Re-evaluation Decision RVD2020-05

Dimethomorph and Its Associated End-use Products

Final Decision

(publié aussi en français)

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Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental 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. Currently registered products containing dimethomorph can be found in the Pesticide Label Search and in Appendix I.

The regulatory approach for the re-evaluation of dimethomorph was first presented in the Proposed Re-evaluation Decision PRVD2019-03, *Dimethomorph and Its Associated End-use Products*,[1] which underwent a 90-day consultation period ending on 28 July 2019. PRVD2019-03 proposed continued registration of dimethomorph with certain risk mitigation measures that include new and updated label statements, restricted entry intervals, and buffer zones.

Health Canada received comments relating to the health and environmental assessments. Appendix II presents a summary of these comments along with responses from Health Canada. The comments and information provided did not result in revisions to the risk assessments or any major changes to the proposed regulatory decision described in PRVD2019-03. A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2019-03. References that were unintendedly omitted from the list presented in PRVD2019-03 are provided in Health Canada's response to comments in Appendix II. Appendix IV lists additional information used in the re-evaluation decision presented in this RVD.

This document presents the final regulatory decision[2] for the re-evaluation of dimethomorph, including the required risk mitigation measures to protect human health and the environment, along with label amendments required to bring labels to current standards. All products containing dimethomorph that are registered in Canada are subject to this re-evaluation decision.

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.

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

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

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 acceptable for all dimethomorph uses when used according to the 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 revised label directions, environmental risks associated with the use of dimethomorph are considered acceptable.

Regulatory Decision for Dimethomorph

Health Canada has completed the re-evaluation of dimethomorph. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing dimethomorph is acceptable. An evaluation of available scientific information found that uses of dimethomorph products meet current standards for protection of human health and the environment when used according to revised label directions. Label amendments, as summarized below and listed in Appendix III, are required. No additional data are required.

Risk Mitigation Measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. Required label amendments and mitigation measures resulting from the re-evaluation of dimethomorph are summarized below. Refer to Appendix III for details.

Human Health

Label improvements required to meet current standards include updated statements for personal protective equipment (PPE).

Risk-reduction measures include:

- a label restriction against applications as a mist or fog to protect mixer/loader/applicators,
- updated restricted-entry intervals (REIs) for certain agricultural uses to protect workers entering treated sites,
- and a statement promoting best management practices in order to minimize human exposure and protect bystanders from spray drift.

Residue definition for enforcement:

- The residue definition for the dietary risk assessment and enforcement is expressed as the parent compound, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl] morpholine for all food commodities. No change to the current residue definition is required.

Environment

Risk-reduction measures required to protect the environment include:

- 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.

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Refer to Appendix I for details on specific products impacted by this decision.

Other Information

Any person may file a notice of objection[3] regarding this decision on dimethomorph within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (hc.pmra.info-arla.sc@canada.ca).

The relevant test data on which the decision is based (as referenced in PRVD2019-03 and this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.

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

List of Abbreviations

a.i	active ingredient
ARTF	Agricultural Re-entry Exposure Task Force
Bw	body weight
Cm	centimeter
DFR	dislodgeable foliar residue
E	exponent
EEC	estimated environmental concentrations
EFSA	European Food Safety Authority
ELS	Early Life Stage
e-PRS	Electronic Pesticide Regulatory System
EXP_{derm}	dermal exposure
ha	hectare
hr	hour
kg	kilogram
L	litre
LC50	lethal concentration on 50% of the population
LOC	level of concern
m	meter
Max App Rate	Maximum Application Rate
mg	milligram
MOE	margin of exposure
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
PHI	pre-harvest interval
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	proposed re-evaluation decision
Reg. No.	PMRA registration number
REI	restricted entry interval
RQ	risk quotient
RVD	re-evaluation decision
TC	transfer coefficient
USEPA	United States Environmental Protection Agency
WP	wettable powder
wt	weight

Appendix I Registered Dimethomorph Products in Canada as of December 2019

(Excluding Discontinued Products or Products with a Submission for Discontinuation Based on the PMRA's Electronic Pesticide Regulatory System (e-PRS) database)

Registration Number	Marketing Class	Registrant Name	Product Name	Formulation Type	Active Ingredient
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

Appendix II Comments and Responses

In response to the consultation for the dimethomorph proposed re-evaluation decision, written comments were received from BASF Canada Inc., the sole registrant of dimethomorph products in Canada. The comments were considered during the final decision phase of this re-evaluation. Summarized comments and Health Canada's responses to them are provided below.

