:
Birds and Wild Mai	nmals	-	-
Acute Risk	EEC/LD50 or LC50	1/10	1
Chronic Risk	EEC/NOEC	1	1

#### **PMRA Levels of Concern**

Risk Category	Risk Quotient	Uncertainty Factor	Level Of Concern (LOC) if Risk Quotient Exceeds:
Aquatic Invertebrat	tes and Fish		
Acute Risk	EEC/LC50 or EC50	1/10 (fish); 1/2 (invertebrates)	1
Chronic Risk	EEC/NOEC	1 (fish); 1 (invertebrates)	1
Honeybees			
Acute Risk	EEC/LD50	1	0.4
Chronic Risk	EEC/NOEC	1	1
<b>Terrestrial Inverteb</b>	orates		
Arthropods	EEC/LC50	1	<ul> <li>2 (glass plate tests for <i>T. pyri</i> and <i>A. rhopalosiphi</i>)</li> <li>1 (extended tests and other glass plate test species)</li> </ul>
Earthworms	EEC/LC50	1/2	1
Non-Target Aquation	e or Terrestrial Plants		
Aquatic Plants	EEC/(EC25 or EC50)	1/2	1
Terrestrial Plants	EEC/EC25	1	1

If the screening level RQ is below the LOC, the risk is considered to be negligible and no further risk characterization is required. If the screening level RQ is equal to or above the application LOC, then a refined risk assessment is performed to further characterize the risk. Refined assessments take into consideration more realistic exposure scenarios (including drift and runoff from field to non-target environments) and may consider alternate toxicity endpoints. Additional refinements that may be considered include exposure modelling data, available monitoring data, incident reports and results from field or mesocosm studies. The refined risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

## 4.2.1 Risks to Terrestrial Organisms

For assessment of risk, toxicity endpoints from the most sensitive test species were used as surrogates for the wide range of species that can be potentially exposed following exposure to dimethomorph.

At the screening level, risks to earthworms, honeybees, predators, parasitoids, birds, wild mammals and terrestrial plants were not of concern (Appendix IX, Tables 1–12). When used according to label directions, dimethomorph is not expected to pose a risk of concern to terrestrial organisms.

#### 4.2.2 Risks to Aquatic Organisms

A summary of aquatic toxicity data is presented in Appendix VI, Table 2. At the screening level, RQs exceeded the LOCs for freshwater invertebrates, amphibians, freshwater fish and estuarine/marine fish (Appendix IX, Tables 13–15). Risks to freshwater algae, freshwater vascular plants, saltwater algae (using the surrogate freshwater algae endpoint) and marine/estuarine invertebrates were not of concern (Appendix IX, Tables 16–18). A refined risk assessment for spray drift indicated small risks of concern (RQ <1.25) for amphibians and freshwater fish associated with airblast treatments in orchards (Appendix IX, Table 19). The refined spray drift assessment indicated no risk of concern for other aquatic organisms. A refined

risk assessment for runoff used modelled EECs and available freshwater monitoring data. Risks of concern from runoff are not expected for aquatic organisms (Appendix IX, Table 20).

# 4.2.3 Environmental Incident Reports

There are no environmental incident reports in Canadian and American databases

# 5.0 Value Assessment

Dimethomorph is registered for use as a foliar application to control or suppress the economically important diseases phytophthora blight and downy mildew on a number of vegetable crops, grapes, ginseng, hops and ornamentals. It is particularly important for the management of potato late blight in the field since a mid- to late-season foliar application can also suppress post-harvest late blight tuber rot. There are few registered alternatives to manage this disease.

Dimethomorph is also one of only a few fungicides available to control downy mildew on many high-value greenhouse and outdoor ornamental crops. It is of value for the suppression of sudden oak death (*Phytophthora ramorum*) on many high value outdoor, container and field grown ornamental plants in nurseries and landscape plantings. Sudden oak death is listed as a quarantine disease by the Canadian Food Inspection Agency. Consequently, dimethomorph plays an important role in the phytosanitary treatment of imported and exported material. There are only two registered alternatives to dimethomorph to suppress sudden oak death: metalaxyl-M and S-isomer and fosetyl-aluminum. Metalaxyl-M and S-isomer poses a high risk of disease resistance development and resistance management is required.

Dimethomorph is one of two fungicides registered in Canada with a Group 40 mode of action, which poses a low to medium risk for disease resistance development. To date, resistance to this fungicide has only been identified in populations of the grape downy mildew pathogen. Its protectant and antisporulant activity make dimethomorph a valuable tank-mix partner or rotational alternative to fungicides from other mode of action groups to manage resistance development.

# 6.0 Pest Control Product 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, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*]. During the review process, Dimethomorph and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03<sup>3</sup> and evaluated against the Track 1 criteria.

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

#### 6.1 Toxic Substances Management Policy Considerations

In accordance with the PMRA Regulatory Directive DIR99-03, the assessment of Dimethomorph against Track 1 criteria of TSMP under *Canadian Environmental Protection Act* was conducted. It determined that:

- Dimethomorph does not meet all Track 1 criteria, and is not considered a Track 1 substance (refer to Appendix X).
- Dimethomorph does not form any transformation products that meet all Track 1 criteria.
- The use of dimethomorph is not expected to result in the entry of TSMP Track-1 substances into the environment.

#### 6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical grade active ingredient and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.<sup>4</sup> The list is used as described in the PMRA Notice of Intent NOI2005-01<sup>5</sup> and is based on existing policies and regulations including DIR99-03 and DIR2006-02,<sup>6</sup> 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 dimethomorph and related commercial end-use product as well as other domestic formulations of dimethomorph do not contain any formulants of health or environmental concern identified in the *Canada Gazette*.
- The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

# 7.0 Conclusion of Science Evaluation

In addition to uses on various vegetables and fruit crops, dimethomorph is important for the management of potato late blight tuber rot, and sudden oak death on many high value outdoor, container and field grown ornamental plants in nurseries and landscape plantings, especially considering the limited number of registered alternatives for these diseases. Due to its protectant and antisporulant activity, and lower risk for resistance development, dimethomorph is valued as a rotational product in disease management programs.

<sup>&</sup>lt;sup>4</sup> 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.

<sup>&</sup>lt;sup>5</sup> NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

<sup>&</sup>lt;sup>6</sup> DIR2006-02, Formulants Policy and Implementation Guidance Document.

With respect to human health, risks are considered to be acceptable for all dimethomorph uses when used according to the proposed revised label directions. Mitigation measures are required.

When used according to the proposed revised label directions, environmental risks associated with the use of dimethomorph were determined to be acceptable.

# List of Abbreviations

↑	increased
	decreased
↓ ℃ ♀ %	male
0	female
∓ 0∕	
γ0 λ	percentage
	wavelength
μg	microgram
A/G	albumin/globulin ratio
abs	absolute
AD	administered dose
ADI	acceptable daily intake
a.i.	active ingredient
AHETF	Agricultural Handlers Exposure Task Force
ALP	alkaline phosphatase
AOPWIN	Atmospheric Oxidation Program for Microsoft Windows, USEPA
appl.	Application
aq	aqueous
AR	applied radioactivity in % acute reference dose
ARfD ARTF	
ASAE	Agricultural Re-entry Task Force American Society of Agricultural Engineers
ASAL	aspartate aminotransferase
atm	atmosphere
ATN	ametoctradin
ATPD	area treated per day
BAF	bioaccumulation factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
bwg	bodyweight gain
°C	degree in Celsius
CAF	composite assessment factor
CAS	chemical abstracts service
CEC	cation exchange capacity
CEPA	Canadian environmental protection act
CL	concentration levels
cm	centimeter
cm <sup>2</sup>	centimeters squared
d	day(s)
DACO	data code (PMRA)
DAT	day after treatment
DEEM	Dietary Exposure Evaluation Model
dev.per.	developmental period
DFR	dislodgeable foliar residue
DIR	directive

DME	dimethomorph
DOM	dissolved organic matter
DT <sub>50</sub>	time required for 50% dissipation of the initial concentration
DT <sub>90</sub>	time required for 90% dissipation of the initial concentration
EC <sub>50</sub>	effective concentration on $50\%$ of the population
EDE	estimated daily exposure
EEC	estimated environmental concentrations
ELS	early life stage
EPA	Environmental Protection Agency
EPI Suite	estimation programs interface Suite <sup>TM</sup> under Window®
EUP	end-use product
F <sub>0</sub>	parental animals
F <sub>1</sub>	1st generation offspring
F <sub>1a,b</sub>	1st generation offspring in two consecutive litters, a= first and b=second
$F_2$	2nd generation offspring
F <sub>2a,b</sub>	2nd generation offspring in two consecutive litters, a= first and b=second
FAO	Food and Agriculture Organization
fc	food consumption
FDA	US Food and Drug Administration
fe	food efficiency
g	grams
GC-NPD	gas chromatography with nitrogen phosphorous detector
GGT	gamma-glutamyl transferase
GUS	groundwater ubiquity score
ha	hectare
Hb	haemoglobin
HGPRT	hypoxanthine-guanine phosphoribosyltransferase
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with UV detector
hr(s)	hour(s)
IORE	indeterminate order rate equation
IUPAC	International Union of Pure and Applied Chemistry
Κ	constant
kg	kilogram
K <sub>d</sub>	adsorption quotient
K <sub>oc</sub>	adsorption quotient normalized to organic carbon
$K_{ m ow}$	<i>n</i> -octanol-water partition coefficient
L	litre(s)
lbs	pounds
$LC_{50}$	lethal concentration on 50% of the population
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD <sub>50</sub>	lethal dose on 50% of the population
LOAEL	lowest observed adverse effect level
LOC	level of concern
Log	logarithm
LOQ	limit of quantification
LR <sub>50</sub>	lethal rate on 50% of the population

m	meter(s)
М	mole
max	maximum
MCV	mean corpuscular volume
meq	milli equivalent (electric conductivity)
mg	milligram
min	minutes
mL	millilitre
M/L/A	mixer/loader/applicator
mm	millimeter
MOE	margin of exposure
mPa	millipascal
MPHG	mechanically pressurised hand gun
MPHW	manually pressurised hand wand
MRID	master record identification number (USEPA)
MRL	Maximum Residue Limit
N/A	not applicable
n/a	not available
ND	not detected
NER	non-extracted residues
nm	nanometer
No.	number
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOED	no-observed-effect dose
NOEL	no-observed-effect level
NR	not reported
OECD	Organization for Economic Co-operation and Development
OM	organic matter
Pa	Pascal unit of pressure
PCPA	Pest Control Products Act
PEI	Prince Edward Island
рН	hydrogen potential
PHED	pesticide handlers exposure database
рКа	acid dissociation constant on log scale
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
RBC	red blood cells
Reg. No.	PCPA Registration Number
REI	restricted-entry interval
Rep.	reported
RQ	risk quotient
S	sediment phase
SCL	silty clay loam
SFO	single first order kinetics

SRBC	sheep red blood cells
SS	statistically significant
t	time
t <sub>1/2</sub>	half-life
TC	transfer co-efficient
Temp	temperature
TLC	thin layer chromatography
TM	Trademark
TSMP	Toxic Substances Management Policy
UV	ultraviolet
V	version
VUI	verified use information
W	water phase
WBC	white blood cells
wc	water consumption
WP	wettable powder
wt	weight

# Appendix I Dimethomorph Products and Commercial Uses Registered in Canada

Table 1Dimethomorph Products Registered in Canada as of 7 January 2019 Excluding Discontinued Products or Products<br/>with a Submission for Discontinuation Based on the PMRA's Electronic Pesticide Regulatory System (e-PRS)<br/>database.

Registration Number	Marketing Class	Registrant Name	Product Name	Formulation Type	Guarantee
24545	Technical	BASF Canada Inc.	Forum Technical (Dimethomorph)	Solid	98.0%
31306	Manufacturing Concentrate	BASF Canada Inc.	Zampro Bulk	Suspension	225 g/L (+300 g/L ATN)
27700	Commercial	BASF Canada Inc.	Acrobat 50 WP Fungicide	Wettable Powder	50%
30321	Commercial	BASF Canada Inc.	Zampro Fungicide	Suspension	225 g/L (+300 g/L ATN)
32026	Commercial	BASF Canada Inc.	Forum Fungicide	Suspension	500 g/L

ATN = ametoctradin

#### Table 2Registered Commercial uses of Dimethomorph in Canada as of 28 May 2018

Sites	Pests	Formulation Application Methods and Maximum Application R		ation Rate (a.i./ha)	Max Number of	Minimum Interval	
		Туре	Equipment	Single	Cumulative	Application per Year	Between Application (days)
Potato	Late blight and tuber blight ( <i>Phytophthora</i> <i>infestans</i> )	Suspension, Wettable Powder	Ground: field sprayer; Aerial: fixed-wing or rotary aircraft equipment.	{225 g a.i./ha}	{675 g a.i./ha/ year}	3	5
Brassica leafy vegetables	Downy mildew (Peronospora parasitica)	Suspension	Ground: field sprayer; Aerial: fixed-wing or rotary aircraft equipment.	{225 g a.i./ha}	{675 g a.i./ha/ year}	3	7
Brassica vegetables	Downy mildew ( <i>P. parasitica</i> ) - suppression	Suspension, Wettable Powder	Ground: field sprayer; Aerial: fixed-wing or rotary aircraft equipment.	{225 g a.i./ha}	{1125 g a.i./ha/ year}	5	7
Leafy vegetables: lettuce (head and leaf)	Downy mildew ( <i>Bremia</i> <i>lactucae; Peronospora</i> spp.) -suppression	Suspension, Wettable Powder	Ground -field sprayer; Aerial:fixed-wing or rotary aircraft equipment	{225 g a.i./ha}	{1125 g a.i./ha/ year}	5	5
Cucurbit vegetables	Downy mildew (Pseudoperonospora cubensis) -suppression	Suspension, Wettable Powder	Ground: field sprayer; Aerial: fixed- wing or rotary aircraft equipment	{225 g a.i./ha}	{1125 g a.i./ha/ year}	5	5

Sites	Pests	Formulation Type	Application Methods and Equipment	Maximum Application Rate (a.i./ha)		Max Number of	Minimum Interval
				Single	Cumulative	Application per Year	Between Application (days)
	Downy mildew (P. cubensis), phytophthora blight (Phytophthora capsici)	Suspension	Ground: field sprayer; Aerial: fixed-wing or rotary aircraft equipment	{225 g a.i./ha}	{675 g a.i./ha/ year}	3	5
Fruiting vegetables	Phytophthora blight ( <i>P. capsici</i> )- suppression, late blight ( <i>P. infestans</i> )	Suspension	Ground: field sprayer; Aerial: fixed-wing or rotary aircraft equipment	{225 g a.i./ha}	{675 g a.i./ha/ year}	3	5
Fruiting vegetables	Late blight ( <i>P. infestans</i> )	Suspension, Wettable Powder	Ground: field sprayer; Aerial: fixed-wing or rotary aircraft equipment	{225 g a.i./ha}	{1125 g a.i./ha/ year}	5	5
Pepper (all varieties)	Phytophthora blight ( <i>P. capsici</i> ) - suppression	Suspension, Wettable Powder	Ground: Field sprayer	{225 g a.i./ha}	450 g a.i./ha/ year	2	5
Bulb vegetables	Downy mildew (Peronospora destructor)	Suspension, Wettable Powder	Ground: field sprayer; Aerial: fixed-wing or rotary aircraft equipment	{225 g a.i./ha}	{1125 g a.i./ha/ year}	5	5
Grapes	Downy mildew (Plasmopara viticola)	Suspension, Wettable Powder	Ground: airblast	{225 g a.i./ha}	{900 g a.i./ha/ year}	4	7
Hops	Downy mildew (Pseudoperonospora humuli)	Suspension, Wettable Powder	Ground: airblast	{225 g a.i./ha}	{675 g a.i./ha/ year}	3	10
Ginseng	Phytophthora blight ( <i>Phytophthora</i> <i>cactorum</i> ) - suppression	Suspension, Wettable Powder	Ground: field sprayers	225 g a.i./ha	{675 g a.i./ha/ year}	3	5
Outdoor grown ornamentals, herbaceous annual and perennial plants	Downy mildew (P. parasitica, P. antirrhini, P. phlogina, P. sparsa, P. violae)	Suspension, Wettable Powder	Ground application equipment except high pressure handheld equipment and backpack sprayers.	{24 g a.i./ 100 L} (not to exceed 225 g a.i./ha)	{900 g a.i. /ha/ crop season}	4	7
Outdoor, container and field grown ornamental plants (including conifers) in nurseries and landscape plantings	Sudden oak death (Phytophthora ramorum) -suppression	Suspension, Wettable Powder	Ground application equipment	{24 g a.i./ 100 L} (not to exceed 225 g a.i./ha)	{900 g a.i. /ha/ crop season}	4	10
Greenhouse ornamentals	Downy mildew (P. parasitica, P. sparsa, P. antirrhini, P. violae, P. phlogina)	Suspension, Wettable Powder	Ground application equipment except high pressure handheld equipment and backpacks sprayers.	(240g a.i./ ha)	{960 g a.i./ha/ season}	4	7

{ } = Active ingredient (a.i.) rate and cumulative active ingredient (a.i.) rate per year in { } brackets were calculated by the PMRA.

() = Product rate, active ingredient rate and spray volume per hectare for greenhouse ornamentals were provided by the registrant.

# Appendix II Toxicity Profile and Endpoints for Health Risk Assessment

#### Table 1 Toxicology Reference Values for the Human Health Risk Assessment of Dimethomorph

Exposure Scenario	Study	Point of Departure and Endpoint	CAF <sup>1</sup> or Target MOE
ARfD (♀ 13-49)	Developmental toxicity in rats	NOAEL=60 mg/kg bw/day LOAEL=160 mg/kg bw/day based on ↑ incidence of total litter loss (early resorptions)	300 (PCPA=threefold )
ARfD (general population, excluding $\bigcirc$ 13-49)	Acute neurotoxicity in rats	$ARfD = 0.2 \text{ mg/kg bw}$ $LOAEL=250 \text{ mg/kg bw based on } \downarrow \text{ motor}$ $activity, \downarrow \text{ habituation and } \downarrow \text{ rearing}$	300 (threefold for lack of NOAEL)
		ARfD = 0.8 mg/kg bw	,
ADI All populations	1-year dietary in dog supported by 2-year carcinogenicity in rats	Dog: NOAEL=15 mg/kg bw/day LOAEL=45 mg/kg bw/day based on ↑ liver and testis wt and ↓ prostate wt	100
		(Rat: NOAEL=13 mg/kg bw/day ( $\bigcirc$ ) LOAEL=52 mg/kg bw/day ( $\bigcirc$ ) based on $\downarrow$ bw, bwg ( $\bigcirc$ )	
	ADI	I = 0.2  mg/kg bw/day	
Short- term/intermediate dermal and inhalation <sup>2</sup>	Developmental toxicity in rats	NOAEL=60 mg/kg bw/day LOAEL=160 mg/kg bw/day based on ↑ incidence of total litter loss (early resorptions)	300
Long term dermal and inhalation <sup>3</sup>		Dog: NOAEL=15 mg/kg bw/day LOAEL=45 mg/kg bw/day based on ↑ liver and testis wt and ↓ prostate wt (Rat: NOAEL=/13 mg/kg bw/day (♀) LOAEL=52 mg/kg bw/day (♀) based on ↓ bw, bwg (♀) )	100
Cancer	Not oncogenic in rats or mi	ice at doses tested	

Cancer Not oncogenic in rats or mice at doses tested

<sup>1</sup> CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational assessments

<sup>2</sup> Since an oral NOAEL was selected, a dermal absorption factor of 23% was used in a route-to-route extrapolation

<sup>3</sup> Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

# Table 2 Toxicity Profile for Dimethomorph

**NOTE:** Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted

Toxicokinetic and Metabolism Studies				
Study/Species	Results/Effects			
Absorption, Distribution, Metabolism, Elimination - Oral Gavage Sprague Dawley rat	Dose regimen: Low (10 mg/kg bw) or high (500 mg/kg bw) single dose: Dimethomorph (14C-chlorophenyl ring) in 0.1% Tween 80 (aq)			
PMRA# 1161504, 1163731	(expired air collected) <u>Repeated low dose:</u> 14 doses of 10 mg/kg bw/day and one 14C-DME (10 mg/kg bw/day) or 7 doses of 14C-DME (10 mg/kg bw/day) Data collected at 1, 6, 24, 48 and 120h post 7 <sup>th</sup> dose			
	<b>Single high dose:</b> Metabolism: some sex-specific differences in urinary metabolites (different compounds, and/or number of the relative proportions of the individual metabolite fractions from corresponding sampling periods). The metabolite profiles of the extractable fecal residues were similar in both sexes (the unchanged DME ~ 46%/50% of administered dose, AD, $\partial/\varphi$ )			
	Excretion: feces: 86.8% of AD ( $\circlearrowleft$ ), 88.9% of AD ( $\updownarrow$ ) after 7 days dosing urine: 6.2% of AD ( $\circlearrowright$ ), 10.4% of AD ( $\updownarrow$ ) after 7 days dosing carcass: $\ge 0.2\%$ of AD No radioactivity in expired air			
	<b>Single low dose:</b> Metabolism: the most polar metabolite fraction (feces) predominated and only ~5% was as parent compound; there were no sex-related differences in metabolites.			
	Excretion: 90% of dose excreted after 2 days feces: 90.1% of AD ( $\mathcal{F}$ ), 86.4% of AD ( $\mathcal{F}$ ) after 7 days dosing urine: 5.6% of AD ( $\mathcal{F}$ ), 13.6% of AD ( $\mathcal{F}$ ) after 7 days dosing carcass: 0.1% of AD			
	<b>Repeat low dose:</b> Metabolism: similar to single low dose administration			
	Excretion: about 90% of AD after 2 days dosing feces: 89.2% of AD ( $\mathcal{C}$ ), 80.6 of AD ( $\mathcal{C}$ ) after 7 days dosing urine: 7.7% of AD ( $\mathcal{C}$ ), 16.3% of AD ( $\mathcal{C}$ ) after 7 days dosing			

	carcass: 0.4% of AD
	<b>Overall excretion</b> - rapid, mostly in feces (72-88% in 48hrs, 80-90% in 7 days) and urine (5-16% in 48 hrs, 6-16% in 7 days; higher in $\bigcirc$ : 10-16% vs 6-8% in $\bigcirc$ ). The urinary excretion rate of the $\bigcirc$ animals exceeded that of the $\bigcirc$ animal.
	<b>Retention:</b> <0.2% 48 hrs after administration (liver and muscle).
	The amount absorbed was limited at the high dose level. DME was efficiently metabolized and rapidly excreted mainly via the faeces. The main pathways of metabolism are demethylation of the dimethoxyphenyl ring and, to a smaller extent, the oxidation of the morpholine ring.
Bile study (gavage)	10 or 500 mg/kg bw/day
~ ~ .	Bile collected every 3hrs
Sprague Dawley rat	
PMRA# 1161507, 1163731	Single low dose: Absorption: rapidly absorbed, >90% AD in bile within 24 hrs (t $_{1/2}$ =3hr), no
(summary)	sex difference
	Excretion: Faecal and urinary recovery was 15% and 22%, respectively of AD in $\Im$ . First order kinetics, oral AD readily absorbed at low dose and excreted via bile.
	Single high dose:
	<u>Absorption</u> : lower absorption with 49/31% AD in bile after ( $t_{1/2}$ = 11/6 hrs, $\Im/\Im$ ) 48hrs in $\Im/\Im$ respectively, 6/10% of AD in urinary, and 87/89% in fecal excretion in 48 hrs ( $\Im/\Im$ )
	Metabolism: Repeat (low) dose similar to single low dose:
	Urine: oxidative metabolite (CUR 7117) formed via cleavage of
	morpholine ring
	Feces: CUR 7117, low levels of unchanged DME and traces of other polar metabolites
	Bile: partial demethylation of the dimethyloxyphenyl ring and subsequent conjugation with macromolecules (for example, glucuronides but not sulphates), acid-labile metabolites
	Excretion: $\downarrow$ biliary excretion and $\uparrow$ excretion via feces and/or digestive tract with longer elimination $t_{1/2}$ (indicating saturation of absorption and/or metabolism).
	Metabolism: Urine: 2 metabolites formed by demethylation ( at the 4 not 2 position, ratio of 9:1) of the dimethoxyphenyl ring, small amount of unchanged DME, traces of metabolites formed by oxidation of the
	morpholine ring Feces: unchanged DME, traces of demethylated metabolites Bile: similar to low dose minus two minor metabolites noted at low dose, and presence of an additional metabolite (none identified)
	<ul> <li>Two degradation pathways were proposed:</li> <li>1) Demethylation of one of the methoxyl group of the dimethoxy-phenyl ring with subsequent conjugation of the resulting metabolites before excretion in the urine and feces</li> </ul>

	2) Catabolism of morpholine ring
	-, canconom or morphonic ring
Acute Toxicity Studies	
Study/Species	Results/Effects
Acute oral toxicity (gavage)	Rat oral LD50≥3500 mg/kg bw
	(CL 2800-4200 mg/kg bw)
Sprague Dawley rat	<b>•</b> • • •
PMRA# 1256562	Low oral toxicity
PMRA# 1230302	Clinical signs: piloerection, hunched posture, abnormal gait, lethargy, ↓ respiration, ptosis, pallor, ↓ bwg
Acute oral toxicity (gavage)	
reduce of al toxicity (gavage)	$LD50\bigcirc = 4500 \text{ mg/kg bw}$ $LD50\bigcirc = 3500 \text{ mg/kg bw}$
Sprague Dawley rat	$LD50^{\circ}/^{\circ} = 3900 \text{ mg/kg bw}$
1	
PMRA# 1161435	Low oral toxicity
	Clinical signs: Abnormal gait (waddling), lethargy, $\downarrow$ respiration, ptosis,
	pallor, ↓ bwg
	5000 mg/kg: ↑ lacrimation and diarrhoea
Acute oral toxicity (gavage)	Mouse oral LD50≥5000/3700 (♂/♀)
CD1 mouse	
CD1 mouse	<b>Low oral toxicity</b> Clinical signs: hypokinesia, prostration, piloerection, ataxia, soiled coat
PMRA# 1161436	Q were the more sensitive sex
Acute oral toxicity (gavage)	
Z Isomers	
	Low oral toxicity
Wi-AF/Han (SPF) Rat	No treatment related deaths for Z-isomer at 5000 mg/kg bw
	Clinical signs: pale feces
PMRA# 1161438	
	LD50 = 4472  mg/kg bw (3496-5720  mg/kg bw)
E isomers	$LD50^{\circ}_{\circ} = 4715 (4277-5198) \text{ mg/kg bw}$
	LD50 = 4754 (3958/5709) mg/kg bw
Wi-AF/Han (SPF) rat	LD50 $3/2 = 4472$ (3496-5720) mg/kg bw
PMRA# 1161437	Low oral toxicity
	Clinical signs: 15-60 min post-dosing: locomotor disturbance (persistent for
	several days), dyspnea, piloerection, sunken flanks, incomplete eyelid
	closure, pale feces, salivation, blood-crusted snout, retention of feces,
	hunched lateral and abdominal position, diarrhea, haemorrhagic lacrimation,
	wet anal region, transient bw loss, death
Acute dermal toxicity	LD50 >5000 mg/kg bw
	<b>- - - - - - - - - -</b>
Wi-AF/Han (SPF) rat	Low oral toxicity
PMRA# 1161439, 1162746	
Acute dermal toxicity,	Dermal LD50>2000 mg/kg bw
dermal irritation and eye	Low dermal toxicity (rat)
irritation	
	Dermal irritation:
Fischer rat	Non-irritating (rabbit)

NZW rabbits	Eye irritation: crimson-red conjunctiva and slight chemosis 4hrs-post
	application, resolved after 48hrs
PMRA# 1161440	Minimally-irritating (rabbit)
Dermal irritation	
NZW rabbit	Non-irritating
PMRA# 1161443	
Acute inhalation (dust, whole-body)	LC50 >4.24 mg/L, >~643/678 mg/kg bw/day $^{/}_{+}$
Wistar rat	Non-specific abnormal respiration pattern, no mortality
DMDA = 11 - 14 - 42	Low acute inhalation toxicity
PMRA # 1161442	Clicke we do not to an alternation of the descent of a state discharge.
Eye Irritation	Slight redness to conjunctiva, slight chemosis and slight discharge
NZW rabbit	Minimally irritating to the eye
PMRA# 1161443	
Dermal Sensitization	Swollen injection sites for up to 2 days, followed by open wounds and scabs
(Magnusson maximization	No skin reaction following challenge
test)	
Hartley Guinea pigs	Not a dermal sensitizer
PMRA# 1161444	
Dermal sensitization	Not a dermal sensitizer
(Buehler)	
Dunkin-Hartley guinea pigs	
PMRA# 1161446	
Subchronic Toxicity Studio	25
Study/Species	Results/Effects
	Supplemental (range-finding)
CD-1 mouse	1003/926 mg/kg bw/day: ↑ liver wt
PMRA# 1161454, 1161466	
28-day range finding (diet)	Supplemental - low number of animals used/dose
Sprague Dawley rat	$\geq$ 195/215 mg/kg bw/day: $\downarrow$ bw, bwg and fc; $\uparrow$ rel liver wt and hypertrophy,
DMD A # 1161450 1161466	acute inflammation of ileum ( $\bigcirc$ )
PMRA# 1161459, 1161466	$\geq$ 286/290 mg/kg bw/day: bw, bwg & fc, $\uparrow$ rel liver wt and hypertrophy ( $\circlearrowleft$ ); distension of the small intestine (fluid or gelatinous material), $\uparrow$ serosal mononuclear cell infiltration, serosal thickening, and/or mucosal hyperplasia ( $\updownarrow$ )
	372/399 mg/kg bw/day: ↑ piloerection, swollen abdomen, yellow perigenital staining, and/or thinness of animals; distension of the small intestine (fluid or gelatinous material), acute inflammation of ileum, ↑ serosal mononuclear

	call infiltration across this leaving and/or musses hyperplaces + heart we
	cell infiltration, serosal thickening, and/or mucosal hyperplasia, $\downarrow$ heart wt ( $\Im$ ); vacuolation in liver ( $\Im$ )
28-day study (diet)	Supplemental - low number of animals used/dose
Sprague Dawley rat	$\geq$ 81/81 mg/kg bw/day: ↓ pituitary wt (♂); ↑ blood urea nitrogen (BUN), ↓ uterine wt (♀)
PMRA# 1161460	
	306/283 mg/kg bw/day: 3 killed in extremis $(1 \circles, 2 \circles, with distended smalland large intestine filled with fluid), loose stools, swollen abdomen, hunchedposture, piloerection, stained fur, emaciated appearance, stomach distendedwith ingests, \downarrow bw, bwg and fc, \uparrow neutrophils, \uparrow total WBC and plateletcount, \downarrow total blood protein, \downarrow albumin, \uparrow globulin fraction, \uparrow liver wt, \uparrowurine volume with \downarrow specific gravity; \uparrow BUN, empty seminal vesicles (\circles, \downarrow); \downarrowwc, \downarrow pituitary wt (\circles, \downarrow)$
28-day study (gavage) with E-isomer	NOAEL = 10 mg/kg bw/day
Fischer 344 rat	$\geq$ 100 mg/kg bw/day: cecal enlargement, slight mid-zonal hepatocellular cytoplasmic lipid vacuolation (all rats); $\uparrow$ fc, $\uparrow$ liver and adrenal wt ( $\circlearrowleft$ )
PMRA# 1161461	750 mg/kg bw/day: slight normocytic anaemia: $\downarrow$ in total blood Hb, $\uparrow$ platelet counts, $\uparrow$ total protein, bilirubin, cholesterol, calcium, GGT, $\uparrow$ serum urea and creatine levels, dark coloration of the liver; $\downarrow$ spleen wt ( $\circlearrowleft$ ); $\uparrow$ liver wt ( $\bigcirc$ )
28-day (gavage) with Z- isomer	NOAEL = 10 mg/kg bw/day
Fischer 344 rat	≥100 mg/kg bw/day: $\uparrow$ liver wt (9/14%, 36/ 21%, $\eth/\square$ ), liver enlargement (0/0, 1/0, 2/3, 7/7, $\eth/\square$ ) patchy mid-zonal hepatocellular cytoplasmic lipid vacuolation
PMRA# 1161462	vicuolition
	750 mg/kg bw/day: $\uparrow$ total protein, $\uparrow$ bilirubin, $\downarrow$ A/G ratio, liver and cecal enlargement (due to fluid content) and liver discoloration
90 day study (diet)	NOAEL = 14 mg/kg bw/day
Sprague Dawley rat	73/82 mg/kg bw/day: ↓ urinary pH; ↓ total WBC and lymphocyte count (♂); ↑ liver wt, ↑ heart wt, ↑ ovary wt (♀)
PMRA# 1161463	
	Recovery (limited to the hematological, biochemical and urinalysis parameters in 1 control and one high dose animal/sex) : 73/82 mg/kg bw/day: regression of acidity of urine and regression of ↓ WBC; marginal liver wt (♀)
28-day range-finding (diet)	Supplemental Group 1: $\geq 18/24$ mg/kg : $\downarrow$ fc; occasional vomiting, $\uparrow$ urination, subdued
Beagle dog	behaviour, $\uparrow$ micturition, bw loss ( $\Diamond$ )
PMRA# 1161464	Group 2: 41/47 mg/kg bw/day: occasional tremors (♂)
90-day (diet)	NOAEL = 15 mg/kg bw/day
Beagle dog	41/42 mg/kg bw/day: licking of lips, subdued behaviour, occasional tremors; ↓ prostate wt, prostatitis and ↑ fibrosis in prostate, ↑ abs testes wt (♂); ↓ fc, ↑
PMRA# 1161465	For we, colon inflammation ( $\bigcirc$ )

1-year oral toxicity (diet)	NOAEL = 15 mg/kg bw/day
Beagle dog	≥15/16 mg/kg bw/day: $\uparrow$ intracellular lipid in the liver, ( $3$ ); $\uparrow$ abs liver wt
$DMD \wedge # 1161455$	$(\stackrel{\circ}{\mp})$
PMRA# 1161455	45/47 mg/kg bw/day: $\downarrow$ bw, $\uparrow$ thyroid wt, $\uparrow$ serum ALP; $\uparrow$ liver wt, $\uparrow$ kidney
	wt, $\downarrow$ prostate wt, $\uparrow$ testis wt, $\uparrow$ intracellular lipid in the liver ( $\Im$ ); $\uparrow$ rel uterus wt and rel ovary wt ( $\Im$ )
28-day dermal toxicity	NOAEL (systemic toxicity and dermal irritation) $\geq$ 1000 mg/kg bw/day (limit dose) ( $\Im/\Im$ )
Wistar rat	No treatment-related effects
PMRA# 2361498	
<b>Chronic Toxicity/Carcinog</b>	enicity Studies
Study/Species	Results/Effects
2-year oncogenicity (diet)	NOAEL = 100 mg/kg bw/day
CD- 1 mouse	≥10 mg/kg bw/day: ↓ bwg (♂) (non-adverse) 1000 mg/kg bw/day: ↓ bw, moderate dilation and/or villous atrophy in the
PMRA# 1161472, 1161473, 1161474, 1161482	ileum; $\uparrow$ liver wt, $\uparrow$ serum ALP ( $\Im$ ); $\downarrow$ bwg, $\uparrow$ serum AST ( $\bigcirc$ )
	No evidence of oncogenicity
2-year chronic (diet)	NOAEL = 43 mg/kg bw/day ( $3/$ ?)
Sprague Dawley rat	≥61 mg/kg bw/day: ↑ in "ground-glass" foci in liver, slight hypertrophy and/or accumulation of yellow-brown granular pigment in the periacinar
PMRA# 1161456	hepatocytes $(\bigcirc)$
	116/164 mg/kg bw/day: $\uparrow$ incidence of swollen hind feet, $\downarrow$ RBC, $\downarrow$ Hb (mild anemia); $\uparrow$ hepatic pallor and $\uparrow$ incidence of dilated blood vessels, lymph node cysts, stomach mass, dilated mesenteric blood vessels, $\uparrow$ in "ground-glass" foci in liver, slight hypertrophy and/or accumulation of yellow-brown granular pigment in the periacinar hepatocytes, $\uparrow$ arteritis in the abdominal blood vessels ( $\circlearrowleft$ ); $\downarrow$ bw, $\downarrow$ bwg, $\uparrow$ relative kidney wt, $\uparrow$ rel liver wt & slight liver hypertrophy, $\downarrow$ ovary wt, $\uparrow$ lymphocytes, $\downarrow$ hematocrit, $\uparrow$ WBCs, $\uparrow$ MCV (ss), $\uparrow$ cellularity in sternum bone marrow (adaptive to anemia) ( $\diamondsuit$ )
	No evidence of oncogenicity
2-year carcinogenicity (diet)	NOAEL = 13 mg/kg bw/day ( $\bigcirc$ )
Sprague Dawley rat	$\geq$ 53 mg/kg bw/day: $\downarrow$ bw, $\downarrow$ bwg ( $\stackrel{\bigcirc}{+}$ )
PMRA# 1162900	110/145 mg/kg bw/day: severe swollen hind feet, $\uparrow$ in "ground-glass" foci in liver (with pale, granular, acidophilic cytoplasm and variable amount of glycogen); $\downarrow$ bw, $\downarrow$ bwg, cysts in lumbar lymph nodes and dilated mesenteric vessels, arteritis in mesenteric blood vessels, $\uparrow$ dilated abdominal blood vessels (associated with arteritis) ( $\Diamond$ ); swollen hindlimb, 5 $\bigcirc$ sacrificed in extremis (swollen hind limbs week 12), hair loss, $\downarrow$ fc, pancreatic masses, inflammation and arteritis, enlarged lymph nodes, $\uparrow$ accumulation of pigment in periacinar hepatocytes and slight periacinar hepatocyte hypertrophy (adaptive), $\uparrow$ cellularity in sternum bone marrow, spleen

	hematopoiesis, ovarian cysts ( $\mathcal{Q}$ )						
	No evidence of oncogenicity						
Developmental/Reproductive Toxicity Studies							
Study/Species	Results/Effects						
2-generation reproductive	Maternal NOAEL = 50/15 mg/kg bw/day						
toxicity (diet)	50 mg/kg bw/day: ↓ bw, bwg ( $\stackrel{\bigcirc}{+}$ )						
Sprague Dawley rat	Reproductive NOAEL = 50 mg/kg bw/day						
Sprague Dawley Tai	Reproductive parameters were not affected						
PMRA# 1161458,	Reproductive parameters were not arrected						
1161467	Offspring NOAEL = $50 \text{ mg/kg bw/day}$						
	50 mg/kg bw/day: slight delay in tooth eruption in $F_{1a}$ and $F_{2a}$ pups						
	(equivocal)						
	No evidence of sensitivity of the young						
Developmental toxicity	Maternal NOAEL = 60 mg/kg bw/day 160 mg/kg bw/day: ↓fc, ↓bw, ↓bwg, ↑incidence of early resorptions (total						
(gavage)	litter loss )						
Sprague Dawley rat							
~Pragae 2 anney rat	Developmental NOAEL= 60 mg/kg bw/day						
PMRA# 1161474	160 mg/kg bw/day: ↑ incidence of early resorptions (total intrauterine litter						
	loss)						
	No evidence of treatment-related malformations						
	No evidence of sensitivity of the young						
Range-finding	Supplemental						
developmental toxicity	Maternal Toxicity						
(gavage)	≥600 mg/kg bw/day: ↓ bwg						
	1000 mg/kg bw/day: $\downarrow$ wc, $\downarrow$ fc, $\uparrow$ incidence of abortions(6/8), 1 total litter						
NZW rabbit	loss						
PMRA# 1161475	Developmental toxicity						
1 WIX // 1101475	1000 mg/kg bw/day: ↓ fetal bw						
	No evidence of treatment-related malformations						
Developmental toxicity	Maternal NOAEL=300 mg/kg bw/day						
(gavage)	$\geq$ 135 mg/kg bw: $\downarrow$ fc						
	≥300 mg/kg bw:↓ bwg						
NZW rabbit	650 mg/kg bw: $\uparrow$ incidence of abortions (1, 1, 0, 3 from control to high dose,						
PMRA# 1161476	respectively)						
1 1/11/1 1/1 1/1 1/1 1/1	Developmental NOAEL = 300 mg/kg bw/day						
	650 mg/kg bw: ↑ incidence of abortions						
	No evidence of treatment-related malformations						
	No evidence of sensitivity of the young						

Genotoxicity Studies	
Study/Species	Results/Effects
Reverse Mutation <i>in vitro</i>	Negative with and without metabolic activation
Reverse Mutation in vitro	
Salmonella typhimurium	
strains TA98, TA100, TA	
1535 and TA1537;	
Escherichia coli WP2 uvra	
Escherichia coli wF2 uvia	
PMRA# 116148, 1161479,	
1161478	
Gene mutation in vitro	No induction of $\uparrow$ mutant colonies ±S9
	NY C
Chinese hamster	Negative
V79 cells (HGPRT)	
DMD 4#1161490	
PMRA#1161480	
Chromosome aberration in	Equivocal positive results (only at 1 time point)
vitro	12–170 µg/mL
Chinese hamster	no clear dose response
V79 cells (HGPRT)	
	160/170 $\mu$ g/mL ±S9: $\uparrow$ chromosome aberrations (including gaps) 3.5-2.7-
PMRA# 1161481	fold at 7hrs
	Supplemental due to absence of adequate positive control
Chromosome aberration in	110–150 µg/mL: 94–98% survival rate + S9, and 85–86% -S9
vitro	
	Slight $\uparrow$ (1.5-2.5-fold) in chromosome aberrations at 7hrs
Chinese hamster	
V79 cells (HGPRT)	Positive for increased chromosome aberrations at high doses and only at one
	time point
PMRA# 1161468	*
(confirmatory to the study	Negative at 18hrs
above)	
Transformation Assay	Negative
Syrian hamster embryo	
(SHE) cells	
PMRA# 1161469	
Mouse micronucleus test <i>in</i>	Negative
vivo (gavage)	
(Surage)	
mice	
PMRA# 1161470	
Unscheduled DNA	Negative
synthesis test <i>in vitro</i>	
synthesis test in villo	
Wistar rat;	
mistai iat,	

Primary hepatocytes	
PMRA# 1161471	
Immunotoxicity Studies	
Study/Species	Results/Effects
28-day immunotoxicity (diet)	NOAEL = 184 mg/kg bw/day (high-dose treatment)
Primary T-cell dependent	No treatment-related effects on spleen or thymus wt or on the humoral immune response
antibody response (anti- SRBC IgM ELISA)	184 mg/kg bw/day: ↓ overall bwg
PMRA# 2361502	No evidence of immunotoxicity.
Neurotoxicity Studies	
Study/Species	Results/Effects
Acute oral neurotoxicity (gavage)	LOAEL = 250 mg/kg bw in $3/2$ (low-dose treatment)
Wistar rat	No treatment-related effects on body weight, brain weight, gross pathology or neuropathology.
PMRA# 2361503	$\geq 250 \text{ mg/kg bw: } \downarrow \text{ motor activity, } \downarrow \text{ rearing; } \downarrow \text{ habituation } (\mathcal{T}) \\\geq 500 \text{ mg/kg bw: } \downarrow \text{ habituation; } \downarrow \text{ exploration activity } (\mathcal{T})\text{; gait impairment} \\ (\downarrow \text{ movement) } (\mathcal{P}) \\2000 \text{ mg/kg bw: gait impairment } (\downarrow \text{ movement) } (\mathcal{T})\text{; } \uparrow \text{ clinical signs of} \\\text{toxicity, } \uparrow \text{ mortality, } \downarrow \text{ exploration activity } (\mathcal{P}) \end{cases}$
	No evidence of selective neurotoxicity
90-day neurotoxicity (diet)	NOAEL = 59/ 70 mg/kg bw/day ( $\mathcal{O}/\mathcal{Q}$ )
Wistar rat	178/204 mg/kg bw/day: $\downarrow$ bw, $\downarrow$ bwg, $\downarrow$ fc, $\downarrow$ fe
PMRA# 2361508	No evidence of selective neurotoxicity

### Appendix III Dietary Exposure and Risk Estimates for Dimethomorph

Population Subgroup	Acute Dietary <sup>1</sup> (Food and Drinking Water) 95 <sup>th</sup> percentile of exposure				
i opulation Subgroup	Dietary Exposure (mg/kg bw)	%ARfD			
General Population <sup>2</sup>	N/A	N/A			
All Infants (< 1 year old)	0.075849	9			
Children 1–2 years old	0.131843	15			
Children 3–5 years old	0.117535	14			
Children 6–12 years old	0.076026	9			
Males 13–19 years old	0.053971	7			
Males 20–49 years old	0.064053	8			
Adults 50+ years old	0.075490	9			
Females 13–49 years old <sup>3</sup>	0.079159	40			

#### Table 1 Acute Dietary Exposure and Risk Estimates for Dimethomorph

<sup>1</sup>Acute Reference Dose (ARfD) of 0.8 mg/kg bw for all population subgroups excluding females 13-49 years old. <sup>2</sup>The risk estimate was not determined for the general population, as separate ARfDs were selected for females aged 13–49 years and the other population groups. <sup>3</sup>Acute Reference Dose (ARfD) of 0.2 mg/kg bw for females 13-49 years old

Table 2	<b>Chronic Dietary</b>	<b>Exposure and</b>	<b>Risk Estimates</b>	for Dimethomorph
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Donulation Subgroup	Chronic Dietary <sup>1</sup> (Food and Drinking Water)				
Population Subgroup	Dietary Exposure (mg/kg bw/day)	%ADI			
General Population (total)	0.025270	17			
All Infants (< 1 year old)	0.027284	18			
Children 1–2 years old	0.046904	31			
Children 3–5 years old	0.039067	26			
Children 6–12 years old	0.024988	17			
Youth 13–19 years old	0.018492	12			
Adults 20-49 years old	0.024452	16			
Adults 50+ years old	0.024759	17			
Females 13–49 years old	0.024297	16			

<sup>1</sup>Acceptable Daily Intake (ADI) of 0.2 mg/kg bw/day for all population subgroups

### Appendix IV Food Residue Chemistry Summary

Dimethomorph is a morpholine fungicide registered in Canada for foliar use, on brassica vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, ginseng, grapes, hops, leafy vegetables, potatoes, greenhouse ornamentals and outdoor (container and field) grown ornamentals. It inhibits the formation of oomycete cell walls through inhibition of sterol synthesis. Dimethomorph is used to treat downy mildew, phytophthora blight and late blight in vegetables, late blight and tuber blight in potatoes and sudden oak death and downy mildew in field grown or greenhouse ornamentals. End-use products are formulated as wettable powders or suspension. Dimethomorph can be applied by field sprayer, airblast or aerial application. The maximum label application rate is 225 g ai/ha.

The nature of the residue in livestock and plant commodities is adequately understood based on acceptable metabolism studies in ruminants, poultry, lettuce, potatoes, grapes and tomatoes. The residue definition in all plant commodities for enforcement and risk assessment is expressed as the parent dimethomorph.