1.0 Comments Related to the Health Risk Assessment

1.1 Comments Related to Dietary Exposure

1.1.1 Comment related to the residue definition for enforcement:

The registrant, BASF Canada, requested clarification of the residue definition for enforcement.

Health Canada Response:

Health Canada acknowledges that the residue definition on page 2 of PRVD2019-03 was incorrectly stated. The correct residue definition for enforcement is 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, which is consistent with the residue definition listed on the Pesticides and Food page of the Canada.ca website. As indicated in the proposed re-evaluation decision document, no changes have been made to the existing residue definition for dimethomorph.

1.2 Comments Related to Occupational / Residential Exposure

1.2.1 Comment related to mechanically-assisted harvesting of hops:

The registrant requested clarification as to why Health Canada identified the highest contact postapplication activity in hops as "Harvesting (mechanically)".

Health Canada Response:

Health Canada agrees that the text for this postapplication activity is unclear. For clarity, Health Canada has updated this postapplication activity to say "Harvesting (mechanically-assisted)." A revised Table IV.3 for hops is presented in Section 1.2.2 below.

1.2.2 Comment related to the transfer coefficient (TC) assigned by the Health Canada for mechanical harvesting of hops:

The registrant requested clarification as to why Health Canada used a TC of 19,300 cm^2/hr to represent the post application activity Harvesting (mechanically) or Harvesting (mechanically-assisted) for hops. The registrant noted that a lower TC has already been accepted by the USEPA, based on a document prepared by the Agricultural Re-entry Exposure Task Force (ARTF) (submitted in 2013). The USEPA reviewed and partially accepted ARTF's position in August, 2015 and the TC for the post application activity Harvesting (mechanically-assisted) for hops was changed from 19,300 cm^2/hr to 1400 cm^2/hr. Additionally, the registrant commented that the USEPA added a "No TC" designation for the post application activity Harvesting (mechanical).

Health Canada Response:

This comment submitted in response to the dimethomorph PRVD did not provide new information on current Canadian practices. Health Canada had previously received the above-cited ARTF report and had reviewed it when submitted. Based on a Health Canada analysis of agricultural practices for hops across Canada, hop harvesting in Canada is significantly less automated compared to the United States. Therefore, Health Canada had not revised the TC for harvesting (mechanically-assisted) for hops.

Currently, there are no specific exposure studies for workers harvesting hops. The 'Tx' TC cluster, derived from the ARTF studies, is used for harvesting hops, which is based on a study that monitored workers while cane turning in grapes (AR1015). As noted in the comment above, the ARTF had submitted a rationale to the USEPA and Health Canada, to change the TC from the 'Tx' TC cluster (19,300 cm^2/hr), where there is exposure across the body (hands, legs, arms, front of torso), to 'THb' TC cluster (1400 cm^2/hr), which is based on a study that monitored workers harvesting blackberries (ARF020), with most of the exposure occurring to the hands (80%) and forearms. This rationale included a summary of the current cultural practices in the United States for hop harvesting, which indicated that there was a high level of mechanization.

As discussed in the USEPA memo, hop harvesting in the United States is primarily mechanical or mechanically-assisted. In most American farms (95%), mature hop vines (bines) are mechanically cut at the base and top of the trellis. The bines then fall into a truck/trailer for transport to a picking/ stripping facility. For 67% of the stripping facilities, workers attach the bines to a system of hooks that slide along a rail after which there is no additional worker contact. Worker exposure for this activity is expected to be primarily to hands and forearms. For the other 33% of facilities, bines are mechanically unloaded at the facility and with minimal worker contact. In a few farms (5%), harvest is primarily mechanical, with a field combine mechanically stripping the cones and leaves from the bines while they hang from the trellis. Worker contact is expected to be minimal. Based on this, the USEPA had revised their TC for hop harvesting from 19,300 cm^2/hr to 1400 cm^2/hr for 'mechanically-assisted harvesting.' They also added a 'mechanically harvested' activity, which was not assigned a TC, indicating there is "no potential for human exposure".