MRLs have been established for dimethomorph and published in the *PMRA MRL database* for MRLs regulated under the *Pest Control Products Act*. No changes to the existing MRLs are proposed for dimethomorph.

Analytical methods were previously reviewed and found to be adequate for data collection and enforcement. The reviewed methods use HPLC-UV, GC-NPD, HPLC-MS/MS and LC-MS/MS with recoveries within the 70%–120% range and LOQs of 0.01- 0.05 ppm. All methods were validated as data-gathering methods and some were found adequate as enforcement methods. According to the results of the *Food and Drugs Act* Multiresidue Analytical Method, Protocol D, Section 232.4 procedures are suitable for the analysis of dimethomorph in crop matrices.

No data deficiencies according to the OECD Guidelines for the Testing of Chemicals, Section 5 were identified for dimethomorph. Sufficient field trial residue data was available to adequately assess the dietary exposure and risk from dimethomorph use. Estimation of potential contamination of drinking water sources, *i.e.*, modelling of EECs was conducted. The dietary exposure and risk assessment included the food and water residue values based on the current uses in Canada and potentially treated imported food commodities.

The dietary (acute and chronic) risk assessment for dimethomorph is a conservative assessment using Canadian MRLs or American Tolerances for residue values, highest experimental or default processing factors, 100% crop treated, and drinking water EECs based on modelling. Since the risk estimates were shown to be acceptable, no refinements to the dietary risk assessment inputs were required.

### Appendix V Agricultural Mixer/Loader/Applicator and Postapplication Risk Assessment

#### Table 1 Mixer/Loader/Applicator Exposure and Risk Assessment of Dimethomorph, Short-, Intermediate-Term

Formulation	Application Equipment	Max Rate (kg a.i./ha)	ATPD (ha/day)	Dermal Exposure <sup>a</sup> (mg/kg bw/day)	Inhalation Exposure <sup>b</sup> (mg/kg bw/day)	Dermal MOE <sup>c</sup>	Inhalation MOE <sup>c</sup>	Combined MOE <sup>d</sup>
Open M/L, Op	en Cab Applica	ation, Base	line PPE: lo	ong-sleeved sl	nirt, long pants	, chemical	resistant glov	es
	GB Farmer LFC		107	5.81E-03	6.95E-04	10330	86310	9230
	GB Custom LFC	0.005	360	1.95E-02	2.34E-03	3070	25650	2740
	GB V&F	0.225	26	1.41E-03	1.69E-04	42520	355200	37970
L	Aerial		400	2.50E-03	7.88E-05	24010	761900	23270
	Aerial		400	1.51E-02	7.09E-04	3970	84660	3790
	Airblast		20	4.95E-02	5.46E-04	1210	109850	1200
	MPHW	0.240 <sup>e</sup>	150 <sup>f</sup>	1.95E-04	4.07E-05	307255	1474926	254283
	Backpack		150 <sup>f</sup>	1.13E-03	3.52E-05	53224	1705030	51613
	MPHG		3800 <sup>f</sup>	2.93E-02	3.44E-03	2048	17428	1833
	GB Farmer LFC		107	2.74E-02	2.20E-03	2186	27312	2024
	GB Custom LFC		360	9.23E-02	7.39E-03	650	8118	602
	GB V&F	0.225	26	1.41E-03	1.69E-04	42520	355200	37974
WP	Aerial		400	2.50E-03	7.88E-05	24005	761905	23271
	Aerial	1	400	9.60E-02	6.32E-03	625	9490	586
	Airblast		20	5.36E-02	8.27E-04	1120	72562	1103
	MPHW		150 <sup>f</sup>	4.09E-03	1.28E-03	14680	46849	11178
	Backpack	0.240 <sup>e</sup>	150 <sup>f</sup>	1.20E-03	4.02E-05	49829	1490757	48217
	MPHG		3800 <sup>f</sup>	3.12E-02	3.57E-03	1921	16802	1724

ATPD = area treated per day, MOE = margin of exposure, L = liquid, WP = wettable powder. M/L = Mix/Load,

A = Application, GB = Groundboom, LFC = Large Field Crops, V&F = Vegetables and Fruit, MPHW =

Manually Pressurized Handwand, MPHG = Mechanically Pressurized Hand Gun

<sup>a</sup> Dermal exposure (mg/kg bw/day) = (dermal unit exposure  $\times$  ATPD  $\times$  maximum application rate  $\times$  23% dermal absorption)/80 kg body weight

<sup>b</sup> Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/80 kg body weight

<sup>c</sup> Short-, Intermediate-Term: Based on a NOAEL of 60 mg/kg bw/day from a dietary dog study, Target MOE = 300.

<sup>d</sup> Combined MOE = NOAEL/(EXP<sub>derm</sub>+EXP<sub>inh</sub>), Short-, Intermediate-Term Target MOE = 300

<sup>e</sup> Spray Volume = 500 L/ha

f Litres/day

Сгор	Activity	TC (cm²/hr) <sup>a</sup>	Max App Rate (kg ai/ha)	Maximum Applications per year	Dermal Exposure (mg/kg bw /day) <sup>b</sup>	Dermal MOE (Day <sub>0</sub> ) <sup>c</sup>	REI (days)
Short-, Interme	ediate-Term						
	Irrigation (handset)	1750		5	5.13E-02	1170	0.5
	Harvesting (hand/mechanically assisted), Turning, Training	550	0.225	5	1.61E-02	3720	0.5
Vegetables,	Transplanting	230		5	6.74E-03	8900	0.5
hairy <sup>d</sup>	Scouting, Weeding (hand), Pruning (hand), Thinning fruit (hand)	90		5	2.64E-03	22700	0.5
	Irrigation (non- handset), Weeding (mechanical)	NO TC	REI not required <sup>e</sup>				
	Irrigation (handset)	1750	0.225	5	5.13E-02	1170	0.5
	Harvesting (hand)	1100		5	3.23E-02	1860	0.5
	Transplanting	230		5	6.74E-03	8900	0.5
Vegetables	Scouting	210		5	6.16E-03	9740	0.5
smooth <sup>f</sup>	Weeding (hand)	70		5	2.05E-03	29200	0.5
	Irrigation (non- handset), Weeding (mechanical)	NO TC	REI not required <sup>e</sup>				
	Harvesting (hand)	5150		5	1.51E-01	397	0.5
	Weeding (hand)	4400		5	1.29E-01	465	0.5
	Scouting	4000	0.225	5	1.17E-01	512	0.5
	Irrigation (handset)	1750	0.225	5	5.13E-02	1169	0.5
Vegetables,	Scouting, Thinning	1300		5	3.81E-02	1574	0.5
waxy <sup>g</sup>	Transplanting	230		5	6.74E-03	8896	0.5
-	Irrigation (non- handset), Weeding (mechanical),	NO TC		RE	I not required <sup>e</sup>		

## Table 2 Dermal Postapplication Exposure and Risk Assessment of Dimethomorph, Field Vegetables

Max App Rate = Maximum Application Rate, TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = Margin of Exposure, REI = restricted entry interval

Since no DFR studies were submitted, a peak default DFR value of 25% of the application rate and dissipation rate of

10%/day were used. Maximum applications per year and minimum interval between applications were assumed.

Fertilizing (injection)

<sup>a</sup> The TC values are based on ARTF Studies (2008). The TC value for maximum foliage density was considered as a worst case scenario for the risk assessment.

<sup>b</sup> Dermal exposure (mg/kg bw/day) = DFR (ug/cm<sup>2</sup>) × TC (cm<sup>2</sup>/hr) × work duration (8 hr) × 23% Dermal Absorption / BW (80 kg)

<sup>c</sup> Dermal  $MOE = NOAEL/(EXP_{derm})$ , Short-, Intermediate-Term: Based on a NOAEL of 60 mg/kg bw/day from a dietary dog study, Target MOE = 300

<sup>d</sup>TC values for cantaloupe were chosen to represent the hairy leaf vegetables. Includes Cucurbit Vegetables, Fruiting Vegetables.

<sup>f</sup>TC values for celery were chosen to represent the smooth leaf vegetables. Includes Leafy Vegetables, Fruiting Vegetables, Bulb Vegetables, Potatoes and Ginseng.

<sup>g</sup> TC values for broccoli were chosen to represent the waxy leaf vegetables. Includes Brassica Vegetables, Fruiting Vegetables, Bulb Vegetables.

### Table 3 Dermal Postapplication Exposure and Risk Assessment of Dimethomorph, Hops

Crop	Activity	TC (cm²/hr) <sup>a</sup>	Max App Rate (kg ai/ha)	Dermal Exposure (mg/kg/day) <sup>b</sup>	Dermal MOE <sup>c</sup>	REI (days)
Short-,	Intermediate-Term					
	Harvesting (mechanically)	19300		3.67E-01	163 <sup>d</sup>	6
	Irrigation (handset)	1750		3.33E-02	1800	0.5
Hops	Weeding (hand)	640	0.225	1.22E-02	4930	0.5
Hops	Stripping, scouting, tying, training	640	0.225	1.22E-02	4930	0.5
	Transplanting	230		4.37E-03	13700	0.5

Max App Rate = Maximum Application Rate, TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = Margin of Exposure, REI = restricted entry interval

Since no DFR studies were submitted, a peak default DFR value of 25% of the application rate and dissipation rate of 10%/day were used. 3 applications per year with a minimum interval between applications of 10 days. <sup>a</sup> The TC values are based on ARTF Studies (2008). The TC value for maximum foliage density was considered as a worst case scenario for the risk assessment. <sup>b</sup> Dermal exposure (mg/kg bw/day) = DFR (ug/cm<sup>2</sup>) × TC (cm<sup>2</sup>/hr) × work duration (8 hr) × 23% / BW (80 kg)

<sup>c</sup> Dermal  $MOE = NOAEL/(EXP_{derm})$ , Short-, Intermediate-Term: Based on a NOAEL of 60 mg/kg bw/day, from a dietary dog study. Target MOE = 300

<sup>d</sup> Since the pre-harvest Interval of 7 days is specified on the label, the REI does not to be added to the label.

## Table 4Dermal Postapplication Exposure and Risk Assessment of Dimethomorph,<br/>Grapes

Сгор	Activity	TC (cm²/hr) <sup>a</sup>	Max App Rate (kg ai/ha)	Dermal Exposure (mg/kg/day) <sup>b</sup>	Dermal MOE <sup>c</sup>	REI (days) <sup>d</sup>
Short-, I	ntermediate-Term					
	Girdling, turning	19300		4.54E-01	132	8
	Harvesting, tying, training, leaf pulling	8500		2.00E-01	300	0.5
Cromos	Irrigation	1750	0.225	4.11E-02	1463	0.5
Grapes	Weeding, propagating, bird control, trellis repair, pruning, scouting	640	0.225	1.50E-02	3990	0.5
	Transplanting 230			5.41E-03	11100	0.5

Max App Rate = Maximum Application Rate, TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = Margin of Exposure, REI = restricted entry interval

Since no DFR studies were submitted, a peak default DFR value of 25% of the application rate and dissipation rate of 10%/day were used. 4 applications per year with a minimum interval between applications of 7 days

<sup>a</sup> The TC values are based on ARTF Studies (2008). The TC value for maximum foliage density was considered as a worst case scenario for the risk assessment.

<sup>b</sup> Dermal exposure (mg/kg bw/day) = DFR (ug/cm<sup>2</sup>) × TC (cm<sup>2</sup>/hr) × work duration (8 hr) × 23% / BW (80 kg)

<sup>c</sup> Dermal MOE = NOAEL/(EXP<sub>derm</sub>), Short-, Intermediate-Term: Based on a NOAEL of 60 mg/kg bw/day, from a dietary dog study, Target MOE = 300

<sup>d</sup> The current label REI of 19-20 days can be reduced to 8 days for girlding and turning. Other label REIs for training, thinning and hand pruning can be reduced to 12 hours or captured under "All Other Activities" on the label with the current REI of 12 hours.

## Table 5Dermal Postapplication Exposure and Risk Assessment of Dimethomorph,<br/>Outdoor, container grown ornamentals, herbaceous and perennial plants

Сгор	Activity	vity TC (cm²/hr) <sup>a</sup> Max App Rate (kg ai/ha)		Dermal Exposure (mg/kg/day) <sup>b</sup>	Dermal MOE <sup>c</sup>	REI (days)
Short-, Intermediate-Term						
Outdoor grown	Irrigation, hand	1750	0.225	4.11E-02	1460	0.5
ornamentals, herbaceous and perennial plants	All other activities	230	0.225	5.41E-03	11100	0.5

Max App Rate = Maximum Application Rate, TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = Margin of Exposure, REI = restricted entry interval

Since no DFR studies were submitted, a peak default DFR value of 25% of the application rate and dissipation rate of 10%/day were used. 4 applications per year with a minimum interval between applications of 7 days. <sup>a</sup> The TC values are based on ARTF Studies (2008). The TC value for maximum foliage density was considered as a worst case scenario for the risk assessment. <sup>b</sup> Dermal exposure (mg/kg bw/day) = DFR (ug/cm<sup>2</sup>) × TC (cm<sup>2</sup>/hr) × work duration (8 hr) × 23% / BW (80 kg)

<sup>c</sup> Dermal MOE = NOAEL/(EXP<sub>derm</sub>), Short-, Intermediate-Term: Based on a NOAEL of 60 mg/kg bw/day, from a dietary dog study, Target MOE = 300

# Table 6Dermal Postapplication Exposure and Risk Assessment of Dimethomorph,<br/>Outdoor, container grown ornamental plants (including conifers) in nurseries<br/>and landscape plantings

Сгор	Activity	TC (cm²/hr) <sup>a</sup>	App rate (kg ai/ha)	Dermal Exposure (mg/kg/day) <sup>b</sup>	Dermal MOE <sup>c</sup>	REI (days)
Short-, Intermediate-Term						
Outdoor grown ornamentals,	Irrigation, hand	1750		3.43E-02	1750	0.5
herbaceous and perennial plants, incl. conifers and Christmas trees	Transplanting. Other activities	230	0.225	4.50E-03	13300	0.5

Max App Rate = Maximum Application Rate, TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = Margin of Exposure, REI = restricted entry interval

Since no DFR studies were submitted, a peak default DFR value of 25% of the application rate and dissipation rate of 10%/day were used. 4 applications per year with a minimum interval between applications of 10 days. <sup>a</sup> The TC values are based on ARTF Studies (2008). The TC value for maximum foliage density was considered as a worst case scenario for the risk assessment. <sup>b</sup> Dermal exposure (mg/kg bw/day) = DFR (ug/cm<sup>2</sup>) × TC (cm<sup>2</sup>/hr) × work duration (8 hr) × 23% / BW (80 kg)

<sup>c</sup> Dermal MOE = NOAEL/(EXP<sub>derm</sub>), Short-, Intermediate-Term: Based on a NOAEL of 60 mg/kg bw/day, from a dietary dog study, Target MOE = 300

## Table 7Dermal Postapplication Exposure and Risk Assessment of Dimethomorph,<br/>Greenhouse ornamentals

Сгор	Activity	TC (cm²/hr) <sup>a</sup>	Max App Rate (kg ai/ha)	Dermal Exposure (mg/kg/day) <sup>b</sup>	Dermal MOE <sup>c</sup>	REI (days)
Long-Term						
Greenhouse ornamental s	All activities	230	0.225	9.48E-03	1580	0.5

Max App Rate = Maximum Application Rate, TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = Margin of Exposure, REI = restricted entry interval

Since no DFR studies were submitted, a peak default DFR value of 25% of the application rate and dissipation rate of 2.3%/day were used. 4 applications per year with a minimum interval between applications of 10 days. <sup>a</sup> The TC values are based on ARTF Studies (2008). The TC value for maximum foliage density was considered as a worst case scenario for the risk assessment. <sup>b</sup> Dermal exposure (mg/kg bw/day) = DFR (ug/cm<sup>2</sup>) × TC (cm<sup>2</sup>/hr) × work duration (8 hr) × 23% / BW (80 kg)

<sup>c</sup> Dermal MOE = NOAEL/(EXP<sub>derm</sub>), Long-Term: Based on a NOAEL of 15 mg/kg bw/day, from a dietary dog study, Long-Term Target MOE = 100

### Appendix VI Environmental Exposure and Risk Assessment

#### Table 1 Abiotic and Biotic Transformation of Dimethomorph in Terrestrial and Aquatic Environments

Type of study	Compound	System	Temp <sup>1</sup> (°C)	pH <sup>2</sup>	OM <sup>3</sup> (%)	Reported DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model	Comments <sup>4,5,6</sup>	References
		Buffer solution	70	4	N/A	Stable	Stable	SFO		
		Buffer solution	70	7	N/A	Stable	Stable	SFO		1161495
Hydrolysis	DME <sup>14</sup> C-	Buffer solution	70	9	N/A	Stable	Stable	SFO	Not a major route of transformation at all	2930940 2930942
Hydrofysis	chlorophenyl ring	Buffer solution	90	4	N/A	Stable	504.0	SFO	tested pHs	1164004
		Buffer solution	90	7	N/A	Stable	1162.0	SFO	tested pris	current review
		Buffer solution	90	9	N/A	Stable	Stable	SFO		
Photo- transformation on soil	DME <sup>14</sup> C- chlorophenyl ring	Ingelheim sandy loam	22.1	7	1.9	75-150	97.8	SFO	Not a major route of transformation. Slightly degradable.	1161497 2930940 1164004 2930942 current review
	DME <sup>14</sup> C-	Aqueous buffer solution,				Irradiated: 25-28 Dark: stable	29.6-33.1	SFO	Fairly degradable.	1161496 current review
Photo- transformation	chlorophenyl ring	Xenon arc lamp	25	5	None	Irradiated: 50-60 Dark: stable	NR	SFO	shallow water in mid- summer	2930940 1164004 2930942
in water	DME	Lamps: Philips TLK 05 UVA, Philips TL 01 UVB, Philips TLD 18W/16	> 0 ~ 25	N/A	DOM rich	10-60	N/A	Pseudo SFO		2930946
Photo- transformation in air	NR	12 hours of sunlight	NA	NA	N/A	NR	0.05	NA	No volatilization expected and rapid atmospheric photo- oxidation breakdown of DME. No long range transport expected	USEPA AOPWIN <sup>TM</sup> v1.92A
	DME <sup>14</sup> C- morpholine ring	Woodstock silty clay loam	22	5.8	1.6	80-90	115	t <sub>R</sub> IORE	Moderately persistent	1161505 current review
Aerobic soil bio- transformation	DME <sup>14</sup> C- morpholine ring	Speyer 2.2 loamy sand	20	5.7	2.5	77	131	Slow t <sub>1/2</sub>	Moderately persistent	2930941 current review
	DME <sup>14</sup> C- chlorophenyl	New Jersey sandy loam	25	6.8	13.0	51-60	55.5	t <sub>R</sub> IORE	Moderately persistent	2930941 current review

Type of study	Compound	System	Temp <sup>1</sup> (°C)	pH <sup>2</sup>	OM <sup>3</sup> (%)	Reported DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model	Comments <sup>4,5,6</sup>	References	
	DME <sup>14</sup> C- morpholine ring	Sandy loam	10	5.7	1.3	74	109	Slow t <sub>1/2</sub>	Moderately persistent	2930941 current review	
	DME	NR	NR	NR	NR	66	N/A	N/A	Moderately persistent	2930942	
	DME	NR	NR	NR	NR	117	N/A	N/A	Moderately persistent	2750742	
	DME	SCL (1 mg a.i./kg soil)	20	6.8	2.5	16.3	N/A	N/A	Slightly persistent	2930949	
	DME	SCL (10 mg a.i./kg soil)	20	6.8	2.5	26.6	N/A	N/A	Slightly persistent	2930949	
	DME	SCL (100 mg a.i./kg soil)	20	6.8	2.5	28.5	N/A	N/A	Slightly persistent	2930949	
	PMRA largest DT5	o values of DME <sup>7</sup>					115		Moderately persistent		
Anaerobic soil bio- transformation	DME <sup>14</sup> C- morpholine ring	Woodstock silty clay loam	22	5.8	2.8	20	16.4	SFO	Slightly persistent	1161515	
	<sup>14</sup> C-DME	Bickenbach system	20	8.1 (w), 7.6 (s)	3.2	2.9	3.7	SFO	Non persistent	11(152)	
	<sup>14</sup> C-DME	Unter Widdersheim system	20	8.2 (w), 7.5 (s)	8.6	2.1	2.8	SFO	Non persistent	1161526	
Aerobic aquatic	DME <sup>14</sup> C- morpholine - <sup>14</sup> C- chlorophenyl	Berghauser	20	7.6 (w) 7.8 (s)	2.2	16.0	15.5	SFO	Slightly persistent	2930943 current review	
bio- transformation	DME <sup>14</sup> C- morpholine - <sup>14</sup> C- chlorophenyl	Kellmetschweiher	20	8.5 (w) 8.0 (s)	7.8	59.0	58.8	SFO	Moderately persistent	2930943 current review	
	Not reported (MRID 43917233)	NR	20	NR	NR	24.7	N/A	N/A	Slightly persistent	2930942	
	Not reported (MRID 48326905)	NR	20	NR	NR	56.9	N/A	N/A	Moderately persistent	2930942	
	90 <sup>th</sup> percentile conf	idence bound on the mean l	alf-life				41.6		Slightly persistent		
	DME	Water/sed system 1	20	NR	NR	0.9	N/A	N/A	Non-persistent		
Anaerobic	DME	Water/sed system 2	20	NR	NR	1.3	N/A	N/A	Non-persistent		
aquatic bio-	DME	Water/sed system 3	20	NR	NR	18.1	N/A	N/A	Slightly persistent	2930942	
transformation	DME	Water/sed system 4	20	NR	NR	18.7	N/A	N/A	Non-persistent		
		reported DT50 value	1	<u>г</u>		18.7		Sl	ightly persistent		
Foliar	DME <sup>14</sup> C- chlorophenyl	Tomato plants	NR	NR	NR	13	N/A	N/A	N/A	2818374	
dissipation	NR	NR	NR	NR	NR	35	N/A	N/A	Default EPA DT50	2930942	
	NR	NR	NR	NR	NR	10	10.0	N/A	Default PMRA DT50	1930629	
Canadian Terrestrial Field	DME	Minto loam (Manitoba)	N/A	7.7	6.5	25	112	(t <sub>R</sub> IORE)	12.3 ppb residues at 7.5- 15 cm depth at 13 DAT3	1174822	

Type of study	Compound	System	Temp <sup>1</sup> (°C)	pH <sup>2</sup>	OM <sup>3</sup> (%)	Reported DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model	Comments <sup>4,5,6</sup>	References
Dissipation and									Moderately persistent	
equivalent ecoregion	DME	New Glasgow sandy loam (PEI)	N/A	5.7	4.0	35	43.7	(SFO)	60 ppb residues at 0-15 cm depth at 366 DAT Slightly persistent	1174823
	DME	North Rose loamy sand (New York, USA)	N/A	6.9	3.3	8	43.2	(t <sub>R</sub> IORE)	22.5 ppb at 15-30 cm depth Slightly persistent	1174824
	90 <sup>th</sup> percentile con	fidence bound on the mean l	alf-life		-		109.4		Moderately persistent	
	DME	Schwabenheim sandy loam	N/A	7.3	2.89	33.8	51.1	(t <sub>R</sub> IORE)	Slightly persistent	1163525
	DME	Malborn sandy loam	N/A	5.2	4.65	38.9	39.4	(SFO)	Sligthly persistent	1163527
	DME	Leibertingen clay soil	N/A	7.3	6.8	40.1	46.4	(SFO)	Slightly persistent	1163528
	DME	Schwabenheim sandy loam	N/A	7.3	2.89	45.7	68.7	(t <sub>R</sub> IORE)	0.181 ppm at 0-10 cm Moderately persistent	1163529
	DME	Kragsberg loamy sand	N/A	6.6	1.07	52.9	52.3	(SFO)	0.01 ppm at 0-10 cm Moderately persistent	1163530
Other	DME	UK loamy sand	N/A	6.5	0.4	61	N/A	N/A	Detected at 0-10 cm Moderately persistent	2930941
Terrestrial Field Dissipation with	DME	France loamy sand	N/A	6.5	NR	34	N/A	N/A	Detected at 0-10 cm Sligthly persistent	2930941
Ecoregions not Equivalent to	DME	Spain sandy soil	N/A	6.7	1.5	10	N/A	N/A	Detected at 0-10 cm Non-persistent	2930941
Canada	DME	USA soil 1	N/A	NR	NR	44.4	N/A	N/A	Detected at 7.5-15 cm Slightly persistent	2930942
	DME	USA soil 2	N/A	NR	NR	21.2	N/A	N/A	Detected at 15-30 cm Slightly persistent	2930942
	DME	USA soil 3	N/A	NR	NR	9.8	N/A	N/A	Detected at 15-30 cm Non-persistent	2930942
	DME	USA soil 4	N/A	NR	NR	122	N/A	N/A	Detected at 30-45 cm Moderately persistent	2930942
	DME	Hefei sandy loam (China)	N/A	8.23	1.66	18.1	N/A	N/A	Slightly persistent	2930947
	DME	Zhengzhou sandy loam (China)	N/A	7.26	3.28	11.5	N/A	N/A	Non-persistent	2930947
	DME	Qingdao sandy clay loam (China)	N/A	6.78	1.94	18.5	N/A	N/A	Slightly persistent	2930947

Type of study	Compound	System	Temp <sup>1</sup> (°C)	pH <sup>2</sup>	OM <sup>3</sup> (%)	Reported DT <sub>50</sub> (day)	Calculated DT50 by PMRA (days)	Kinetic model	Comments 4,5,6	References
	DME	Beijing sandy loam (China)	N/A	6.57	2.31	18.2	N/A	N/A	Slightly persistent for Dimethomorph	2930948

<sup>1</sup> Temp. = temperature; <sup>2</sup>for pH, (w) = water phase; (s) = sediment phase; <sup>3</sup> OM = Organic Matter; <sup>4</sup>Classification of Goring *et al.* 1975 for soils (PMRA 2037242); <sup>5</sup>Classification of McEwen and Stephenson for water (PMRA 2876402); <sup>6</sup> Classification of the FAO (2000); <sup>7</sup> Only the soil biotransformation study of PMRA 1161505 was available for review, other  $DT_{50}$  values are presented as qualitative information only; NA = Not applicable; NR = Not reported; DME = Dimethomorph; DAT = Day after treatment; SCL = Silty clay loam; DOM = dissolved organic matter; **Bold values are used in the environmental risk assessment of DME.** 

#### Table 2 Mobility of Dimethomorph in Terrestrial and Aquatic Environments

Type of study	S	System	Temp <sup>1</sup> (°C)	pH	OM <sup>2</sup> (%)	CEC <sup>3</sup> (meq/100g)	Reported Kd value	Reported K <sub>oc</sub> value	Mobility <sup>4</sup>	References
	BBA - soil 2.1 - San	dy soil	NR	5.7	1.4	4.7	4.47	566	Low	
	BBA - soil 2.2 - Hur	nus sand	NR	6.1	5.0	9.3	11.67	402	Medium	1161500
	BBA - soil 2.3 - San	dy loam	NR	5.4	1.2	5.0	2.09	290	Medium	
	Schwabenheim sand	y loamy silt	NR	5.8	1.7	10.0	4.94	515	Low	
	Ingelheim-Moers II	sandy loam	NR	7.5	2.3	15.0	8.51	377	Medium	1161501
Soil adsorption/	Standard soil 2.1 san	ıdy soil	NR	6.0	3.9	5.0	2.72	388	Medium	1101501
desorption	Standard soil 2.3 silt	y sand	NR	5.4	1.7	8.0	3.03	316	Medium	
	Unknown 1		NR	NR	NR	NR	10.1	787	Low	
	Unknown 2		NR	NR	NR	NR	19.0	1588	Low	2020042
	Unknown 3		NR	NR	NR	NR	11.9	1158	Low	2930942
Ē	Unknown 4	NR	NR	NR	NR	15.7	1485	low		
	PMRA 20 <sup>th</sup> centile			•		3.03	377	Medium mobility		
Type of study	Compound	System	Temp (°C)	рН	OM (%)	CEC (meq/100g)	Max. soil depth detection (cm)	Detection in leachate (% AR)	Comments	References
	Morpholine- <sup>14</sup> C- Dimethomorph	Aged Woodstock silty clay loam	22	5.8	2.8	17.8	0-10	1.0	DME has limited potential for leaching	1161502
	Chlorophenyl- <sup>14</sup> C- Dimethomorph	German soil 2.1 sandy soil	22	5.4	1.3	5.0	5-10	3.4	DME has limited potential for leaching	1164503
Soil column leaching	NR	German soil 2.1 sandy soil	25	5.8	1.2	5	NR	ND	DME has limited potential for leaching	
louoning	NR	German soil 2.2 sandy soil	25	6.0	4.4	10	NR	0.67	DME has limited potential for leaching	1161683
	NR	German soil 2.3 silty sand	25	4.9	1.7	8	NR	ND	DME has limited potential for leaching	

	NR	Ingelheim field sandy loam	25	7.7	2.7		15		NR	ND	DME has limited potential for leaching		
Type of study	Compound	Properties	Criteria indicating a potential for leaching			Value		Meet criteria	Comments				
		Solubility in water		> 30 mg/L				18 1	mg/L	No	Soluble		
		K <sub>d</sub>	< 5 a	nd usually <	< 1 or 2			3.03	mL/g	No	N/A		
		K <sub>oc</sub>		< 300					mL/g	No	Moderately mobile		
		Henry's Law Constant		$10^{-2} \text{ atm.m}^{-3}$			2.06-		$\times 10^{-10}$ atm mole	Yes	Not volatile		
Criteria of Cohen (1984) <sup>5</sup>	DME	рКа	partia	charged (e ally) at ambi	ient pH	ly or		pKa	= -1.3	Yes	Very strong acid	1918520	
Conen (1904)		Hydrolysis half-life	> 14	40 d (> 20 w	weeks)		St	table	at pH 7	Yes	Stable		
		Soil phototransformation half-life	>	> 7 d ( 1 wee	ek)			97.8	3 days	Yes	Slightly persistent		
		Soil biotransformation half-life (non-sterile)	> 14 to 21 days (> 2 to 3 weeks)		Ľ	DT <sub>50</sub> = 115 d		Yes	Moderately persistent				
	PMRA Interpretat	ion					Five cri	iteria	over eight were	met suggesting di	methomorph has some potent	ial for leaching	
Type of study	Compound	-	Parameter						Values		Comments	References	
DME GUS Score <sup>6</sup>	DME	PMRA repr. DT <sub>50</sub> in soil = 3.03 mL/g; GUS = log10 (115) × (4 –			ntile Koc	=	GUS score = 7.24			24	DME is expected to be a borderline leacher to a leacher	1918524	
Type of study	Compound	1	Parameter				Values				Comments	References	
ETF volatilization	DME	from river model	e v4.11 – Vo					6.8	$2.0 \times 10^{-10}$ Pa $8 \times 10^{-16}$ atm m <sup>3</sup> 0.05 days $2.73 \times 10^{10}$ day $2.98 \times 10^{11}$ day	/mole ys	Overall, dimethomorph is not considered to be volatile and is not expected to have a long range transport in the atmosphere	USEPA EPISuite v4.11 (2000)	
Type of study	Compound	Paramete	meter Temp (°C) Isomer			K <sub>ow</sub> value		Log Kow	value	Comments	References		
		Octanol/water partition co	efficient	20	0	Е	430		2.63	3		1161499	
Bio- accumulation	DMF		20 Z			Z	543	2.73		3	Low potential for bioaccumulation		
	Bioconcentration factor						BCF = 50				2885745		

<sup>1</sup>Temp. = temperature; <sup>2</sup>OM = Organic Matter; <sup>3</sup>CEC = Cation Exchange Capacity; <sup>4</sup>Classification of McCall *et al.* 1981 for adsorption/desorption (PMRA 2024011); <sup>5</sup> Criteria of Cohen *et al.* 1984 for potential of leaching (PMRA 1918520); <sup>6</sup> GUS Score from Gustafson, 1989 (PMRA 1918524); NA = Not applicable; NR = Not reported; DME = Dimethomorph; DAT = Day after treatment; BCF = bioconcentration factor; **Bold values are used in the environmental risk assessment of DME.** 

### Appendix VII Toxicity

### Table 1 Summary of Terrestrial Toxicity Data Following Exposure to Dimethomorph Technical and Formulations

Compound-Code	Organism	Species	Toxicity type	No. of days	Endpoint	Symbols <sup>1</sup>	Value	PMRA#
Earthworms	-		-	-	-	-	-	
Dimethomorph technical	Earthworms	Eisenia foetida	Acute	14	LC <sub>50</sub>	=	3309.9 mg a.i./kg soil	2930949
Dimethomorph technical	Earthworms	Eisenia foetida	Acute	NR	LC <sub>50</sub>	>	500 mg a.i./kg soil	2930943
Dimethomorph formulation (Forum)	Earthworms	Eisenia foetida	Acute	NR	LC50	>	99.5 mg a.i./kg soil	2930943
Dimethomorph technical	Earthworms	Eisenia foetida	Reproduction (chronic)	56	NOEC	>	76.0 mg a.i./kg soil	1871649
Dimethomorph technical	Earthworms	Eisenia foetida	Reproduction (chronic)	NR	NOEC	=	60.0 mg a.i./kg soil	2930943
Dimethomorph formulation (Forum)	Earthworms	Eisenia foetida	Reproduction (chronic)	NR	NOEC	=	6.4 mg a.i./kg soil	2930943
Honey bees								
Dimethomorph technical	Honey bees	Apis mellifera	Acute contact	2	LD50	>	102.0 µg a.i./bee	2930943
Dimethomorph technical (50%)	Honey bees	Apis mellifera	Acute contact	NR	LD50	>	50.0 µg a.i./bee	2930942
Dimethomorph formulation (BAS 651 00 F; 20.2%)	Honey bees	Apis mellifera	Acute contact	NR	LD50	>	42.3 µg a.i./bee	2930942
Dimethomorph technical (50%)	Honey bees	Apis mellifera	Acute oral	NR	LD50	>	50.0 µg a.i./bee	2930942
Dimethomorph formulation (BAS 651 00 F; 20.2%)	Honey bees	Apis mellifera	Acute oral	2	LD50	>	117 μg a.i./bee	1871637
Dimethomorph formulation (BAS 651 00 F; 20.2%)	Honey bees	Apis mellifera	Acute oral	NR	LD50	>	49.6 µg a.i./bee	2930942
Dimethomorph formulation (BAS 550 01 F; 50%)	Honey bees	Apis mellifera	Acute larvae	3	LD <sub>50</sub> NOED	> =	118.9 µg a.i./bee/d 37.4 µg a.i./larvae/dev. per.	2885738
Dimethomorph formulation (BAS 550 01 F; 50%)	Honey bees	Apis mellifera	Chronic adult	10	1-d NOED 10-d NOED	>  >	<b>273.3 μg a.i./bee/d</b> 2733 μg a.i./bee	2885739
Parasitoids								
Dimethomorph technical	Parasitoid hymenopteran	Aphidius rhopalosiphi	Extended lab - mortality	NR	LR <sub>50</sub>	>	1800 g a.i./ha	2930943
Dimethomorph technical	Parasitoid hymenopteran	Aphidius rhopalosiphi	Extended lab - reproduction	NR	ER50	>	1800 g a.i./ha	2930943
Dimethomorph formulation (BAS 651 00 F, 20.2%))	Parasitoid hymenopteran	Aphidius rhopalosiphi	Acute	NR	LR <sub>50</sub>	>	716.8 g a.i/ha	2930942
Dimethomorph formulation (BAS 651 00 F, 20.2%))	Parasitoid hymenopteran	Aphidius rhopalosiphi	Acute	NR	LR50	>	548.8 g a.i./ha	2930942

Compound-Code	Organism	Species	Toxicity type	No. of days	Endpoint	Symbols <sup>1</sup>	Value	PMRA#
Predators	<u>.</u>	-	-	<u> </u>	-	<u>.</u>	·	
Dimethomorph technical	Predatory mite (nymph stage)	Phytoseiulus persimilis	Acute (floating leaf technique)	1	LR <sub>50</sub>	>	2000 g a.i./ha	2930940
Dimethomorph technical (50%)	Predatory mite (adult)	Phytoseiulus persimilis	Acute	NR	LR50	>	996.8 g a.i./ha	2930942
Dimethomorph formulation (CYA 15107)	Predatory mite (proto nymph)	Phytoseiulus persimilis	Acute	NR	LR50	>	115 g EUP/ha	2930943
Dimethomorph formulation (BAS 651 00 F, 20.2%))	Predatory mite (adult)	Typhlodromus pyri	Acute	NR	LR50	>	716.8 g a.i./ha	2930942
Dimethomorph formulation (CYA 15107)	Predatory mite (proto nymph	Typhlodromus pyri	Extended lab	NR	LR50	>	115 g EUP/ha	2930943
Dimethomorph technical	Predatory mite (proto nymph)	Typhlodromus pyri	Extended lab - mortality	NR	LR50	>	1800 g a.i./ha	2930943
Dimethomorph technical	Predatory mite (proto nymph)	Typhlodromus pyri	Extended lab - reproduction	NR	ER <sub>50</sub>	>	1800 g a.i./ha	2930943
Beneficial arthropods								
Dimethomorph formulation (BAS 651 00 F, 20.2%)	Green lacewing	Chrysoperla carnea	Acute	NR	LR <sub>50</sub>	>	728 g a.i./ha	2930942
Dimethomorph technical	Carabid beetles	Pterostichus melanarius	Field (pit trap)	10	LR50	>	180 g a.i./ha	2930940
Dimethomorph formulation (Acrobat MZ)	Carabid beetles	Pterostichus melanarius	Field (pit trap)	10	LR <sub>50</sub>	>	180 g a.i./ha	2930940
Dimethomorph technical	Carabid beetles	Harpalus rufipes	Field (pit trap)	10	LR <sub>50</sub>	>	180 g a.i./ha	2930940
Dimethomorph formulation (Acrobat MZ)	Carabid beetles	Harpalus rufipes	Field (pit trap)	10	LR <sub>50</sub>	>	180 g a.i./ha	2930940
Dimethomorph technical	Carabid beetles	Bembidion lampros	Field (pit trap)	10	LR <sub>50</sub>	>	180 g a.i./ha	2930940
Dimethomorph formulation (Acrobat MZ)	Carabid beetles	Bembidion lampros	Field (pit trap)	10	LR50	>	180 g a.i./ha	2930940
Dimethomorph technical	Carabid beetles	Trechus quadristratus	Field (pit trap)	10	LR <sub>50</sub>	>	180 g a.i./ha	2930940
Dimethomorph formulation (Acrobat MZ)	Carabid beetles	Trechus quadristratus	Field (pit trap)	10	LR50	>	180 g a.i./ha	2930940
Dimethomorph technical	Staphylinid beetles	Aleocharinae sp.	Field (pit trap)	10	LR50	>	180 g a.i./ha	2930940
Dimethomorph formulation (Acrobat MZ)	Staphylinid beetles	Aleocharinae sp.	Field (pit trap)	10	LR50	>	180 g a.i./ha	2930940
Dimethomorph technical	Staphylinid beetles	Oxytelianae sp.	Field (pit trap)	10	LR50	>	180 g a.i./ha	2930940
Dimethomorph formulation (Acrobat MZ)	Staphylinid beetles	Oxytelianae sp.	Field (pit trap)	10	LR <sub>50</sub>	>	180 g a.i./ha	2930940
Dimethomorph technical	Staphylinid	Tachyporinae sp	Field (pit trap)	10	LR50	>	180 g a.i./ha	2930940

Compound-Code	Organism	Species	Toxicity type	No. of days	Endpoint	Symbols <sup>1</sup>	Value	PMRA#
	beetles							
Dimethomorph formulation (Acrobat MZ)	Staphylinid beetles	Tachyporinae sp	Field (pit trap)	10	LR <sub>50</sub>	>	180 g a.i./ha	2930940
Dimethomorph technical	Linyphid spiders	NR	Field (pit trap)	10	LR <sub>50</sub>	>	180 g a.i./ha	2930940
Dimethomorph formulation (Acrobat MZ)	Linyphid spiders	NR	Field (pit trap)	10	LR50	>	180 g a.i./ha	2930940
Dimethomorph formulation (BAS 651 00 F, 20.2%)	Springtails	Folsomia candida	Chronic	NR	NOAEC	=	204.8 g a.i./ha	2930942
Wild Birds				<u> </u>				
Dimethomorph technical (96.6%)	Northern bobwhite quail	Colinus virginianus	Acute oral	14	LD <sub>50</sub>	>	2000 mg a.i./kg bw	2930940 2930942
Dimethomorph formulation (Forum 150 DC)	Northern bobwhite quail	Colinus virginianus	Acute oral	14	LD <sub>50</sub>	>	1243 mg a.i./kg bw (186 mg a.i./kg bw/d)	2930943
Dimethomorph formulation (BAS 650 00 F, 20.2%)	Northern bobwhite quail	Colinus virginianus	Acute oral	14	LD50	>	404 mg a.i./kg bw	2930942
Dimethomorph technical (96.6%)	Mallard duck	Anas platyrhynchus	Acute oral	14	LD <sub>50</sub>	>	2000 mg a.i./kg bw	2930940 2930942
Dimethomorph technical (99.7%)	Canary	Serinus canaria	Acute oral	NR	LD <sub>50</sub>	>	2000 mg a.i./kg bw	2930942
Dimethomorph technical	Northern bobwhite quail	Colinus virginianus	Dietary	14	LC50	>	5200 mg/kg diet (728.3 mg a.i./kg bw/d)	2930940, 2930943
Dimethomorph technical (96.6%)	Northern bobwhite quail	Colinus virginianus	Dietary	NR	LC <sub>50</sub>	>	5310 mg/kg diet	2930942
Dimethomorph technical	Mallard duck	Anas platyrhynchus	Dietary	14	LC50	>	5200 mg/kg diet (937.5 mg a.i./kg bw/d)	2930940, 2930943
Dimethomorph technical (96.6%)	Mallard duck	Anas platyrhynchus	Dietary	14	LC50	>	5310 mg/kg diet	2930942
Dimethomorph technical	Northern bobwhite quail	Colinus virginianus	Chronic, reproduction	NR	NOEL	=	58.4 mg a.i./kg bw/d	2930943
Dimethomorph technical (98.0%)	Northern bobwhite quail	Colinus virginianus	Chronic (adult female and hatchling body weight)	NR	NOAEC	=	200 mg a.i./kg diet	2930942
Dimethomorph technical	Mallard duck	Anas platyrhynchus	Chronic, reproduction	NR	NOEL	=	78.4 mg a.i./kg bw/d	2930943
Dimethomorph technical (98.0%)	Mallard duck	Anas platyrhynchus	Chronic, reproduction	NR	NOAEC	=	800 mg a.i./kg diet	2930942

Compound-Code	Organism	Species	Toxicity type	No. of days	Endpoint	Symbols <sup>1</sup>	Value	PMRA#
Wild Mammals	-							
Dimethomorph technical	Rat	Rattus norvegicus	Acute oral	NR	LD50	$\geq$	3500 mg a.i./kg bw/d	1256562
Dimethomorph technical	Rat	Rattus norvegicus	Dietary	NR	NOAEL	=	15 mg a.i./kg/d	2930942
Dimethomorph technical	Rat	Rattus norvegicus	Chronic, multi- generation, reproduction	NR	NOAEC	=	50 mg a.i./kg bw/d	1161458
Terrestrial Plants								
Dimethomorph technical	All species	N/A	Seedling emergence	NR	EC25	>	1100 g a.i./ha <sup>2</sup>	2930942
Dimethomorph formulation (BAS 651 00 F, 20.2%)	All species	N/A	Seedling emergence	NR	EC25	>	1098 g a.i./ha	2930942
Dimethomorph formulation (Acrobat MZ, 8.9%)	All species	N/A	Seedling emergence	NR	EC25	>	224 g a.i./ha	2930942
Dimethomorph technical	All species	N/A	Vegetative vigour	NR	EC25	>	1100 g a.i./ha	2930942
Dimethomorph formulation (BAS 651 00 F, 20.2%)	All species	N/A	Vegetative vigour	NR	EC <sub>25</sub>	>	1098 g a.i./ha	2930942
Dimethomorph formulation (Acrobat MZ, 8.9%)	All species	N/A	Vegetative vigour	NR	EC <sub>25</sub>	>	224 g a.i./ha	2930942

<sup>1</sup> Symbols are greater than, equal, less than. <sup>2</sup>Original value given in lbs a.i./acre × conversion factor of 1.12 = kg a.i./ha. (1 lb = 1120 g, 1 acre = .4047 ha); NR = not reported; NA = Not applicable; **dev. per.** = developmental period

### Table 2 Aquatic Toxicity Data Following Exposure to Dimethomorph Technical and Formulations

Compound-Code	Purity (%)	System/ medium	Organism	Species	Toxicity type	No. of days	Endpoint	Symbols <sup>1</sup>	Value (mg a.i./L)	PMRA#
Freshwater Organisms	-	-	-	-	-	-	-	-		
Freshwater Invertebrates Acute Exposure										
Dimethomorph technical	NR	Static	Water flea	Daphnia magna	Acute	2	EC50	=	20.0	2930940
Dimethomorph technical	NR	Static	Water flea	Daphnia magna	Acute	2	EC <sub>50</sub>	>	10.6	2930942 2930943
Dimethomorph/mancozeb formulation (Acrobat MZ)	8.9	Static	Water flea	Daphnia magna	Acute	2	EC50	=	0.41	2930940 2930942
Dimethomorph/mancozeb formulation (Acrobat MZ)	8.9	NR	Water flea	Daphnia magna	Acute	NR	EC50	=	0.14	2930942
Dimethomorph formulation (BAS 651 00 F)	20.2	NR	Water flea	Daphnia magna	Acute	NR	EC50	>	20.2	2930942 1871633