To determine whether Canada could adopt a similar approach, Health Canada had sent a questionnaire to provincial minor use coordinators regarding agricultural practices in hop harvesting. The results of this survey indicated that much of the hop harvesting in Canada is done by hand. This includes high exposure activities such as loading the bines into the truck/trailer, loading the bines on the stripping table, and stripping by hand. These activities involve a large amount of contact of the bines with the body. Therefore, due to the fact, that a significant amount of hop harvesting in Canada occurs by hand, Health Canada did not revise the TC for hop harvesting.

Additionally, Health Canada agrees that the post application activity Harvesting (mechanical) has the "No TC" designation. This has been captured in the postapplication assessment as "All other activities" with "No TC". See revised Table IV.3 for hops below.

[Revised from PRVD 2019-03]

Table IV.3 Dermal Postapplication Exposure and Risk Assessment of Dimethomorph for Hops

Crop	Activity	TC (cm^2/hr)[a]	Max App Rate (kg ai/ha)	Dermal Exposure (mg/kg/day)[b]	Dermal MOE[c]	REI (days)
Short-, Intermediate-Term						
Hops	Harvesting (mechanically-assisted)	19300	0.225	3.67E-01	163	6[d]
	Irrigation (handset)	1750		3.33E-02	1800	0.5
	Weeding (hand)	640		1.22E-02	4930	0.5
	Stripping, scouting, tying, training	640		1.22E-02	4930	0.5
	Transplanting	230		4.37E-03	13700	0.5
	All other activities	No TC				

Max App Rate = Maximum Application Rate, TC = Transfer coefficient, MOE = Margin of Exposure, REI = restricted-entry interval
Since no Dislodgeable Foliar Residue (DFR) studies were submitted, a peak default DFR value of 25% of the application rate and dissipation rate of 10%/day were used. Three (3) applications per year with a minimum interval between applications of 10 days.
[a] 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.
[b] Dermal exposure (mg/kg bw/day) = DFR (ug/cm^2) × TC (cm^2/hr) × work duration (8 hr) × 23% /bw (80 kg).
[c] 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.
[d] Since the PHI of 7 days is specified on the label, the REI does not need to be added to the label, or the REI will default to the PHI.

1.2.3 Comment related to the proposed REI for postapplication activity in hops:

As a result of the postapplication risk assessment, the registrant noted that an REI (6 days) for the postapplication activity of mechanically-assisted harvesting of hops would not be necessary to include on the label, since the pre-harvest interval (PHI) (7 days) for hops is greater than that of the REI for mechanically-assisted harvesting.

Health Canada Response:

Updated label statements regarding the REI and PHI have been added to the required label statements for the product labels.

1.2.4 Comment related to the use of gloves in a closed cab or cockpit:

Although a closed cab/cockpit was not required, the registrant would like to ensure that the label requirement “gloves are not required during application within a closed cab or cockpit” be added to all end-use product labels, as this is a common practice for growers who operate using a closed cab/cockpit.

Health Canada Response:

This statement has been added to required label statements for the remaining two product labels.

2.0 Comments Related to the Environmental Risk Assessment

2.1 Comment related to missing references:

The registrant highlighted a number of studies listed in the ecotoxicology summary tables in Appendix VII of PRVD2019-03 that were not in the list of references at the end of the document. The PMRA reference number for these studies are 2885738, 2885739, 2885747, 2885749, 2885750, 2885741, 2885742, 2885743, and 2885744.

Health Canada Response:

The references appearing in the ecotoxicology summary tables that were unintendedly omitted from the reference list in PRVD2019-03 are identified in Appendix IV.