Compound-Code	Purity (%)	System/ medium	Organism	Species	Toxicity type	No. of days	Endpoint	Symbols <sup>1</sup>	Value (mg a.i./L)	PMRA#
Freshwater Invertebrates Chro	nic Exposure	e	-	-	-	-		-	-	
Dimethomorph technical	95.6	Semi-static	Water flea	Daphnia magna	Chronic	22	NOAEC	=	0.1	2930940 2930942
Dimethomorph technical	98.0	NR	Water flea	Daphnia magna	Chronic (growth length)	NR	NOAEC	=	0.11	2930942
Dimethomorph/mancozeb formulation 90/600)	NR	Semi-static	Water flea	Daphnia magna	Chronic	21	NOEC	=	0.056	2930940
Freshwater Fish Acute Exposu	re									
Dimethomorph technical	NR	Static, pH 7.3	Rainbow trout	Onchorhynchus mykiss	Acute	4	LC <sub>50</sub>	=	3.4	2930940, 2930943
Dimethomorph technical	94.8	NR	Rainbow trout	Onchorhynchus mykiss	Acute	4	LC50	=	6.2	2930942
Dimethomorph formulation (BAS 651 00 F)	20.2	Static, pH 7.5-8.5	Rainbow trout	Onchorhynchus mykiss	Acute	4	LC50	=	4.9	2930942 1871631
Dimethomorph formulation (Acrobat MZ)	8.9	Semi- static, pH 7.3	Rainbow trout	Onchorhynchus mykiss	Acute	4	LC <sub>50</sub>	=	0.061 0.68 mg/ EUP/L	2930942 2930940
Dimethomorph formulation (Acrobat MZ)	8.9	Semi- static, pH 8.6	Rainbow trout	Onchorhynchus mykiss	Acute	4	LC50	=	0.053 0.6 mg EUP/L	2930940
Dimethomorph formulation (Forum)	NR	Semi-static	Rainbow trout	Onchorhynchus mykiss	Acute	4	LC50	=	2.64 mg EUP/L (nominal)	2930940
Dimethomorph technical	NR	Static	Carp	Cyprinus carpio	Acute	4	LC <sub>50</sub>	=	14.0	2930940
Dimethomorph technical	94.8	NR	Carp	Cyprinus carpio	Acute	NR	LC50	=	18.7	2930942
Dimethomorph technical	NR	Static, pH 7.5	Bluegill	Lepomis macrichirus	Acute	4	LC50	=	25.0	2930940
Dimethomorph technical	98.3	NR	Bluegill	Lepomis macrichirus	Acute	NR	LC50	>	9.5	2930942
Dimethomorph technical	99.7	NR	Fathead minnow	Pimephales promelas	Acute	NR	LC50	>	8.4	2930942
Freshwater Fish Chronic Expos	sure									
Dimethomorph technical	95.6	Flow- through, pH 7.8	Rainbow trout	Onchorhynchus mykiss	Chronic (prolonged)	21	NOEC	=	0.48	2930940 2930942
Dimethomorph technical	NR	Flow- through	Rainbow trout	Onchorhynchus mykiss	Chronic ELS	60	NOEC	=	0.056	2930943
Dimethomorph technical	98.0	NR	Rainbow trout	Onchorhynchus mykiss	Growth	NR	NOAEC	<	0.341 <sup>2</sup>	2930943
Dimethomorph formulation (Acrobat MZ)	8.9	Flow- through, pH 7.2	Rainbow trout	Onchorhynchus mykiss	Chronic	14	NOAEC	=	0.0085	2930940 2930942
Dimethomorph formulation	NR	Flow-	Rainbow trout	Onchorhynchus mykiss	Chronic	28	NOEC	=	0.07 mg	2930943

Compound-Code	Purity (%)	System/ medium	Organism	Species	Toxicity type	No. of days	Endpoint	Symbols <sup>1</sup>	Value (mg a.i./L)	PMRA#	
(Forum)		through							EUP/L		
Dimethomorph technical	98.3	NR	Fathead minnow	Pimephales promelas	Embryo survival	NR	NOAEC	=	0.11	2930942	
Freshwater Algae Acute Exposu	re										
Dimethomorph technical (CME 151)	94.8	Static	Green algae	Scenedesmus subspicatus chodat	Acute	4	EC <sub>50</sub> NOEC	=	29.2 9.8	1161531, 2930940	
Dimethomorph formulation (Acrobat MZ 690)	NR	Static	Green algae	Scenedesmus subspicatus chodat	Acute	NR	EC <sub>50</sub>	=	25.3	1164004 2930944	
Dimethomorph technical	94.8	NR	Green algae	Pseudokirchneriella subcapitata	Acute	NR	EC <sub>50</sub> NOEC	=	23.8 16.3	2930942	
Dimethomorph technical (BAS 550 F)	98.3	Static	Green algae	Pseudokirchneriella subcapitata	Acute	3	EC50 NOEC	=	41.4 82.2	2885747 2930942	
Dimethomorph formulation (BAS 651 00 F)	20.2	Static	Green algae	Pseudokirchneriella subcapitata	Acute	3	EC50 NOEC	=	14.7 5.03	1871635 2930942 1871635	
Dimethomorph formulation (Acrobat MZ)	8.9	Static	Green algae	Pseudokirchneriella subcapitata	Acute	5	EC <sub>50</sub>	=	0.0098	2885751 2930942	
Dimethomorph formulation (Acrobat MZ)	8.9	Static	Blue green algae	Anabaena flos-aquae	Acute	5	EC50	=	0.0113	2885749 2930942	
Dimethomorph formulation (Acrobat MZ)	8.9	Static	Freshwater diatom	Navicula pelliculosa	Acute	NR	EC <sub>50</sub>	=	0.00125	2885750 2930942	
Freshwater Vascular Plant Acut	e Exposure										
Dimethomorph technical	50.5	NR	Duckweed	Lemna gibba	Acute	7	EC50 NOEC	=	22.04 3.07	2930942 1888446	
Dimethomorph formulation (Acrobat MZ)	8.9	NR	Duckweed	Lemna gibba	Acute	NR	EC50 NOEC	=	0.77 0.30	2930942 1888445	
Marine/Estuarine Invertebrates	Acute Expo	sure									
Dimethomorph technical	97.6	NR	Mysid (shrimp)	Mysidopsis bahia (Americamysis bahia)	Acute	NR	EC50	=	33.0	2930942	
Dimethomorph technical	NR	Flow- through	Mysid (shrimp)	Mysidopsis bahia (Americamysis bahia)	Acute	4	EC <sub>50</sub>	=	7.9	2930943	
Dimethomorph technical	98.0	NR	Eastern oyster	Crassostrea viginica	Acute	4	EC <sub>50</sub>	=	5.13	2930942	
Dimethomorph technical (AC 336379)	97.6	Flow- through	Eastern oyster	Crassostrea viginica	Acute	4	EC <sub>50</sub>	=	4.42	2885741 2930943	
Marine/Estuarine Invertebrates Chronic Exposure											
Dimethomorph technical (BAS 550 F)	97.5	Flow through	Mysid (shrimp)	Mysidopsis bahia (Americamysis bahia)	Chronic (repro.)	28	NOAEC	=	0.241	2885742 2930942	

Compound-Code	Purity (%)	System/ medium	Organism	Species	Toxicity type	No. of days	Endpoint	Symbols <sup>1</sup>	Value (mg a.i./L)	PMRA#
Marine/Estuarine Fish Acute Exposure										
Dimethomorph technical (AC 336379)	97.6	Flow through	Sheepshead minnow	Cyprinodon variegatus	Acute	4	LC <sub>50</sub>	=	11.3	2885744 2930942
Marine/Estuarine Fish Chronic	Exposure									
Dimethomorph technical (BAS 550 F)	97.5	Flow through	Sheepshead minnow	Cyprinodon variegatus	Chronic (ELS)	40/32	NOAEC	<	0.063	2885743 2930942

<sup>1</sup> Symbols are greater than, equal, less than. <sup>2</sup> A NOAEC could not be determined due to adverse effects in all treatment levels; NR = Not reported; bold and shaded values are to be use in the environmental risk assessment.

### Appendix VIII Estimated Environmental Concentration

## Table 1Crop and Maximum Application Rate of Canadian Registered Products<br/>Containing Dimethomorph Using a Soil DT50 of 115 Days

Сгор	Application Equipment	Timing <sup>1</sup>	No. of appl.	Droplet size	Max rate of applic. (g a.i./ha)	Time interval between application (day)	Soil EEC, 15 cm depth (mg a.i./kg soil)	Refined drift (%)	Refined Soil EEC, 15 cm depth for drift (mg a.i./kg soil)
Cucurbits	Groundboom	Post emergence	5	Medium	225	5	0.471	6	0.028
Cucurbits	Aerial	Post emergence	5	Medium	225	5	0.471	23	0.108
Grapes	Airblast	Post emergence	4	Fine	225	7	0.376	74	0.278

<sup>1</sup>Based on PMRA Appendix II, VUI Table (PMRA 2718691).

# Table 2The Estimated Environmental Concentration of Dimethomorph in Water (mg<br/>a.i./L) at 15 and 80 cm Depth as a Result of Direct Application From Uses on<br/>Various Crop scenarios and Using a DT50 of 41.6 Days

Сгор	Application Equipment	Timing <sup>1</sup>	No. of appl.	Droplet size	Max rate of applic. (g a.i./ha)	Time interval between application (day)	EEC in 15 cm depth (mg a.i./L)	EEC in 80 cm depth (mg a.i./L)
Cucurbits	Groundboom	Post emergence	5	Medium	225	5	0.639	0.120
Cucurbits	Aerial	Post emergence	5	Medium	225	5	0.639	0.120
Grapes	Airblast	Post emergence	4	Fine	225	7	0.508	0.095

# Table 3Refined Estimated Environmental Concentration of Dimethomorph in<br/>Freshwater and Marine/Estuarine water (mg a.i./L) at 15 and 80 cm Depth as a<br/>Result of Spray Drift From Different Technologies Used to Treat Crops

Сгор	Application Equipment	Droplet size	Max rate of applic. (g a.i./ha)	EEC in 15 cm water depth (mg a.i./L)	EEC in 80 cm water depth (mg a.i./L)	Refined drift (%)	Refined EEC in 15 cm depth (mg a.i./L)	Refined EEC in 80 cm depth (mg a.i./L)
Freshwater								
Cucurbits	Groundboom	Medium	958.99	0.639	0.120	6	0.038	0.007
Cucurbits	Aerial	Medium	958.99	0.639	0.120	23	0.147	0.028
Grapes	Airblast	Fine	762.01	0.508	0.095	74	0.376	0.070
Marine and	estuarine water		•					
Cucurbits	Groundboom	Medium	225	0.150	0.028	6	N/A	0.002
Cucurbits	Aerial	Medium	225	0.150	0.028	23	N/A	0.006
Grapes	Airblast	Fine	225	0.150	0.028	74	N/A	0.021

### Appendix IX Risk Assessment for Non-target Organisms

Formulation Type	Reported Endpoint	Endpoint value (mg a.i./kg soil)	Crop scenario	EEC (mg a.i./kg soil)	RQ	LOC exceeded
Dimethomorph					-	
Acute Toxicity						
Dimethomorph technical	<sup>1</sup> / <sub>2</sub> 14-d LC <sub>50</sub>	1655	Cucurbits (groundboom)	0.471	< 0.0003	No
Dimethomorph technical	<sup>1</sup> ∕2 14-d LC <sub>50</sub>	1655	Cucurbits (aerial)	0.471	< 0.0003	No
Dimethomorph technical	<sup>1</sup> ∕2 14-d LC <sub>50</sub>	1655	Grapes (airblast)	0.376	< 0.0002	No
Chronic toxicity						
Dimethomorph technical	NOEC	76	Cucurbits (groundboom)	0.471	< 0.006	No
Dimethomorph technical	NOEC	76	Cucurbits (aerial)	0.471	< 0.006	No
Dimethomorph technical	NOEC	76	Grapes (airblast)	0.376	< 0.005	No

Risk quotient (RQ) = EEC / endpoint. Shaded value indicate RQ > LOC.

#### Table 2 Screening Level Risk Assessment for Honey Bees

Measurement Endpoint	Compound	Exposure Route	Application rate (kg a.i./ha)	Exposure Estimate μg a.i./bee <sup>1</sup>	Endpoint (µg a.i./bee/d)	RQ	LOC (0.4) exceeded?
Foliar Applications							
Individual Survival (adults)	DME	Contact		0.540	LD50>102	< 0.005	No
Individual Survival (adults)	DME formulation	Dietary	0.00.5	6.525	LD50>117	< 0.056	No
Individual Survival (larvae)	DME formulation	Acute dietary	$0.225^2$	2.378	LD50 >118.9	< 0.02	No
Individual Survival (adults)	DME formulation	Chronic dietary		5.466	NOED ≥ 273.3	< 0.02	No
Soil Applications							
Individual Survival (adults)	DME formulation	Dietary		N/A	LD50>117	< 0.01	No
Individual Survival (larvae)	DME formulation	Acute dietary	1.11 <sup>3</sup>	N/A	LD50 >118.9	< 0.01	No
Individual Survival (adults)	DME formulation	Chronic dietary		N/A	NOED ≥ 273.3	< 0.01	No

<sup>1</sup>For foliar contact exposure, the exposure estimate =  $(2.4 \ \mu g \ a.i./bee)$ \*(application rate in kg a.i./ha); For foliar dietary exposure, the exposure estimate =  $(29 \ \mu g \ a.i./bee)$ \*(application rate in kg a.i./ha). This is based on 98  $\mu g \ a.i./g \ per 1 \ kg \ a.i./ha \times 0.292 \ g/day$  (28.6  $\mu g \ a.i./bee \ per \ kg \ a.i./ha$ ); <sup>2</sup> Based on single maximum application rate; <sup>3</sup> Soil EEC value based on 5 applications of 225 g a.i./ha at 5-day interval between applications; N/A = not applicable.

Organism	Exposure Route	Single Maximum Rate of Application (g a.i./ha)	Endpoint type	Value (g a.i./ha)	RQ	LOC (2.0) exceeded?
Foliar Application	-	-		-		
Parasitoid						
	Extended lab	225 (cucurbits – groundboom)	Acute, LR50	> 1800.0	< 0.13	No
Aphidius rhopalosiphi	Extended lab	225 (cucurbits – aerial)	Acute, LR50	> 1800.0	< 0.13	No
	Extended lab	225 (grapes)	Acute, LR50	> 1800.0	< 0.13	No
Predator			-			
Typhlodromus pyri	Extended lab	225 (cucurbits – groundboom)	Acute, LR50	> 1800.0	< 0.13	No
Typniouromus pyri	Extended lab	225 (cucurbits – aerial)	Acute, LR50	> 1800.0	< 0.13	No
	Extended lab	225 (grapes)	Acute, LR <sub>50</sub>	> 1800.0	< 0.13	No
Beneficials						
Pterostichus	Field (pit trap)	225 (cucurbits - groundboom)	Acute, LR <sub>50</sub>	> 180.0	1.25	No
Pterosticnus melanarius	Field (pit trap)	225 (cucurbits – aerial)	Acute, LR50	> 180.0	1.25	No
meianarias	Field (pit trap)	225 (grapes)	Acute, LR <sub>50</sub>	> 180.0	1.25	No
	NR	225 (cucurbits – groundboom)	Chronic, NOAEC	204.8 <sup>1</sup>	1.10	No
Folsomia candida	NR	225 (cucurbits – aerial)	Chronic, NOAEC	204.81	1.10	No
	NR	225 (grapes)	Chronic, NOAEC	204.81	1.10	No

## Table 3Screening Level Risk Assessment for Predators and Parasitoids Exposed to<br/>Dimethomorph Technical

<sup>1</sup> This value was obtained with dimethomorph formulation (BAS 651 00 F, 20.2%).

# Table 3Screening Level Risk Assessment for Dimethomorph Technical to Wild Birds in<br/>Cucurbit-Groundboom and Cucurbit-Aerial Production Scenarios Using<br/>Maximum Nomogram Values

Animal size and endpoint type	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE <sup>1</sup> (mg a.i./kg bw)	RQ	LOC exceeded?
Small Bird (0.02 kg)					
Acute	18.60	Insectivore	57.63	3.10	Yes
Reproduction	58.40	Insectivore	57.63	0.99	No
Medium Sized Bird (0.1 kg)					
Acute	18.60	Insectivore	44.97	2.42	Yes
Reproduction	58.40	Insectivore	44.97	0.77	No
Large Sized Bird (1 kg)		-			
Acute	18.60	Herbivore (short grass)	29.05	1.56	Yes
Reproduction	58.40	Herbivore (short grass)	29.05	0.50	No

<sup>1</sup> EDE = Estimated Daily Exposure. Bold and shaded values are above LOC.

# Table 5Screening Level Risk Assessment for Dimethomorph to Wild Birds in Cucurbits-<br/>Groundboom Scenario Using On-Field and Off-Field Maximum and Mean<br/>Nomogram Values

	Toxici		Maximu	m nom	ogram residu	es	Mean	nomog	gram residue	es
Bird sizes	ty		On-fiel	dl	Off Fiel	d	On-field	d	Off Fi	eld
and endpoint type	(mg a.i./ kg bw/d)	Food guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird	(0.02 kg)	-	-	-		-		-	-	
Acute	18.60	Insectivore	57.63	3.1	3.46	0.2	39.79	2.1	2.39	0.13
	18.60	Granivore (grain and seeds)	8.92	0.5	0.54	0.0	4.25	0.2	0.26	0.01
	18.60	Frugivore (fruit)	17.84	1.0	1.07	0.1	8.51	0.5	0.51	0.03
Dietary	72.83	Insectivore	57.63	0.8	3.46	0.0	39.79	0.6	2.39	0.03
	72.83	Granivore (grain and seeds)	8.92	0.1	0.54	0.0	4.25	0.1	0.26	0.00
	72.83	Frugivore (fruit)	17.84	0.2	1.07	0.0	8.51	0.1	0.51	0.01
Reproducti on	58.40	Insectivore	57.63	1.0	3.46	0.1	39.79	0.7	2.39	0.04
	58.40	Granivore (grain and seeds)	8.92	0.2	0.54	0.0	4.25	0.1	0.26	0.00
	58.40	Frugivore (fruit)	17.84	0.3	1.07	0.0	8.51	0.2	0.51	0.01
Medium Siz	ed Bird (	0.1 kg)								
Acute	18.60	Insectivore	44.97	2.4	2.70	0.1	31.05	1.7	1.86	0.10
	18.60	Granivore (grain and seeds)	6.96	0.4	0.42	0.0	3.32	0.2	0.20	0.01
	18.60	Frugivore (fruit)	13.92	0.7	0.84	0.0	6.64	0.4	0.40	0.02
Dietary	72.83	Insectivore	44.97	0.6	2.70	0.0	31.05	0.4	1.86	0.03
	72.83	Granivore (grain and seeds)	6.96	0.1	0.42	0.0	3.32	0.1	0.20	0.00
	72.83	Frugivore (fruit)	13.92	0.2	0.84	0.0	6.64	0.1	0.40	0.01
Reproducti on	58.40	Insectivore	44.97	0.8	2.70	0.0	31.05	0.5	1.86	0.03
	58.40	Granivore (grain and seeds)	6.96	0.1	0.42	0.0	3.32	0.1	0.20	0.00
	58.40	Frugivore (fruit)	13.92	0.2	0.84	0.0	6.64	0.1	0.40	0.01
Large Sized		0.	1	1				[	1	
Acute	18.60	Insectivore	13.13	0.7	0.79	0.0	9.07	0.5	0.54	0.03
	18.60	Granivore (grain and seeds)	2.03	0.1	0.12	0.0	9.07	0.5	0.06	0.00
	18.60	Frugivore (fruit)	4.06	0.2	0.24	0.0	1.94	0.1	0.12	0.01
	18.60	Herbivore (short grass)	29.05	1.6	1.74	0.1	10.32	0.6	0.62	0.03
	18.60	Herbivore (long grass)	17.74	1.0	1.06	0.1	5.79	0.3	0.35	0.02
	18.60	Herbivore (Broadleaf plants)	26.88	1.4	1.61	0.1	8.89	0.5	0.53	0.03
Dietary	72.83	Insectivore	13.13	0.2	0.79	0.0	9.07	0.1	0.54	0.01
	72.83	Granivore (grain and seeds)	2.03	0.0	0.12	0.0	9.07	0.1	0.06	0.00
	72.83	Frugivore (fruit)	4.06	0.1	0.24	0.0	1.94	0.0	0.12	0.00
	72.83	Herbivore (short grass)	29.05	0.4	1.74	0.0	10.32	0.1	0.62	0.01
	72.83	Herbivore (long grass)	17.74	0.2	1.06	0.0	5.79	0.1	0.35	0.00

	Toxici		Maximu	m nom	ogram residu	es	Mean	nomog	ram residue	s
Bird sizes	ty		On-field	ł	Off Fiel	d	On-fiel	d	Off Fi	eld
and endpoint type	(mg a.i./ kg bw/d)	Food guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
	72.83	Herbivore (Broadleaf plants)	26.88	0.4	1.61	0.0	8.89	0.1	0.53	0.01
Reproducti on	58.40	Insectivore	13.13	0.2	0.79	0.0	9.07	0.2	0.54	0.01
	58.40	Granivore (grain and seeds)	2.03	0.0	0.12	0.0	9.07	0.2	0.06	0.00
	58.40	Frugivore (fruit)	4.06	0.1	0.24	0.0	1.94	0.0	0.12	0.00
	58.40	Herbivore (short grass)	29.05	0.5	1.74	0.0	10.32	0.2	0.62	0.01
	58.40	Herbivore (long grass)	17.74	0.3	1.06	0.0	5.79	0.1	0.35	0.01
	58.40	Herbivore (Broadleaf plants)	26.88	0.5	1.61	0.0	8.89	0.2	0.53	0.01

Bold and shaded values are above the LOC

## Table 6Screening Level Risk Assessment for Dimethomorph Technical to Wild Birds in<br/>Grape-Airblast Production Scenarios Using Maximum Nomogram Values

Animal size and endpoint type	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE <sup>1</sup> (mg a.i./kg bw)	RQ	LOC exceeded?
Small Bird (0.02 kg)					
Acute	18.60	Insectivore	45.59	2.45	Yes
Reproduction	58.40	Insectivore	45.59	0.78	No
Medium Sized Bird (0.1 kg)					
Acute	18.60	Insectivore	35.58	1.91	Yes
Reproduction	58.40	Insectivore	35.58	0.61	No
Large Sized Bird (1 kg)					
Acute	18.60	Herbivore (short grass)	22.98	1.24	Yes
Reproduction	58.40	Herbivore (short grass)	22.98	0.39	No

 $^{1}$ EDE = Estimated Daily Exposure. Bold and shaded values are above LOC.

# Table 7Screening Level Risk Assessment for Dimethomorph to Wild Birds in Grapes-<br/>airblast Scenario Using On-Field and Off-Field Maximum and Mean Nomogram<br/>Values

			Ma		nomograi dues	n	M	Mean nomogram residues			
	Toriater		On-fi	ield	Off Fi	eld	On-fi	eld	Off Fi	ield	
Bird sizes and endpoint type	Toxicity (mg a.i./ kg bw/d)	Food guild (food item)	EDE (mg a.i./kg bw)	ЪД	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./k g bw)	QA	EDE (mg a.i./k g bw)	RQ	
Small Bird (0.02 kg)		-	-				-			-	
Acute	18.60	Insectivore	45.59	2.5	33.73	1.8	31.48	1.7	23.29	1.3	
Acute	18.60	Granivore (grain and seeds)	7.06	0.4	5.22	0.3	3.36	0.2	2.49	0.1	
	18.60	Frugivore (fruit)	14.11	0.8	10.44	0.6	6.73	0.4	4.98	0.3	
Dietary	72.83	Insectivore	45.59	0.6	33.73	0.5	31.48	0.4	23.29	0.3	
	72.83	Granivore (grain and	7.06	0.1	5.22	0.1	3.36	0.0	2.49	0.0	

			Max	ximum resio	nomogran lues	n	M	ean no resio	mogran dues	1
			On-fi	eld	Off Fi	eld	On-fi	ield	Off F	ield
Bird sizes and endpoint type	Toxicity (mg a.i./ kg bw/d)	Food guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./k g bw)	RQ	EDE (mg a.i./k g bw)	RQ
		seeds)								
	72.83	Frugivore (fruit)	14.11	0.2	10.44	0.1	6.73	0.1	4.98	0.1
Reproduction	58.40	Insectivore	45.59	0.8	33.73	0.6	31.48	0.5	23.29	0.4
Reproduction	58.40	Granivore (grain and seeds)	7.06	0.1	5.22	0.1	3.36	0.1	2.49	0.0
	58.40	Frugivore (fruit)	14.11	0.2	10.44	0.2	6.73	0.1	4.98	0.1
Medium Sized Bird	(0.1 kg)						-		-	
Acute	18.60	Insectivore	35.58	1.9	26.33	1.4	24.56	1.3	18.18	1.0
Acute	18.60	Granivore (grain and seeds)	5.51	0.3	4.07	0.2	2.63	0.1	1.94	0.1
	18.60	Frugivore (fruit)	11.01	0.6	8.15	0.4	5.25	0.3	3.89	0.2
Dietary	72.83	Insectivore	35.58	0.5	26.33	0.4	24.56	0.3	18.18	0.2
Dictary	72.83	Granivore (grain and seeds)	5.51	0.1	4.07	0.1	2.63	0.0	1.94	0.0
	72.83	Frugivore (fruit)	11.01	0.2	8.15	0.1	5.25	0.1	3.89	0.1
Reproduction	58.40	Insectivore	35.58	0.6	26.33	0.5	24.56	0.4	18.18	0.3
Reproduction	58.40	Granivore (grain and seeds)	5.51	0.1	4.07	0.1	2.63	0.0	1.94	0.0
	58.40	Frugivore (fruit)	11.01	0.2	8.15	0.1	5.25	0.1	3.89	0.1
Large Sized Bird (1	kg)	1							1	
	18.60	Insectivore	10.39	0.6	7.69	0.4	7.17	0.4	5.31	0.3
Acute	18.60	Granivore (grain and seeds)	1.61	0.1	1.19	0.1	7.17	0.4	0.57	0.0
	18.60	Frugivore (fruit)	3.21	0.2	2.38	0.1	1.53	0.1	1.13	0.1
	18.60	Herbivore (short grass)	22.98	1.2	17.00	0.9	8.16	0.4	6.04	0.3
	18.60	Herbivore (long grass)	14.03	0.8	10.38	0.6	4.58	0.2	3.39	0.2
	18.60	Herbivore (Broadleaf plants)	21.26	1.1	15.73	0.8	7.03	0.4	5.20	0.3
	72.83	Insectivore	10.39	0.1	7.69	0.1	7.17	0.1	5.31	0.1
Dietary	72.83	Granivore (grain and seeds)	1.61	0.0	1.19	0.0	7.17	0.1	0.57	0.0
	72.83	Frugivore (fruit)	3.21	0.0	2.38	0.0	1.53	0.0	1.13	0.0
	72.83	Herbivore (short grass)	22.98	0.3	17.00	0.2	8.16	0.1	6.04	0.1
	72.83	Herbivore (long grass)	14.03	0.2	10.38	0.1	4.58	0.1	3.39	0.0
	72.83	Herbivore (Broadleaf plants)	21.26	0.3	15.73	0.2	7.03	0.1	5.20	0.1
	58.40	Insectivore	10.39	0.2	7.69	0.1	7.17	0.1	5.31	0.1
Reproduction	58.40	Granivore (grain and seeds)	1.61	0.0	1.19	0.0	7.17	0.1	0.57	0.0
	58.40	Frugivore (fruit)	3.21	0.1	2.38	0.0	1.53	0.0	1.13	0.0
	58.40	Herbivore (short grass)	22.98	0.4	17.00	0.3	8.16	0.1	6.04	0.1
	58.40	Herbivore (long grass)	14.03	0.2	10.38	0.2	4.58	0.1	3.39	0.1
	58.40 are above the LC	Herbivore (Broadleaf plants)	21.26	0.4	15.73	0.3	7.03	0.1	5.20	0.1

# Table 8Screening Level Risk Assessment for Dimethomorph Technical to Wild Mammals<br/>in Cucurbit-Groundboom and Cucurbit-Aerial Production Scenarios Using<br/>Maximum Nomogram Values

Animal size and endpoint type	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE <sup>1</sup> (mg a.i./kg bw)	RQ	LOC exceeded?
Small Mammal (0.015 kg)					
Acute	350.00	Insectivore	33.15	0.09	No
Reproduction	50.00	Insectivore	33.15	0.66	No
Medium Sized Mammal (0.035 kg	g)		Insectivore		
Acute	350.00	Herbivore (short grass)	64.29	0.18	No
Reproduction	50.00	Herbivore (short grass)	64.29	1.29	Yes
Large Sized Mammal (1 kg)					
Acute	350.00	Herbivore (short grass)	34.35	0.10	No
Reproduction	50.00	Herbivore (short grass)	34.35	0.69	No

 $^{1}$ EDE = Estimated Daily Exposure. Bold and shaded values are above LOC.

Table 9Screening Level Risk Assessment for Dimethomorph to Wild Mammals in<br/>Cucurbits-Groundboom Scenario Using On-Field and Off-Field Maximum and<br/>Mean Nomogram Values

			Maxim	ım nomoş	gram resid	lues	Mean	n nomog	ogram residues			
Mammal	Toxicity	Food Guild	On-fi	eld	Off Fi	eld	On-fie	eld	Off Fi	eld		
sizes and endpoint type	(mg a.i./ kg bw/d)	food Guild (food item)	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ		
Small Mamma	l (0.015 kg)											
	350.00	Insectivore	33.15	0.1	1.99	0.01	22.89	0.1	1.37	0.0		
Acute	350.00	Granivore (grain and seeds)	5.13	0.0	0.31	0.00	2.45	0.0	0.15	0.0		
	350.00	Frugivore (fruit)	10.26	0.0	0.62	0.00	4.89	0.0	0.29	0.0		
	50.00	Insectivore	33.15	0.7	1.99	0.04	22.89	0.5	1.37	0.0		
Reproduction	50.00	Granivore (grain and seeds)	5.13	0.1	0.31	0.01	2.45	0.0	0.15	0.0		
	50.00	Frugivore (fruit)	10.26	0.2	0.62	0.01	4.89	0.1	0.29	0.0		
Medium Sized	Mammal (0.	035 kg)										
	350.00	Insectivore	29.06	0.1	1.74	0.00	20.06	0.1	1.20	0.0		
	350.00	Granivore (grain and seeds)	4.50	0.0	0.27	0.00	2.14	0.0	0.13	0.0		
	350.00	Frugivore (fruit)	8.99	0.0	0.54	0.00	4.29	0.0	0.26	0.0		
Acute	350.00	Herbivore (short grass)	64.29	0.2	3.86	0.01	22.83	0.1	1.37	0.0		
	350.00	Herbivore (long grass)	39.25	0.1	2.36	0.01	12.82	0.0	0.77	0.0		
	350.00	Herbivore (forage crops)	59.48	0.2	3.57	0.01	19.66	0.1	1.18	0.0		
	50.00	Insectivore	29.06	0.6	1.74	0.03	20.06	0.4	1.20	0.0		
Reproduction	50.00	Granivore (grain and seeds)	4.50	0.1	0.27	0.01	2.14	0.0	0.13	0.0		
Reproduction	50.00	Frugivore (fruit)	8.99	0.2	0.54	0.01	4.29	0.1	0.26	0.0		
	50.00	Herbivore (short grass)	64.29	1.3	3.86	0.08	22.83	0.5	1.37	0.0		

			Maxim	ım nomoş	gram resid	lues	Mean	nomog	gram residu	ies
Mammal sizes and	Toxicity	Food Guild	On-fi	eld	Off Fi	eld	On-fie	ld	Off Fi	eld
endpoint type	(mg a.i./ kg bw/d)	(food item)	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ
	50.00	Herbivore (long grass)	39.25	0.8	2.36	0.05	12.82	0.3	0.77	0.0
	50.00	Herbivore (Broadleaf plants)	59.48	1.2	3.57	0.07	19.66	0.4	1.18	0.0
Large Sized M	ammal (1 kg	)								
	350.00	Insectivore	15.53	0.0	0.93	0.00	10.72	0.0	0.64	0.0
	350.00	Granivore (grain and seeds)	2.40	0.0	0.14	0.00	1.15	0.0	0.07	0.0
	350.00	Frugivore (fruit)	4.81	0.0	0.29	0.00	2.29	0.0	0.14	0.0
Acute	350.00	Herbivore (short grass)	34.35	0.1	2.06	0.01	12.20	0.0	0.73	0.0
	350.00	Herbivore (long grass)	20.97	0.1	1.26	0.00	6.85	0.0	0.41	0.0
	350.00	Herbivore (Broadleaf plants)	31.78	0.1	1.91	0.01	10.51	0.0	0.63	0.0
	50.00	Insectivore	15.53	0.3	0.93	0.02	10.72	0.2	0.64	0.0
	50.00	Granivore (grain and seeds)	2.40	0.0	0.14	0.00	1.15	0.0	0.07	0.0
	50.00	Frugivore (fruit)	4.81	0.1	0.29	0.01	2.29	0.0	0.14	0.0
Reproduction	50.00	Herbivore (short grass)	34.35	0.7	2.06	0.04	12.20	0.2	0.73	0.0
	50.00	Herbivore (long grass)	20.97	0.4	1.26	0.03	6.85	0.1	0.41	0.0
	50.00	Herbivore (Broadleaf plants)	31.78	0.6	1.91	0.04	10.51	0.2	0.63	0.0

Bold and shaded values are above the LOC

#### Table 10 Screening Level Risk Assessment for Dimethomorph Technical to Wild Mammals in Grape-Airblast Production Scenarios Using Maximum Nomogram Values

Animal size and endpoint type	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE <sup>1</sup> (mg a.i./kg bw)	RQ	LOC exceeded?
Small Mammal (0.015 kg)					
Acute	350.00	Insectivore	26.22	0.07	No
Reproduction	50.00	Insectivore	26.22	0.52	No
Medium Sized Mammal (0.	035 kg)				
Acute	350.00	Herbivore (short grass)	50.85	0.15	No
Reproduction	50.00	Herbivore (short grass)	50.85	1.02	Yes
Large Sized Mammal (1 kg	)				
Acute	350.00	Herbivore (short grass)	27.17	0.08	No
Reproduction	50.00	Herbivore (short grass)	27.17	0.54	No

<sup>1</sup> EDE = Estimated Daily Exposure. Bold and shaded values are above LOC.

# Table 11 Screening Level Risk Assessment for Dimethomorph to Wild Mammals in<br/>Grapes-airblast Scenario Using On-Field and Off-Field Maximum and Mean<br/>Nomogram Values

	Toxicity (mg a.i. /kg bw/d)	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
Mammal sizes and endpoint type			On-field		Off Field		On-field		Off Field	
			EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ
Small Mamma	l (0.015 kg)	-		-	-	-	-	-		
Acute	350.00	Insectivore	26.22	0.1	19.40	0.1	18.10	0.1	13.40	0.0
	350.00	Granivore (grain and seeds)	4.06	0.0	3.00	0.0	1.94	0.0	1.43	0.0
	350.00	Frugivore (fruit)	8.12	0.0	6.01	0.0	3.87	0.0	2.86	0.0
	50.00	Insectivore	26.22	0.5	19.40	0.4	18.10	0.4	13.40	0.3
Reproduction	50.00	Granivore (grain and seeds)	4.06	0.1	3.00	0.1	1.94	0.0	1.43	0.0
	50.00	Frugivore (fruit)	8.12	0.2	6.01	0.1	3.87	0.1	2.86	0.1
Medium Sized Mammal (0.035 kg)										
	350.00	Insectivore	22.98	0.1	17.01	0.0	15.87	0.0	11.74	0.0
	350.00	Granivore (grain and seeds)	3.56	0.0	2.63	0.0	1.70	0.0	1.26	0.0
	350.00	Frugivore (fruit)	7.11	0.0	5.26	0.0	3.39	0.0	2.51	0.0
Acute	350.00	Herbivore (short grass)	50.85	0.1	37.63	0.1	18.06	0.1	13.36	0.0
	350.00	Herbivore (long grass)	31.05	0.1	22.98	0.1	10.14	0.0	7.50	0.0
	350.00	Herbivore (forage crops)	47.05	0.1	34.82	0.1	15.55	0.0	11.51	0.0
	50.00	Insectivore	22.98	0.5	17.01	0.3	15.87	0.3	11.74	0.2
	50.00	Granivore (grain and seeds)	3.56	0.1	2.63	0.1	1.70	0.0	1.26	0.0
	50.00	Frugivore (fruit)	7.11	0.1	5.26	0.1	3.39	0.1	2.51	0.1
Reproduction	50.00	Herbivore (short grass)	50.85	1.0	37.63	0.8	18.06	0.4	13.36	0.3
	50.00	Herbivore (long grass)	31.05	0.6	22.98	0.5	10.14	0.2	7.50	0.2
	50.00	Herbivore (Broadleaf plants)	47.05	0.9	34.82	0.7	15.55	0.3	11.51	0.2
Large Sized Mammal (1 kg)										
Acute	350.00	Insectivore	12.28	0.0	9.09	0.0	8.48	0.0	6.28	0.0
	350.00	Granivore (grain and seeds)	1.90	0.0	1.41	0.0	0.91	0.0	0.67	0.0
	350.00	Frugivore (fruit)	3.80	0.0	2.81	0.0	1.81	0.0	1.34	0.0
	350.00	Herbivore (short grass)	27.17	0.1	20.11	0.1	9.65	0.0	7.14	0.0
	350.00	Herbivore (long grass)	16.59	0.0	12.28	0.0	5.42	0.0	4.01	0.0
	350.00	Herbivore (Broadleaf plants)	25.14	0.1	18.60	0.1	8.31	0.0	6.15	0.0
Damas de ci	50.00	Insectivore	12.28	0.2	9.09	0.2	8.48	0.2	6.28	0.1
Reproduction	50.00	Granivore (grain and seeds)	1.90	0.0	1.41	0.0	0.91	0.0	0.67	0.0

Mammal sizes and endpoint type	Toxicity (mg a.i. /kg bw/d)	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
			EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ
	50.00	Frugivore (fruit)	3.80	0.1	2.81	0.1	1.81	0.0	1.34	0.0
	50.00	Herbivore (short grass)	27.17	0.5	20.11	0.4	9.65	0.2	7.14	0.1
	50.00	Herbivore (long grass)	16.59	0.3	12.28	0.2	5.42	0.1	4.01	0.1
	50.00	Herbivore (Broadleaf plants)	25.14	0.5	18.60	0.4	8.31	0.2	6.15	0.1

Bold and shaded values are above the LOC

# Table 12 Risk Assessment (on-field and off-field) and Risk Quotients for Terrestrial<br/>Vascular Plants (Seedling Emergence and Vegetative Vigour) at the Maximum<br/>Rate of Application for Dimethomorph in Three Crop Scenarios

Organism Exposure		Species	Endpoint value (g a.i./ha)	Site	EEC	RQ <sup>1</sup>	Exceed LOC?			
Non-Target Terrestrial										
Cucurbit-groundboom scenario										
	Seedling emergence	All species	EC <sub>25</sub> = 1100	On-field	0.49 g a.i./ha	0.0004	No			
Terrestrial Vascular				Off-field <sup>2</sup>	0.03 g a.i./ha	0.00003	No			
plants	Vegetative vigour	All species	EC <sub>25</sub> = 1100	On-field	708.0 g a.i./ha	0.64	No			
				Off-field <sup>2</sup>	42.4 g a.i./ha	0.04	No			
Cucurbit-aerial scenario										
	Seedling emergence	All species	EC <sub>25</sub> = 1100	On-field	0.49 g a.i./ha	0.0004	No			
Terrestrial Vascular				Off-field <sup>2</sup>	0.11 g a.i./ha	0.0001	No			
plants	Vegetative vigour	All species	EC <sub>25</sub> = 1100	On-field	708.0 g a.i./ha	0.64	No			
				Off-field <sup>2</sup>	162.8 g a.i./ha	0.15	No			
Grape-airblast scenario										
	Seedling emergence	All species	$EC_{25} = 1100$	On-field	0.40 g a.i./ha	0.0004	No			
Terrestrial Vascular				Off-field <sup>2</sup>	0.29 g a.i./ha	0.0003	No			
plants	Vegetative vigour	All species	EC <sub>25</sub> = 1100	On-field	560.1 g a.i./ha	0.51	No			
				Off-field <sup>2</sup>	414.4 g a.i./ha	0.38	No			

<sup>1</sup> Shaded cells and **bold values** indicate that the level of concern is exceeded (RQ > 1); <sup>2</sup> Off –field = groundboom technology and 6% drift); <sup>3</sup> soil depth of 3 cm for seedling emergence.

### Table 13 Screening Level Risk Assessment of Dimethomorph to Freshwater InvertebratesFollowing Application in the Three Crop Scenarios but using DT50 of 41.6 Days

Organism	Species	Exposure	Endpoint	Endpoint value (mg a.i./L)	Spray rate (g a.i./ha)	Depth (cm)	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?
Cucurbit-gr	oundboom	and aerial so	enario						
Water flea	Daphnia magna	Acute	1/2 EC50	10	959	80	0.120	0.01	No
water nea	Daphnia magna	Chronic	NOAEC	0.1	959	80	0.120	1.2	Yes
Grape-airbl	ast scenario	D							
Water flea	Daphnia magna	Acute	1/2 EC50	10	762	80	0.095	0.01	No
water nea	Daphnia magna	Chronic	NOAEC	0.1	762	80	0.095	0.95	No

<sup>1</sup>Single species freshwater invertebrate toxicity endpoints used in the acute exposure risk assessment are derived by dividing the  $EC_{50}$ ,  $LC_{50}$  from the appropriate laboratory study by a factor of two (2). Bold and Shaded values indicate that the screening level RQ exceeds the LOC of 1.0.

### Table 14 Screening Level Risk Assessment of Dimethomorph to Freshwater Fish and<br/>Amphibians Following Application in the Three Crop Scenarios

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?
Cucurbit-grou	indboom and aerial s	scenario				-		-	-
Amphibian (surrogate)	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	959	15	0.639	1.88	Yes
Rainbow trout	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	959	80	0.120	0.35	No
Rainbow trout	Onchorhynchus mykiss	Chronic	NOAEC	0.056	959	80	0.120	2.14	Yes
Grape-airblas	t scenario								
Amphibian (surrogate)	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	762	15	0.508	1.49	Yes
Rainbow trout	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	762	80	0.095	0.28	No
Rainbow trout	Onchorhynchus mykiss	Chronic	NOAEC	0.056	762	80	0.095	1.70	Yes

<sup>1</sup>Single species freshwater fish toxicity endpoints used in the acute exposure risk assessment are derived by dividing the  $LC_{50}$  from the appropriate laboratory study by a factor of ten (10). Amphibian risk assessment is based on the surrogate rainbow trout endpoint in 15 cm water depth; bold and shaded values are above the LOC

## Table 15Screening Level Risk Assessment of Dimethomorph to Marine/Estuarine Fish<br/>Following Application in the Three Crop Scenarios.

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?
Marine/estua	arine Fish Acut	e Exposure	_	-	-	-		-	
Cucurbit-gro	oundboom and	aerial scenar	rios						
Sheepshead minnow	Cyprinodon variegatus	Acute	1/10 LC <sub>50</sub>	5.65	959	80	0.120	0.02	No
Grape-airbla	st scenarios								
Sheepshead minnow	Cyprinodon variegatus	Acute	1/10 LC50	5.65	762	80	0.095	0.02	No

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?			
Marine/Estu	arine Fish Chr	onic Exposur	·e	-	-	-			-			
Cucurbit-gro	Cucurbit-groundboom and aerial scenarios											
Sheepshead minnow	Cyprinodon variegatus	Chronic	NOEC	0.063	959	80	0.120	1.9	Yes			
Grape-airbla	ast scenarios											
Sheepshead minnow	Cyprinodon variegatus	Chronic	NOEC	0.063	762	80	0.095	1.5	Yes			

Shaded cells indicate that the screening level RQ exceeds the LOC of 1.0.

### Table 16 Screening Level Risk Assessment of Dimethomorph to Freshwater Algae and Plants Following Application in the Three Crop Scenarios

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?	
Freshwater al	gae									
Cucurbit-groundboom and aerial scenarios										
Green algae	Pseudokirchneriella subcapitata	Acute	1/2 EC <sub>50</sub>	11.9	959	80	0.120	0.01	No	
Grape-airblas	t scenarios									
Green algae	Pseudokirchneriella subcapitata	Acute	1/2 EC <sub>50</sub>	11.9	762	80	0.095	0.008	No	
Freshwater va	scular plants									
Cucurbit-grou	indboom and aerial s	cenarios								
Duckweed	Lemna gibba	Acute	1/2 EC50	11.02	959	80	0.120	0.011	No	
Grape-airblas	t scenarios									
Duckweed	Lemna gibba	Acute	$1/2 EC_{50}$	11.02	762	80	0.095	0.009	No	
<sup>1</sup> Single species f	reshwater algae and plant	toxicity endr	points used in	the acute exp	osure risk ass	essment a	re derived by div	iding the EC.	from the	

<sup>1</sup>Single species freshwater algae and plant toxicity endpoints used in the acute exposure risk assessment are derived by dividing the  $EC_{50}$  from the appropriate laboratory study by a factor of two (2). Shaded cells indicate that the screening level RQ exceeds the LOC of 1.0.

### Table 17 Screening Level Risk Assessment of Dimethomorph to Marine/EstuarineInvertebrates Following Application in the Three Crop Scenarios

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?
Marine/estuari Exposure	ne Invertebrates Acu	ite							
Cucurbit-groundboom and aerial scenarios									
Mysid shrimp	Americamysis bahia	Acute	1/2 EC50	2.2	959	80	0.120	0.05	No
Grape-airblast	scenarios								
Mysid shrimp	Americamysis bahia	Acute	1/2 EC50	2.2	762	80	0.095	0.04	No
Marine/Estuar Exposure	ine Invertebrates Ch	ronic							
Cucurbit-grou	ndboom and aerial sc	enarios							
Mysid shrimp	Americamysis bahia	Chronic	NOEC	0.241	959	80	0.120	0.50	No
Grape-airblast	scenarios								

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?
Mysid shrimp	Americamysis bahia	Chronic	NOEC	0.241	762	80	0.095	0.39	No

<sup>1</sup>Single species marine/estuarine algae toxicity endpoints used in the acute exposure risk assessment are derived by dividing the  $EC_{50}$  from the appropriate laboratory study by a factor of two (2). Shaded cells indicate that the screening level RQ exceeds the LOC of 1.0.

# Table 18Screening Level Risk Assessment of Dimethomorph to surrogate<br/>Marine/Estuarine Algae Following Application for the Three Crop Scenarios<br/>with DT50 of 41.6 Days

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?		
Marine/estuarine Invertebrates Acute						-					
Exposure	Exposure										
Cucurbit-groun	ndboom and aerial sc	enarios									
Surrogate Green algae	Pseudokirchneriella subcapitata	Acute	1/2 EC50	11.9	959	80	0.120	0.01	No		
Grape-airblast scenarios											
Surrogate Green algae	Pseudokirchneriella subcapitata	Acute	1/2 EC50	11.9	762	80	0.095	0.008	No		

<sup>1</sup>Single species marine/estuarine algae toxicity endpoints used in the acute exposure risk assessment are derived by dividing the  $EC_{50}$  from the appropriate laboratory study by a factor of two (2). Shaded cells indicate that the screening level RQ exceeds the LOC of 1.0.