2.2 Comment related to calculations of buffer zones:

Whereas maximum buffer zones for aerial and airblast applications on the Acrobat 50 WP and Forum labels are currently only 1 meter, buffer zones up to 10 m were proposed in Appendix XI of PRVD2019-03. The registrant pointed to the fact that all the RQs in Table 19 of PRVD2019-03 were close to or less than the LOC of one when refined EECs are calculated using standard drift values with a 1 m buffer zone. The registrant asserts that the wider buffer zones proposed are unnecessary as those of 1 m used in the determination of RQs appeared to be sufficient to reduce these to acceptable levels for all applications (groundboom, aerial, and airblast). The registrant has requested a re-examination of the buffer zone calculations for Acrobat and Forum labels.

Health Canada Response:

In 2006, EFSA based their long-term risk assessment for aquatic organisms on the chronic NOEC of 0.056 mg dimethomorph/L from an early life stage test on rainbow trout (PMRA# 2930943). In this study, while no critical singular developmental steps were affected, effects on growth were detected. Health Canada agrees with the EFSA conclusion, especially for an early life stage where growth can be critical for the survival of the fish and/or amphibians. This chronic fish endpoint is reported in PRVD2019-03 (Page 53, Table 2 “Aquatic Toxicity Data Following Exposure to Dimethomorph Technical and Formulations”).

The buffer zone for the amphibian habitat in 15-cm water depth was calculated using this chronic NOEC endpoint of 0.056 µg a.i./L for rainbow trout (early life stage) as a surrogate for amphibian rather than the 1/10 of the acute 96-h LC_{50} endpoint value of 0.34 mg a.i/L. This endpoint was omitted from three tables in PRVD 2019-03. Additional lines (shaded rows) have been added in corrected versions of Tables 14 and 19 below. In addition, the table identified as “Table 4 Further Risk Characterization of Dimethomorph Exposed to Aquatic Organisms Using Canadian and American Freshwater Monitoring Data” on page 70 of PRVD2019-03 should have been identified as Table 20. This table has also been updated with the amphibian surrogate (rainbow trout) NOEC value of 0.056 mg a.i./L for the three scenarios presented in the environmental risk assessment.

The buffer zones are correctly calculated, up to 10 m for aerial and airblast applications, when the appropriate endpoint (ELS NOEC) is used.

[Revised from PRVD 2019-03]

Table 14 Screening Level Risk Assessment of Dimethomorph to Freshwater Fish and 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[1]	Exceed LOC?
Cucurbit-groundboom and aerial scenario									
Amphibian (surrogate)	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	959	15	0.639	**1.88**	**Yes**
		Chronic	NOEC (ELS)	0.056	959	15	0.639	**11.4**	**Yes**
Rainbow trout	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	959	80	0.120	0.35	No
		Chronic	NOEC (ELS)	0.056	959	80	0.120	**2.14**	**Yes**
Grape-airblast scenario									
Amphibian (surrogate)	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	762	15	0.508	**1.49**	**Yes**
		Chronic	NOEC (ELS)	0.056	762	15	0.508	**9.07**	**Yes**
Rainbow trout	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	762	80	0.095	0.28	No
		Chronic	NOEC (ELS)	0.056	762	80	0.095	**1.70**	**Yes**

[1] 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; ELS = Early Life Stage; cells with values in bold font indicate that the RQ exceeded the LOC. Shaded rows contain newly inserted information that was missing from the original table in PRVD2019-03.

[Revised from PRVD 2019-03]

Table 19 Further Risk Characterization of Dimethomorph to Aquatic Organisms Following 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[1] (mg a.i./L)	RQ[2]	Exceed LOC?
Freshwater invertebrates chronic exposure										
Cucurbit groundboom scenario										
Water flea	*Daphnia magna*	Chronic	NOAEC	0.1	959	80	0.06	0.007	0.07	No
Cucurbit aerial scenario										
Water flea	*Daphnia magna*	Chronic	NOAEC	0.1	959	80	0.23	0.028	0.28	No
Grape airblast scenario										
Water flea	*Daphnia magna*	Chronic	NOAEC	0.1	762	80	0.74	0.07	0.70	No
Amphibian (surrogate rainbow fish)										
Cucurbit groundboom scenario										
Rainbow trout	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	959	15	0.06	0.038	0.11	No
		Chronic	NOEC (ELS)	0.056	959	15	0.06	0.038	0.68	No
Cucurbit aerial scenario										
Rainbow trout	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	959	15	0.23	0.147	0.43	No
		Chronic	NOEC (ELS)	0.056	959	15	0.23	0.147	**2.63**	**Yes**