### Table 19 Further Risk Characterization of Dimethomorph to Aquatic OrganismsFollowing Drift Refinement from the three Crop Scenarios

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	drift	EEC <sup>1</sup> (mg a.i./L)	RQ <sup>2</sup>	Exceed LOC?		
Freshwater	invertebrates chronic ex	posure	-		-	-	-		_			
Cucurbit gr	Cucurbit groundboom scenario											
Water flea	Daphnia magna	Chronic	NOAEC	0.1	959	80	0.06	0.007	0.07	No		
Cucurbit ae	rial scenario											
Water flea	Daphnia magna	Chronic	NOAEC	0.1	959	80	0.23	0.028	0.28	No		
Grape airbla	ast scenario											
Water flea	Daphnia magna	Chronic	NOAEC	0.1	762	80	0.74	0.07	0.70	No		
Amphibian												
Cucurbit gr	oundboom scenario											
Rainbow trout	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	959	15	0.06	0.038	0.11	No		
Cucurbit ae	rial scenario											
Rainbow trout	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	959	15	0.23	0.147	0.43	No		
Grape airbla	ast scenario											
Rainbow trout	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	762	15	0.74	0.380	1.11	Yes		

Organism	Species	Exposure	Endpoint	Value (mg	Applic. Rate	Water depth	drift	EEC <sup>1</sup> (mg	RQ <sup>2</sup>	Exceed LOC?		
Freshwater	fish chronic exposure			a.i./L)	(g a.i./ha)	(cm)	-	a.i./L)				
	Cucurbit groundboom scenario											
Rainbow trout	Onchorhynchus mykiss	Chronic	NOAEC	0.056	959	80	0.06	0.007	0.13	No		
Cucurbit ae	rial scenario											
Rainbow trout	Onchorhynchus mykiss	Chronic	NOAEC	0.056	959	80	0.23	0.028	0.50	No		
Grape airbla	ast scenario											
Rainbow trout	Onchorhynchus mykiss	Chronic	NOAEC	0.056	762	80	0.74	0.07	1.25	Yes		
Marine/estu exposure	arine fish chronic											
Cucurbit gr	oundboom scenario											
Sheepshead minnow	Cyprinodon variegatus	Chronic	NOAEC	0.063	225	80	0.06	0.002	0.03	No		
Cucurbit ae	rial scenario											
Sheepshead minnow	Cyprinodon variegatus	Chronic	NOAEC	0.063	225	80	0.23	0.006	0.1	No		
Grape airbla	ast scenario											
Sheepshead minnow	Cyprinodon variegatus	Chronic	NOAEC	0.063	225	80	0.74	0.021	0.33	No		

<sup>1</sup>Only a single application is considered in marine/estuarine drift RQ calculatons; Shaded cells indicate that the screening level RQ exceeds the LOC of 1.0.

## Table 4Further Risk Characterization of Dimethomorph Exposed to Aquatic Organisms<br/>Using Canadian and American Freshwater Monitoring Data

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	Drift	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?
Freshwater	invertebrates	-	-			-	-	-	-	-
Cucurbit grossenario	oundboom									
Water flea	Daphnia magna	Chronic	NOAEC	0.1	959	80	None	0.011	0.11	No
Cucurbit ae	rial scenario									
Water flea	Daphnia magna	Chronic	NOAEC	0.1	959	80	None	0.011	0.11	No
Grape airbla	ast scenario									
Water flea	Daphnia magna	Chronic	NOAEC	0.1	762	80	None	0.011	0.11	No
Amphibian										
Cucurbit gro scenario	oundboom									
Rainbow trout	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	959	15	None	0.044	0.13	No
Cucurbit ae	rial scenario									
Rainbow trout	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	959	15	None	0.044	0.13	No
Grape airbla	ast scenario									
Rainbow trout	Onchorhynchus mykiss	Acute	1/10 LC50	0.34	762	15	None	0.044	0.13	No
Freshwater	fish									
Cucurbit gro scenario	oundboom									
Rainbow	Onchorhynchus	Chronic	NOAEC	0.056	959	80	None	0.011	0.20	No

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	Drift	EEC (mg a.i./L)	RQ <sup>1</sup>	Exceed LOC?
trout	mykiss									
Cucurbit ae	rial scenario									
Rainbow trout	Onchorhynchus mykiss	Chronic	NOAEC	0.056	959	80	None	0.011	0.20	No
Grape airbla	ast scenario									
Rainbow trout	Onchorhynchus mykiss	Chronic	NOAEC	0.056	762	80	None	0.011	0.20	No
Marine/estu	arine fish									
Cucurbit gr scenario	oundboom									
Sheepshead minnow	Cyprinodon variegatus	Chronic	NOAEC	0.063	225	80	None	0.011	0.17	No
Cucurbit ae	rial scenario									
Sheepshead minnow	Cyprinodon variegatus	Chronic	NOAEC	0.063	225	80	None	0.011	0.17	No
Grape airbla	ast scenario									
Sheepshead minnow	Cyprinodon variegatus	Chronic	NOAEC	0.063	225	80	None	0.011	0.17	No

Shaded cells indicate that the screening level RQ exceeds the LOC of 1.0.

### Appendix X

### Table 1Toxic Substances Management Policy Considerations; Dimethomorph<br/>Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Dimethomorph	Meet criteria
CEPA toxic or CEPA toxic equivalent <sup>1</sup>		Yes	Yes	Yes
Predominantly anthropogenic <sup>2</sup>		Yes	Yes	Yes
	Soil	Half-life ≥ 182 days	115 days (aerobic soil) 16.4 days (anaerobic soil)	No
	Water	Half-life ≥ 182 days	46.1 days (aerobic water/sediment system)	No
	Sediment	Half-life		Unknown
Persistence <sup>3</sup> :	Air	Half-life ≥ 2 days or evidence of long range transport	Dimethomorph is considered to be of very low volatility, with a vapour pressure of less than $1.0 \times 10^{-6}$ (25°C) and a Henry's Law Constant of $1.15-1.18 \times 10^{-10}$ atm m <sup>3</sup> /mole. Risk of escape from treated soils or water bodies to reach upper atmosphere is minimal. Atmospheric half-life is 1.2 hr/12 hrs of sunlight	No
	Lo	og $K_{OW} \ge 5$	$Log K_{ow} = 2.63 - 2.73$	No
Bioaccumulation <sup>4</sup>		$CF \ge 5000$	NR because of low Log Kow	No
	$BAF \ge 5000$		Not expected due to low Log Kow	Unknown
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?		Not all criteria met	Does not meet TSMP Track 1 criteria.	

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

<sup>2</sup>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. <sup>3</sup> 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. <sup>4</sup>Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log  $K_{ow}$ ).

### Appendix XI Proposed Label Amendments for End-Use Products Containing Dimethomorph

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

**Note:** The following information is divided by products. Each section should be read carefully and required changes made to labels.

# The following amendments are required on the labels for Forum Technical (Dimethomorph) [Reg. No. 24545] and ZAMPRO Bulk [Reg. No.31306]:

### **Under PRECAUTIONS:**

### (On Reg. No. 24545)

Add the following statement:

'DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.'

### (On Reg. No. 24545)

Add the section title "ENVIRONMENTAL PRECAUTIONS" before the "STORAGE" section and add the following statement:

### 'TOXIC to aquatic organisms'

#### (On Reg. No. 31306) Replace the section title "ENVIRONMENTAL HAZARDS" with "ENVIRONMENTAL PRECAUTIONS"

### Under "DISPOSAL AND DECONTAMINATION" (Reg. No. 24545) or "DISPOSAL" ( Reg. No. 31306):

### *Replace (Reg. No. 24545):*

"Canadian formulators should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations.

For additional details and clean up spills, contact the manufacturer and the provincial regulatory agency.

### and (Reg. No. 31306):

"Canadian formulators using this product should dispose of unwanted active ingredient and containers in accordance with municipal or provincial regulations. For additional details and information on clean-up of spills, contact the provincial regulatory agency or the manufacturer.

with:

'Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and cleanup of spills, contact the manufacturer or the provincial regulatory agency.'

# The following amendments are required on all commercial products containing dimethomorph:

### Under "PRECAUTIONS":

(In order to promote best management practices, and to minimize human exposure to spray drift, the following label statement is proposed for all commercial-class labels)

### Add/ensure on label:

'Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools, and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.'

### Add/ensure on label:

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

### Under "STORAGE":

(The following statement is required on all agricultural and domestic product labels under the STORAGE heading)

Add:

• To prevent contamination store this product away from food or feed.

### Under "DIRECTIONS FOR USE":

(The following statements are required on all agricultural and commercial pesticide product labels)

Add (on labels with registered greenhouse uses only; Reg. Nos. 27700 and 32026):

• DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

### Under directions for "FIELD SPRAYER APPLICATION":

replace :

**DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification.

with:

DO NOT apply with spray droplets smaller than the American Society of Agricultural

Engineers (ASAE S572.1) medium classification.

### Under directions for "AERIAL APPLICATION":

#### replace :

**DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length MUST NOT exceed 65 % of the wing- or rotorspan.

#### with:

**DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Reduce drift caused by turbulent wingtip vortices. Nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan.

# The following amendments are required on the labels for Acrobat 50 WP Fungicide [Reg. No. 27700] and Forum Fungicide [Reg. No. 32026]:

Replace the entire 'BUFFER ZONES' section with the following:

### **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 freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of application	Crops		Buffer Zones (metres) Required for the Protection Freshwater Habitat of Depths:	
			< 1 m	>1 m
Field sprayer	Cucurbit vegetables, leafy vegetables, fruiting vegetables, bulb vegetables, brassica leafy vegetables, potatoes, ginseng, outdoor grown ornamentals, including herbaceous perennial and annual plants, container and field grown ornamental plants (including conifers) in nurseries and landscape plantings		1	0
		Early growth stage	10	0
Airblast	Grapes	Late growth stage	4	0
Airdiast	Hops	Early growth stage	5	0
		Late growth stage	3	0
Aerial	Cucurbit vegetables, leafy vegetables, fruiting vegetables group, bulb vegetables, brassica vegetables	Fixed or rotary wing	10	0
	Potatoes	Fixed or rotary wing	5	0

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

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.

# The following amendments are required on the label for Zampro Fungicide [Registration No. 30321]

### **Under PRECAUTIONS:**

Replace:

2. During all activities, worker must wear long pants, long-sleeved shirt and socks and shoes.

During mixing, loading, clean-up and repair activities, workers must also wear chemical resistant gloves.

with:

2. Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab or cockpit.

Replace:

5. For potatoes and fruiting vegetables, do not enter treated areas within 12 hours after application. For all other crops, see the specific Application Rate Table for the restricted entry interval.

with:

5. **DO NOT** enter or allow worker entry into treated areas during the restricted entry intervals

(REIs) specified in the Application Rate Tables.

Update REIs in the specific Application Rate Tables as follows:

Crop	Post Application Activity	Restricted Entry Interval (REI)
Potatoes; Cucurbit vegetables; Brassica vegetables; Leafy vegetables; Fruiting vegetables; Bulb vegetables; Hops	All activities	12 hours
Grapas	Girdling, turning	8 days
Grapes	All other activities	12 hours

*Replace the entire* '**BUFFER ZONES**' *section with the following:* 

### **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 freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of			Buffer Zones (metres) Required for the Protection of:			
application	Crops		Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:	
			< 1 m	> 1 m	< 1 m	>1 m
Field sprayer	Cucurbit vegetables, leafy vegetables, fruiting vegetables, bulb vegetables, brassica leafy vegetables, potatoes		1	1	1	1
Airblast	Grapes, hops	Early growth stage	10	4	3	1
Airdiast		Late growth stage	5	2	3	1
Aerial	Cucurbit vegetables, leafy vegetables, fruiting vegetables, bulb vegetables, brassica leafy vegetables, potatoes	Fixed or rotary wing	10	1	1	1

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

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.

# The following amendments are required on the label for Acrobat 50 WP Fungicide [Registration No. 27700]

### **Under PRECAUTIONS:**

Replace:

3. During all activities, workers must wear long pants, long-sleeved shirt, chemical-resistant gloves and boots. During mixing, loading, clean-up and repair activities, workers must also wear coveralls and safety goggles or a face shield. During mixing and loading workers must also wear a respirator with a NIOSH/MSHA/BHSE approved vapour removing cartridge with a pre-filter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister for pesticides. If using low-pressure handheld equipment, mixer, loader, and applicator must also wear coveralls and chemical-resistant gloves.

#### with:

3. During all activities, wear long pants, long-sleeved shirt, chemical-resistant gloves and boots. During mixing, loading, clean-up and repair activities, wear coveralls and safety goggles or a face shield. During mixing and loading workers must also wear a respirator with a NIOSH-approved vapour removing cartridge with a pre-filter approved for pesticides

OR a NIOSH-approved canister for pesticides. Wear coveralls when applying by handheld equipment.

Replace:

5. For potatoes and fruiting vegetables, do not enter treated areas within 12 hours after application. For all other crops, see the specific Application Rate Table for the restricted entry interval."

with:

5. **DO NOT** enter or allow worker entry into treated areas during the restricted entry intervals (REIs) specified in the Application Rate Tables.

Update REIs in the specific Application Rate Tables as follows:

Сгор	Post Application Activity	Restricted Entry Interval (REI)	
Potatoes; Cucurbit vegetables; Brassica vegetables; Leafy vegetables; Fruiting vegetables; Bulb vegetables; Hops; Ginseng; Outdoor grown ornamentals, herbaceous annual and perennial plants; Outdoor grown ornamentals, container and field grown ornamental plants in nurseries and landscape plantings; Greenhouse ornamental	All activities	12 hours	
Grapes	Girdling, turning All other activities	8 days 12 hours	

### **Under DIRECTIONS FOR USE:**

Add:

DO NOT apply using handheld mist blower/airblast or handheld fogging equipment.

Remove:

**DO NOT** use high pressure handheld equipment to apply ACROBAT 50 WP Fungicide. **DO NOT** use backpack sprayers to apply ACROBAT 50 WP Fungicide.

# The following amendments are required on the label for Forum Fungicide [Reg. No. 32026]

### **Under PRECAUTIONS:**

Replace:

2. During all activities, workers must wear long pants, long-sleeved shirt, chemicalresistant gloves and boots. During mixing, loading, clean-up and repair activities, workers must also wear coveralls and safety goggles or a face shield. If using low-

	pressure handheld equipment, mixer, loader, and applicator must also wear coveralls and chemical resistant gloves.
with: 2.	During all activities, wear long pants, long-sleeved shirt, chemical-resistant gloves and boots. During mixing, loading, clean-up and repair activities, wear coveralls and safety goggles or a face shield. Wear coveralls when applying by handheld equipment.
Replace:	
4.	For potatoes and fruiting vegetables, do not enter treated areas within 12 hours after application. For all other crops, see the specific Application Rate Table for the restricted entry interval.
with:	
4.	<b>DO NOT</b> enter or allow worker entry into treated areas during the restricted entry intervals (REIs) specified in the Application Rate Tables.

#### Update REIs in the specific Application Rate Tables as follows:

Сгор	Post Application Activities	Restricted Entry Interval	
Potatoes; Cucurbit vegetables; Brassica vegetables; Leafy vegetables; Fruiting vegetables; Bulb vegetables; Hops; Ginseng; Outdoor grown ornamentals, herbaceous annual and perennial plants; Outdoor grown ornamentals, container and field grown ornamental plants in nurseries and landscape plantings; Greenhouse ornamental	All activities	12 hours	
Grapes	Girdling, turning All other activities	8 days 12 hours	

### **Under DIRECTIONS FOR USE:**

Add:

**DO NOT** apply using handheld mist blower/airblast or handheld fogging equipment.

### Remove:

**DO NOT** use high pressure handheld equipment to apply FORUM Fungicide.

**DO NOT** use backpack sprayers to apply FORUM Fungicide.

### References

### Information Considered in the Chemistry Assessment

PMRA	
Document	Reference
Number	
1796084	1997. Dimethomorph pH, DACO: 2.16
1796087	1995. DME-SOF-1 Dimethomorph Spectral Database REPORT AMENDMENT 2,
	DACO: 2.14.12
2337728	2013. Product identity and composition of Acrobat Fungicide Technical
	[Dimethomorph (BAS 550 F) (EPA Reg.No. 241-382)]. DACO: 2.11.1, 2.11.2.
2337730	2013. Product identity and composition of Acrobat Fungicide Technical
	[Dimethomorph (BAS 550 F) (EPA Reg. No. 241-382)], DACO: 2.11.1, 2.11.2
2337739	2007. Characterization of five batches Dimethomorph (BAS 550 F TGAI). DACO:
	2.13.3
2337741	2013. Characterization of Five Batches of BAS 550. DACO: 2.13.3
2795315	2015. Analytical characterization of five representative batches of Dimethomorph
	TGAI (BAS 550 F). DACO: 2.13.3, 2.13.4 CBI
2795317	2016. 2nd Amendment - Analytical characterization of five representative batches
	of Dimethomorph TGAI (BAS 550 F). DACO: 2.13.3, 2.13.4 CBI
2795320	2017. Analysis of five representative batches of Dimethomorph TGAI (BAS 550
	F). DACO: 2.13.3, 2.13.4 CBI

### Information Considered for the Toxicological Risk Assessment

### A. Studies/Information Submitted by Registrant

PMRA	
document	Reference
number	
1161435	1985. Acute oral toxicity to rats of ZTH 236 Z50.(DK-411-004;151AA-421-
	004;851074D/ CMK5/AC) (Dimethomorph). DACO: 4.2.1
1161436	1986. CME 151: Acute oral toxicity test in mice. (DK-411-012;151AE-421-
	008;3651;235257) (Dimethomorph) DACO: 4.2.1
1161437	1987. CME 151/E-isomer: Acute toxicity study in rats after oral
	administration.(DK-411-009;151AG-421-
	010;T13053,CME151LOG11/0001.0.0;4/73/87). (Dimethomorph) DACO: 4.2.1
1161438	1987. CME 151/Z-ISOMER: Acute toxicity study in rats after oral
	administration.(DK-411-008;151AG-421-
	009;T13054,TOXLOG9190587/0001.0.0;4 /62/87). (Dimethomorph) DACO: 4.2.1
1161439	1985. Acute toxicity study in rats after epicutaneous administration. EMD ZTH 236
	Z 50. (DK-412-001;151AB-422-001;T12853,TOXLOG4180785;4/70/85).
	(Dimethomorph). DACO: 4.2.2

1162746	1985. Acute Toxicity Study In Rats After Epicutaneous Administration. Emd Zth
	236 Z 50. (DK-412-001;151ab-422-001;T12853,TOXLOG4180785;4/70/85).
	(Dimethomorph) *Note- Last Pages Of The Original Study In Pckg#95406
	Batch#24 Were Unreadable-(Pages 162 & 163)- 2 Higher Quality Replacements
1161440	Pages. DACO: 4.2.2
1161440	1989. CME 151 Technical material: acute dermal toxicity, skin and eye
	irritancy.(DK-412-002;SBGR.89.143;4260).(Dimethomorph) DACO: 4.2.2, 4.2.4,
1161440	4.2.5
1161442	1986. ZTH 236 Z50 Acute inhalation toxicity study in rats 4-hour exposure.(DK-
1161442	413-001; 151AA-423-001; CMK10/86464). (Dimethomorph) DACO: 4.2.3
1161443	1985. Primary skin and eye irritation test in rabbits. EMD ZTH 236 Z 50.(DK-415-
	001;151AB-465-001;T12854;TOXLOG10/10220785/0001.0.0;4/75/85)
1161444	(Dimethomorph). DACO: 4.2.4, 4.2.5
1161444	1985. Skin-sensitization study in guinea pigs using the maximization test according
	to Magnusson. EMD ZTH 236 Z 50.(DK-416-001;151AB-467-001;T12852;
1161446	UALOG4100785;4/68/85).(Dimethomorph) DACO: 4.2.6
1101440	1989. CME 151 Technical material: skin sensitisation potential-guinea pigs.(DK-416-002;4260; SBGR.89.184).(Dimethomorph) DACO: 4.2.6
1161447	1991. Summaries: (dimethomorph). DACO: 4.2
1161454	1986. CME 151: 6 week dietary dose range finding study in mice.(DK-420-
1101434	003;151AE-431-003;3653;435067).(Dimethomorph) DACO: 4.3.1
1161455	1990. SAG 151: 52 week dietary toxicity study in dogs.(DK-427-
1101455	003;5533;636876). (Dimethomorph) DACO: 4.3.1
1161456	1991. SAG 151: 104 week dietary toxicity study in rats.(DK-427-
1101450	004;5788;435140). (Dimethomorph) DACO: 4.4.1
1161458	1990. SAG 151: Two generation oral (dietary administration) reproduction toxicity
1101150	study in the rat (two litters in the $F_1$ generation).(DK-430-001;460-022;763-460-
	022). (Dimethomorph) (Cont'd On Roll#1419) DACO: 4.5.1
1161467	1990. (cont'd from roll#1418) SAG 151: Two Generation Oral (Dietary
1101.07	Administration) reproduction toxicity study in the rat (two litters in the F1
	generation).(DK-430-001;460-022;763-460-022).(Dimethomorph).DACO: 4.5.1
1161457	1990. Summaries: (Dimethomorph). DACO: 4.1
1161459	1986. CME 151: 4 week dietary dose range finding study in rats.(DK-420-
	002;151AE-431-002;3649;435025).(Dimethomorph) DACO: 4.3.1
1161460	1985. ZTH 236 Z 50 preliminary assessment of toxicity to rats by dietary admixture
	for 4 weeks (Final Report).(DK-420-005;151AA-432-
	002;CMK6/851056).(Dimethomorph) DACO: 4.3.1
1161461	1991. SAG 151 E ISOMER: A 28 day oral toxicity study in rats.(DK-470-015;4578;
	SBGR.90.106). (Dimethomorph) DACO: 4.3.1
1161462	1991. SAG 151 Z ISOMER: A 28 day oral toxicity study in rats.(DK-470-016;4580;
	SBGR.90.107). (Dimethomorph) DACO: 4.3.1
1161463	1987. CME 151 toxicity to rats by dietary admixture for 13 weeks with a 4-week
	withdrawal period (Final Report). (DK-425-001;151AA-433-001;CMK7/8624).
	(Dimethomorph) DACO: 4.3.1
1161464	1986. CME 151: dietary maximum tolerated dose study in dogs.(DK-420-
	001;151AE-431-001;3592;635228).(Dimethomorph) DACO: 4.3.1
1161464	(Dimethomorph) DACO: 4.3.1 1986. CME 151: dietary maximum tolerated dose study in dogs.(DK-420-

1161465	1987. CME 151: 13 week dietary toxicity study in dogs.(DK-425-002;151AE-433-
	002;3722; IRI635212). (Dimethomorph) DACO: 4.3.1
1161466	1987. CME 151: histopathological examination of ileum sections taken from the rat
	(IRI Project NO.435025) and mouse (IRI Project NO.435067) dose range finding
	studies.(DK-420-004;151AE-432-003;3770;IRI435596).(Dimethomorph) DACO:
	4.3.1
1161468	1987. CME151-Z50: chromosome aberrations in cells of Chinese hamster cell line
	V79.(DK-435-006;151AE-457-007;LMP275;MB160786;AH230287;AB79RK/F).
	(Dimethomorph) DACO: 4.5.4
1161469	1986. CME151-Z50: cell transformation assay with Syrian hamster embryo (she)
	cells.(DK-435-005;151AE-457-006;LMP180D;MB200886;MB030986;
	TRANSRE;ROT43). (Dimethomorph) DACO: 4.5.4
1161470	1989. Mouse micronucleus test on CME 151 technical material.(DK-435-009;
	SLL169/89932) (Dimethomorph) DACO: 4.5.4
1161471	1986. CME 151-Z50: unscheduled DNA synthesis in hapatocytes of male rats <i>in</i>
1101.71	<i>vitro</i> (UDS Test).(DK-435-002;151AE-457-003;LMP180A;AT030786;
	MB100786;UDSRE). (Dimethomorph) DACO: 4.5.4
1161472	1990. SAG 151: 104 week dietary carcinogenicity study in mice.(DK-428-
	004;5816; IRI435088) (Dimethomorph). DACO: 4.4.2
1161473	1990.104-Week Dietary Oncogenicity Study In Mice With Sag 151- Pathology
1101.70	Report. Pathology Supplement. (DK-428-003;Eplno.104-
	005;Iri435088).(Dimethomorph) (cont'd on roll#1420). DACO: 4.4.2
1161482	1990. (Cont'd From Roll#1419) 104-Week Dietary Oncogenicity Study In Mice
1101102	With Sag 151- Pathology Report. Pathology Supplement.(DK-428-003;Eplno.104-
	005;IRI435088).(Dimethomorph). DACO: 4.4.2
1161474	1989. SAG 151: oral (gavage) teratogenicity study in the rat.(DK-432-
1101171	002;460/23;764-460/23).(Dimethomorph) DACO: 4.5.2
1161475	1987. CME 151: preliminary oral (gavage) embryotoxicity study in the rabbit. Final
1101.70	report.(DK-432-003;460/12;694-460/12;151AE-451-002).(Dimethomorph) DACO:
	4.5.2
1161476	1989. SAG 151: oral (gavage) teratogenicity study in the rabbit. Final report.(DK-
1101170	432-004; 460/24;765-460/24;151AE-451-007).(Dimethomorph) DACO: 4.5.2
1161478	1988. Bacterial mutagenicity studies with CME-151.(DK-435-
11011/0	010;SBGR.88.241;50670769; 4059;AJB/WS4/232). (Dimethomorph). DACO: 4.5.4
1161479	1991. Bacterial mutagenicity studies with CME-151. Addendum TO SBGR.88.241.
11017//	(DK-435-011;SBGR.88.241;4059).(Dimethomorph). DACO: 4.5.4
1161480	1987. CME151-Z50: detection of gene mutations in somatic mammalian cells in
1101100	culture: HGPRT-Test With V79 Cells.(DK-435-003;151AE-457-
	004;LMP180B;K1010886 ;MB191286;HGPRT-RE).(Dimethomorph). DACO:
	4.5.4
1161481	1986. CME151-Z50: chromosome aberrations in cells of Chinese hamster cell line
1101-101	V79. (DK-435-004;151AE-457-005;LMP180C;MB160786;MB140886;
	AB79RK/F). (Dimethomorph). DACO: 4.5.4
1161504	1990. The biokinetics and metabolism of 14c-dimethomorph in the rat.(DK-440-
1101304	001; CUB1/87; SHGR.90.006). DACO: 4.5.9 (Reported as DACO: 6.4)
	1 001, COB1/07, SHOK.70.000). DACO. 4.3.7 (Reported as DACO. 0.4)

1161507	1990. 14C-dimethomorph (CME 151): absorption, distribution, metabolism and
	excretion after bile cannulation and single oral administration to the rat.(DK-440-
	002;255172). DACO: 4.5.9 (reported as DACO: 6.4)
1163731	1991. Summaries - metabolism investigation on the nature of metabolites occurring
	in rats- Dr. W. Ost (1991) (Dimethomorph). DACO: 4.5.9
1162900	1991. SAG 151 104 week dietary carcinogenicity study in rats (DK-428-
	005;435140;5806) (Dimethomorph Technical). DACO: 4.4.1, 4.4.2
2361498	2010. BAS 550 F (Dimethomorph) - Repeated-dose 28-day dermal toxicity study in
	Wistar rats Conducted by Experimental Toxicology and Ecology Laboratory.
	DACO: 4.4.2
2361502	2010. BAS 550 F Dimethomorph) - Immunotoxicity Study in Male Wistar Rats -
	Administration via the Diet for 4 Weeks. Experimental Toxicology and Ecology
	Laboratory. DACO: 4.5.15
2361503	2011. BAS 550 F (Dimethomorph) - Acute Oral Neurotoxicity Study in Wistar Rats
	- Administration via Gavage. Experimental Toxicology and Ecology BASF SE.
	DACO: 4.5.12
2361508	2004. BAS 550 F - Subchronic Neurotoxicity Study in Wistar Rats; Administration
	in the Diet for 3 Months. Experimental Toxicology and Ecology BASF
	Aktiengesellschaft. DACO: 4.5.13

### Information Considered in the Dietary Assessment

### A. Studies/Information Submitted by Registrant

PMRA	
document	Reference
number	
788072	1998. Method for the Determination of Residues of Dimethomorph (CME 151) in
	Potatoes, Tomatoes, Grapes (Including Grape Waste Material, Raisins, Fruit Juice,
	Wine). DACO: 7.2.3
788073	1993. Analysis of Dimethomorph by Multi-Residue Methods in FDA Pesticide
	Analytical Manual Volume I. DACO: 7.2.4
788074	1991. Confirmatory Validation of an Analytical Method for the Determination of the
	Residues of Dimethomorph in Plant Material (FAMS 002-02). DACO: 7.2.4
788075	1991. First Amendment to Report No 307822: Confirmatory Validation of an
	Analytical Method for the Determination of the Residues of Dimethomorph in Plant
	Material (FAMS 002-02). DACO: 7.2.4
1067407	1997. CL 336379 (dimethomorph): Independent Laboratory Validation of GC and
	GC/MS Confirmatory Method M 2639 for the Determination of CL 336379 residues
	in Potato Tubers, Washed Unpeeled Potato, Potato Chops, Wet Peel, Granules,
	Frying Oil and Potato Fish Water. DACO: 7.2.3
1161483	1991. 14C-Dimethomorph (CME 151)(Morpholine Ring Label)- Metabolism And
	Translocation In Potato Plants- Supplemental Data. Supplemental Report To Report
	SHGR.89.070. DACO: 6.3
1161484	1987. Macroautoradiographic Studies On The Translocation Behaviour Of 14C-
	Labelled CME 151 After Leaf Application In Wine. (Dimethomorph). DACO: 6.3

1161485	1990. <sup>14</sup> C-Dimethomorph (CME 151): Absorption, Distribution, Metabolism And
1101405	Excretion After Repeated Oral Administration To Laying Hens.(DK-440-
	003;214740) (Dimethomorph). DACO: 6.4
1161486	1991. <sup>14</sup> C-Dimethomorph (CME 151): Absorption, Distribution, Metabolism And
1101100	Excretion After Repeated Oral Administration To Laying Hens. First Amendment
	To Report DK-440-003.(DK-440-007;214740).(Dimethomorph). DACO: 6.4
1161487	Summaries: Dimethomorph. DACO: 7.1
1161488	1990. <sup>14</sup> C-Dimethomorph (CME 151)-Confined Accumulation Study On Rotational
1101100	Crops (DK-640-008;CUB2/87;SHGR.90.004). DACO: 7.4.2
1161489	1991. Dimethomorph: Determination Of CME 151 Residues And Metabolites In
	Milk.(DK-705-002;CUA90/661;SHGR.91.005). DACO: 7.5
1161490	1991. Dimethomorph: Determination Of CME 151 Residues And Metabolites In
	Processed Milk.(DK-705-001;CUA90/662;SHGR.91.006). DACO: 7.5
1161491	1991. CME 151 (Dimethomorph) Technical: Residues In Milk And Tissues Of
	Dairy Cows. Volume I,II,III.(DK-705-007;CMK61/91644). DACO: 7.5
1161493	1990. Summaries: Dimethomorph. DACO: 6.1
1161504	1990. The Biokinetics And Metabolism Of 14c-Dimethomorph In The Rat.(DK-
	440-001; CUB1/87;SHGR.90.006). DACO: 6.4
1161507	1990. <sup>14</sup> C-Dimethomorph (CME 151): Absorption, Distribution, Metabolism And
	Excretion After Bile Cannulation And Single Oral Administration To The Rat.(DK-
	440-002;255172). DACO: 6.4
1161508	1990. <sup>14</sup> C-Dimethomorph (CME 151): Absorption, Distribution, Metabolism And
	Excretion After Repeated Oral Administration To Lactating Goats.(DK-440-
	005;213928). DACO: 6.4
1161509	1991. <sup>14</sup> C-Dimethomorph (CME 151): Absorption, Distribution, Metabolism And
	Excretion After Repeated Oral Administration To Lactating Goats. First
	Amendment To Report. (22 PAGES).(DK-440-008;213928). DACO: 6.4
1161510	1990. 14C-Dimethomorph (CME 151)(Chlorophenyl Ring Label)- Metabolism And
	Translocation In Potato Plants. DACO: 6.3
1161511	1991. 14C-Dimethomorph (CME 151)(Chlorophenyl Ring Label)- Metabolism And
	Translocation In Potato Plants- Supplemental Data. Supplemental Report To
1161510	RepORT SHGR.89.071. DACO: 6.3
1161512	1990. 14C-Dimethomorph (CME 151)(Morpholine Ring Label)- Metabolism And
1161600	Translocation In Potato Plants. DACO: 6.3
1161680	1995. Summaries: Acrobat Fungicide. Dimethomorph/Mancozeb. Submitted:
1161601	October (Acrobat MZ Fungicide). DACO: 7.1
1161681	1992. Dimethomorph: Determination Of Residues In Potatoes Grown In The UK IN
	1990 After Treatment With 75 G/KG Wettable Powder, SY50588, OR 90 G/KG
	Wettable Powder, SY50586, OR 500 G/KG Wettable Powder, SY50574, Under Field Conditions (DK 724 016:DK 724 016:SHCP 02 033:CUA01/723:
	Field Conditions.(DK-724-016;DK-724-016;SHGR.92.033;CUA91/723; SUKF90449;SUKF90450). DACO: 7.4.2
1161682	1992. Dimethomorph: Storage Stability At <= -18'C In Potato.(DK-326-
1101062	004;SHGR.92.001; CU89/626).(Acrobat MZ Fungicide) DACO: 7.3
1162862	1995. Residue Summaries - Forum 50WP, FAMS 002-02, Method For The
1102002	Determination Of Residues Of Dimethomorph (CME 151) In Potatoes, Tomatoes,
	Grapes (Including Grape Waste Material, Raisins, Fruit Juice, Wine). DACO: 7.1
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1162863	1989. Method For The Determination Of Residues Of Dimethomorph (CME 151) In
	Potatoes, Tomatoes, Grapes (Including Grape Waste Material, Raisins, Fruit Juice,
	Wine)(FAMS 002-02;DK-244-002)(01.02.1989)(Forum 50WP). DACO: 7.21
1162864	1993. Dimethomorph: Determination Of Residues In Potatoes Grown In France In
	1990 After Treatment With 500 G/KG Wettable Powder, SY 50574, Under Field
	Condition (CUA91/719;SHGR.92.030;RSF 9071;SFRF90271;SFRF90465;
	SFRF90510;DK-724-018)(Forum 50WP). DACO: 7.42
1162865	1989. Residue Analysis Of CME 151 (Dimethomorph) In The Potato (Solanum
	<i>tuberosum</i> L.) 1985-1988: A Review(SHGR.89.001;DK-724-001)(Forum 50WP).
	DACO: 7.4.2
1163683	1991. Dimethomorph: Determination Of CME 151 Residues And Metabolites In
	Bovine Tissues - Supplemental Data - (SHGR.91.032;663;CUA 90/663;Supplement
	To SHGR.91.007). DACO: 7.5
1163684	1991. Dimethomorph: Detemination Of CME 151 Residues And Metabolites In
	Milk - Supplemental Data - (SHGR.91.030;DK-705-004;CUA 90/661;661). DACO:
11.00.00	7.5
1163685	1991. Dimethomorph: Determination Of CME 151 Residues And Metabolites In
	Processed Milk - Supplemental Data - (CUA 90/662;662;DU-705-
11(2721	005;SHGR.91.031). DACO: 7.5
1163731	1991. Summaries - Metabolism - (Dimethomorph) DACO: 6.1
1163742	1991. 14C-Dimethomorph (CME 151): Investigation On The Nature Ofmetabolites
	Occuring In Rats (DK-440-006;SKGR.91.010;CUB 91/2)(Dimethomorph). DACO:
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1163753	1992. Dimethomorph (CME 151)(Chlorophenyl Ring-14C) Metabolism: The Nature
1163753	Of The Residue In Potato Tubers (Supplemental Report To SHGR.89.071). DACO:
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1163762	Of The Residue In Potato Tubers (Supplemental Report To SHGR.89.071). DACO: 6.3 1991. Summaries - Residues Studies – Dimethomorph. DACO: 7.1
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1163762 1163763	Of The Residue In Potato Tubers (Supplemental Report To SHGR.89.071). DACO: 6.3 1991. Summaries - Residues Studies – Dimethomorph. DACO: 7.1 1991. Dimethomorph: Determination Of CME 151 Residues And Metabolites In Bovine Tissues (CUA90/663;663;DK-705-003;SHGR.91.007). DACO: 7.5
1163762	Of The Residue In Potato Tubers (Supplemental Report To SHGR.89.071). DACO: 6.3 1991. Summaries - Residues Studies – Dimethomorph. DACO: 7.1 1991. Dimethomorph: Determination Of CME 151 Residues And Metabolites In Bovine Tissues (CUA90/663;663;DK-705-003;SHGR.91.007). DACO: 7.5 1994. <sup>14</sup> C-Dimethomorph: Additional Investigations On The Nature Of Metabolites
1163762 1163763 1163934	Of The Residue In Potato Tubers (Supplemental Report To SHGR.89.071). DACO: 6.3 1991. Summaries - Residues Studies – Dimethomorph. DACO: 7.1 1991. Dimethomorph: Determination Of CME 151 Residues And Metabolites In Bovine Tissues (CUA90/663;663;DK-705-003;SHGR.91.007). DACO: 7.5 1994. <sup>14</sup> C-Dimethomorph: Additional Investigations On The Nature Of Metabolites Occurring In Rats.(CFS1994-076;DK-440-010;CUB91/5). DACO: 6.4
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1161501	1991. [Chlorophenyl-14C] Dimethomorph (CME151). Soil Adsorption/Desorption.
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Number	
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1161400	DACO: 8.3.2.1, 8.3.2.2
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1161516	1988. The Dietary Toxicity (LC50) Of CME151 To The Bobwhite Quail.(DK-505-002;151AE-445-001;CMK18/871027).(Dimethomorph). DACO: 9.6.2.4
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1161518	Summaries: Dimethomorph. DACO: 9.5.1
1161519	96-Hour Acute Toxicity Study (LC50) With CME151 In The Carp.(DK-511-
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1161528	1986. Acute Toxicity (LC50) Study Of Cme151 To Earthworms. (Index Lists:DK- 551-001;DK-531-00?;151AE-449-00?;068130).(Dimethomorph). DACO: 9.2.3.1
1161529	1986. 48-Hour Acute Toxicity Of CME151 To <i>Daphnia Magna</i> (OECD Immobilization Test).(DK-521-002;151AE-443-001;068128).(Dimethomorph). DACO: 9.3.1
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1161581	Summaries: (Dimethomorph). DACO: 9.6.1
1161592	1987. The Acute Oral Toxicity (LD50) Of Cme151 To The Bobwhite Quail.(DK- 505-001;151AE-441-002;CMK14/861226).(Dimethomorph). DACO: 9.6.2.1
1161595	1987. The Acute Oral Toxicity (LD50) Of CME151 To The Mallard Duck.(DK-505-003;151AE-441-001;CMK15/86919).(Dimethomorph). DACO: 9.6.2.1
1161684	1995. Review Of Environmental Toxicology Dimethomorph And Dimethomorph/ Mancozeb Formulations.(Review Series HSE91.004). (Acrobat MZ Fungicide). DACO: 9.2.1, 9.5.1, 9.6.1, 9.8.1
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1161686	1991. Dimethomorph: CME151/Mancozeb 90/600 G KG-1 WP (SY50579), Acute Toxicity To <i>Oncorhynchus Mykiss</i> And <i>Daphnia Magna</i> . (DK-560-001; 4901; SBGR.90.250). (Acrobat MZ Fungicide). DACO: 9.3.1, 9.5.2.1
1161687	1991. CME151/Mancozeb 90/600 G KG-1 WP (SY50586): Acute Toxicity To Salmo Gairdneri And Daphnia Magna.(DK-560-002;4467;SBGR.90.159).(Acrobat MZ Fungicide). DACO: 9.3.1, 9.5.2.1
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	Fungicide). DACO: 9.2.7
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1172123	1997. ECO 96-107 Nontarget Terrestrial Plant Seedling Emergence Phytotoxicity
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1871629	2009. BAS 651 00 F - Acute toxicity in the bobwhite quail (Colinus virginianus)
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1871631	2007. BAS 651 00 F - Acute toxicity study on the rainbow trout (Oncorhynchus
	mykiss) in a static system over 96 hours. DACO: 9.5.4, IIIA 10.2.2.1
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-	<i>mykiss</i> ) in a static system over 96 hours. DACO: 9.5.4, IIIA 10.2.2.1
1871633	2007. BAS 651 00 F - Determination of the acute effect on the swimming ability of
	the water flea <i>Daphnia magna</i> Straus. DACO: 9.3.2, 9.3.5, IIIA 10.2.2.2
1871634	2007. BAS 651 00 F - Determination of the acute effect on the swimming ability of
	the water flea <i>Daphnia magna</i> Straus. DACO: 9.3.2, 9.3.5, IIIA 10.2.2.2
1871635	2008. BAS 651 00 F - Determination of the inhibitory effect on the cell
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1071626	Korshikov. DACO: 9.8.2, 9.8.3, 9.8.6, IIIA 10.2.2.3
1871636	2008. BAS 651 00 F - Determination of the inhibitory effect on the cell
	multiplication of the unicellular green algae <i>Pseudokirchneriella subcapitata</i>
1071627	Korshikov. DACO: 9.8.2, 9.8.3, 9.8.6, IIIA 10.2.2.3
1871637	2006. Assessment of side effects of BAS 651 00 F to the honey bee, <i>Apis mellifera</i>
1071620	L. in the laboratory. DACO: 9.2.8, IIIA 10.4.2.1, IIIA 10.4.2.2
1871638	2006. Assessment of side effects of BAS 651 00 F to the honey bee, <i>Apis mellifera</i>
1971620	L. in the laboratory. DACO: 9.2.8, IIIA 10.4.2.1, IIIA 10.4.2.2
1871639	2008. Effects of BAS 651 00 F on the green lacewing <i>Chrysoperla carnea</i> STEPH.
1871640	under laboratory conditions - Rate-response-test. DACO: 9.2.8, IIIA 10.5.1 2008. Effects of BAS 651 00 F on the green lacewing <i>Chrysoperla carnea</i> STEPH.
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	under raboratory conditions - Kate-response-test. DACO. 9.2.0, IIIA 10.3.1

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1871641	2007. Effect of BAS 651 00 F on the parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) in a laboratory trial. DACO: 9.2.8, IIIA 10.5.1
1871642	2007. Effect of BAS 651 00 F on the parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) in a laboratory trial. DACO: 9.2.8, IIIA 10.5.1
1871643	2009. Effect of BAS 651 00 F on the predatory mite ( <i>Typhlodromus pyri</i> ) in a laboratory trial (Including amendment no. 1). DACO: 9.2.8, IIIA 10.5.1
1871644	2009. Effect of BAS 651 00 F on the predatory mite ( <i>Typhlodromus pyri</i> ) in a laboratory trial (Including amendment no. 1). DACO: 9.2.8, IIIA 10.5.1
1871645	2008. Effect of BAS 651 00 F on the parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) in an extended laboratory trial (Including amendment no. 1). DACO: 9.2.8, IIIA 10.5.2
1871646	2008. Effect of BAS 651 00 F on the parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) in an extended laboratory trial (Including amendment no. 1). DACO: 9.2.8, IIIA 10.5.2
1871647	2008. Acute toxicity of BAS 651 00 F on earthworms ( <i>Eisenia fetida</i> ) in artificial soil with 5% peat (Including amendment no. 1). DACO: 9.2.8, IIIA 10.6.2
1871648	2008. Acute toxicity of BAS 651 00 F on earthworms ( <i>Eisenia fetida</i> ) in artificial soil with 5% peat (Including amendment no. 1). DACO: 9.2.8, IIIA 10.6.2
1871649	2007. Sublethal toxicity of BAS 651 00 F to the earthworm <i>Eisenia fetida</i> in artificial soil with 5% peat. DACO: 9.2.8, IIIA 10.6.3
1871650	2007. Sublethal toxicity of BAS 651 00 F to the earthworm <i>Eisenia fetida</i> in artificial soil with 5% peat. DACO: 9.2.8, IIIA 10.6.3
1871651	2007. Effects of BAS 651 00 F on the reproduction of the collembolans <i>Folsomia candida</i> in artificial soil with 5% peat. DACO: 9.2.8, IIIA 10.6.6
1871652	2007. Effects of BAS 651 00 F on the reproduction of the collembolans <i>Folsomia candida</i> in artificial soil with 5% peat. DACO: 9.2.8, IIIA 10.6.6
1871657	2009. BAS 651 00 F: A toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plants. DACO: 9.8.6, IIIA 10.8.1.2
1871658	2009. BAS 651 00 F: A toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plant. DACO: 9.8.6, IIIA 10.8.1.2
1871659	2009. BAS 651 00 F: A toxicity test to determine the effects of the test substance on seedling emergence of ten species of plants. DACO: 9.8.6, IIIA 10.8.1.3
1871660	2009. BAS 651 00 F: A toxicity test to determine the effects of the test substance on seedling emergence of ten species of plants. DACO: 9.8.6, IIIA 10.8.1.3
1888446	2001. Effect of BAS 550 01 F on the Growth of <i>Lemna gibba</i> . DACO: 9.8.5, IIA 8.6

### **B.** Additional Information Considered

### i) Unpublished Information

PMRA	
Document	Reference
Number	
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	fungicide. Health Canada, Pest Management regulatory Agency, Environmental
	Evaluation Division Monograph. DACO: 8.6
2780525	2017. Unpublished surface water and groundwater monitoring data for
	dimethomorph from 2000-2016 submitted by the Ministère du Développement
	durable, de l'Environnement et de la Lutte contre les Changements climatiques in
	response to the PMRA's June 6, 2017 monitoring data request for active ingredients
	undergoing re-evaluation or special review. DACO: 8.6
2791262	2017. Groundwater and Surface water: Unites States Geographical Survey (USGS)
	data from the National Water Information System (NWIS) AND EPA data from the
	Storage and Retrieval program (STORET) downloaded both from the National
	Water Portal. DACO : 8.6
1560632	2003. Pesticide Sampling Program for selected municipal drinking water supplies in
	New Brunswick, Canada. Tables 4-6: results by municipality and QA/QC samples.
	DACO: 8.6
2791260	2017. Surface water monitoring data for dimethomorph from CalDPR surface water
	database. DACO: 8.6

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PMRA Document	Reference
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	of Pesticide Wastes. Am. Chem. Soc., Washington, DC. ACS Symp. Ser. 259. pp.
	297-325. ; DACO: 8.2.4
1918522	1994. Literature review and evaluation of the EPA food chain (Kenaga) nomogram,
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	13:1383 - 1391. ; DACO: 9.6 and 9.7
1918524	1989. Groundwater ubiquity score: a simple method for assessing pesticide
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1918526	1972. Pesticide residues on plants: correlation of representative data as a basis for
	estimation of their magnitude in the environment. In (F. Coulston and F. Korte,
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	I. Global aspects of chemistry, toxicology and technology as applied to the
	environment. Georg Thieme Publishers, Stuttgart, and Academic Press, New York.
	pp. 9–28. ; DACO: 9.6 and 9.7

1918527	1973. Factors to be considered in the evaluation of the toxicity of pesticides to birds in their environment. In (F. Coulston and F. Korte, eds.) Environmental quality and safety: global aspects of chemistry, toxicology and technology as applied to the
1010700	environment. Vol. II. DACO: 9.6
1918529	1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecological Monograph. Vol.57, No.2. DACO: 9.6 and 9.7
1930629	1987. Pesticide Persistence on Foliage. Reviews of Environmental Contamination and Toxicology, Vol. 100. ; DACO: 8.5 and 9.6 and 9.7
2024011	1981. Measurement of sorption coefficients of organic chemicals and their use in
	environmental fate analysis. 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, pp. 89–
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