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha)	Water depth (cm)	drift	EEC[1] (mg a.i./L)	RQ[2]	Exceed LOC?
Grape airblast scenario										
Rainbow trout	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	762	15	0.74	0.380	**1.11**	**Marginal**
		Chronic	NOEC (ELS)	0.056	762	15	0.74	0.380	**6.79**	**Yes**
Freshwater fish chronic exposure										
Cucurbit groundboom scenario										
Rainbow trout	*Onchorhynchus mykiss*	Chronic	NOEC (ELS)	0.056	959	80	0.06	0.007	0.13	No
Cucurbit aerial scenario										
Rainbow trout	*Onchorhynchus mykiss*	Chronic	NOEC (ELS)	0.056	959	80	0.23	0.028	0.50	No
Grape airblast scenario										
Rainbow trout	*Onchorhynchus mykiss*	Chronic	NOEC (ELS)	0.056	762	80	0.74	0.07	**1.25**	**Yes**
Marine/estuarine fish chronic exposure										
Cucurbit groundboom scenario										
Sheepshead minnow	*Cyprinodon variegatus*	Chronic	NOAEC	0.063	225	80	0.06	0.002	0.03	No
Cucurbit aerial scenario										
Sheepshead minnow	*Cyprinodon variegatus*	Chronic	NOAEC	0.063	225	80	0.23	0.006	0.1	No
Grape airblast scenario										
Sheepshead minnow	*Cyprinodon variegatus*	Chronic	NOAEC	0.063	225	80	0.74	0.021	0.33	No

[1] Only a single application is considered in marine/estuarine drift RQ calculations; ELS = Early Life Stage; Cells with values in bold font indicate that the screening level RQ exceeds the LOC of 1.0. Shaded rows contain newly inserted information that was missing from the original table in PRVD2019-03.

[Revised from PRVD 2019-03]

Table 20 Further Risk Characterization of Dimethomorph Exposed to Aquatic Organisms Using Canadian and USA 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[1]	Exceed LOC?
Freshwater invertebrates										
Cucurbit groundboom scenario										
Water flea	*Daphnia magna*	Chronic	NOAEC	0.1	959	80	None	0.011	0.11	No
Cucurbit aerial scenario										
Water flea	*Daphnia magna*	Chronic	NOAEC	0.1	959	80	None	0.011	0.11	No
Grape airblast scenario										
Water flea	*Daphnia magna*	Chronic	NOAEC	0.1	762	80	None	0.011	0.11	No
Amphibian										
Cucurbit groundboom scenario										
Rainbow trout	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	959	15	None	0.044	0.13	No
		Chronic	NOEC (ELS)	0.056	959	15	None	0.044	0.79	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[1]	Exceed LOC?
Cucurbit aerial scenario										
Rainbow trout	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	959	15	None	0.044	0.13	No
		Chronic	NOEC (ELS)	0.056	959	15	None	0.044	0.79	No
Grape airblast scenario										
Rainbow trout	*Onchorhynchus mykiss*	Acute	1/10 LC_{50}	0.34	762	15	None	0.044	0.13	No
		Chronic	NOEC (ELS)	0.056	762	15	None	0.044	0.79	No
Freshwater fish										
Cucurbit groundboom scenario										
Rainbow trout	*Onchorhynchus mykiss*	Chronic	NOEC (ELS)	0.056	959	80	None	0.011	0.20	No
Cucurbit aerial scenario										
Rainbow trout	*Onchorhynchus mykiss*	Chronic	NOEC (ELS)	0.056	959	80	None	0.011	0.20	No
Grape airblast scenario										
Rainbow trout	*Onchorhynchus mykiss*	Chronic	NOEC (ELS)	0.056	762	80	None	0.011	0.20	No
Marine/estuarine fish										
Cucurbit groundboom scenario										
Sheepshead minnow	*Cyprinodon variegatus*	Chronic	NOAEC	0.063	225	80	None	0.011	0.17	No
Cucurbit aerial scenario										
Sheepshead minnow	*Cyprinodon variegatus*	Chronic	NOAEC	0.063	225	80	None	0.011	0.17	No
Grape airblast scenario										
Sheepshead minnow	*Cyprinodon variegatus*	Chronic	NOAEC	0.063	225	80	None	0.011	0.17	No

ELS = Early Life Stage; Cells with values in bold font indicate that the screening level RQ exceeds the LOC of 1.0. Shaded rows contain newly inserted information that was missing from the original version of the table in PRVD2019-03.

Appendix III Label Amendments for Products Containing Dimethomorph

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

I. Label Amendments for TGAI and Manufacturing Concentrates Containing Dimethomorph

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.'

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 (on Forum Technical 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 (on ZAMPRO Bulk 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."

II. Label Amendments for Commercial End-use Products Containing Dimethomorph

The following amendments are required on all commercial products labels:

Under **"PRECAUTIONS"**:

Add:

> "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."

> "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":**

Add:

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

Under **"DIRECTIONS FOR USE"**, add the following on labels with registered greenhouse uses only:

"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 of 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
Airblast	Grapes	Early growth stage	10	0
		Late growth stage	4	0
	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 [Reg. 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	All activities	12 hours
Hops	Harvesting (mechanically-assisted)	7 days
	All other activities	12 hours
Grapes	Girdling, turning	8 days
	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 application	Crops		Buffer Zones (metres) Required for the Protection of:			
			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
		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 [Reg. 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. Gloves are not required during application within a closed cab and/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; 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

Hops	Harvesting (mechanically-assisted)	7 days
	All other activities	12 hours
Grapes	Girdling, turning	8 days
	All other activities	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, 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. 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. Gloves are not required during application within a closed cab and/or cockpit."

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. "**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 Activities	Restricted Entry Interval (REI)
Potatoes; Cucurbit vegetables; Brassica vegetables; Leafy vegetables; Fruiting vegetables; Bulb vegetables; 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
Hops	Harvesting (mechanically-assisted)	7 days
	All other activities	12 hours
Grapes	Girdling, turning	8 days
	All other activities	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."

Appendix IV References

Studies Considered in PRVD2019-03 But Omitted From Reference List

PMRA#	Reference
2885738	Kleebaum, K. 2014. Acute toxicity of BAS 550 01 F to honeybee larvae (*Apis mellifera* L.) under laboratory conditions (in vitro). BASF DocID: 2013/1178041. Final report 13 10 48 077 B; Project ID 425966. 56 p. DACO 9.2.4.3.
2885739	Schmitzer, S. 2014. Chronic Oral Toxicity Test of BAS 550 01 F on the Honey Bee (*Apis mellifera* L.) in the Laboratory. BASF DocID: 2013/1178040. Final report, BASF study ID: 425967, Project ID: 85271136. 39 p. DACO 9.2.4.4.
2885741	Mitchell, G.C., Barker, C.L., Boeri, R.L., Magazu, J. P., Ward, T.J. 1997. Effect of AC 336379 (dimethomorph) on New Shell Growth in the Eastern Oyster (*Crassostrea virgnica*) Under Flow-Through Test Conditions. Report Number: ECO 96-305. American Cyanamid Company Lab ProjectID: 954-96-305; TR Wilbury Laboratories Lab ProjectID: 1181-AC. 105 p. DACO 9.4.4.
2885742	Hicks, S.L. 2010. BAS 550 F: Life-Cycle Toxicity Test of the Saltwater Mysid, *Americamysis bahia*, Conducted Under Flow-Through Conditions. ABC Study No. 65141; BASF Study No. 375483; BASF Report ID: 2010/7008279. 79 p. DACO 9.4.5.
2885743	Hicks, S.L. 2010. BAS 550 F: Early Life-Stage Toxicity Test with the Sheepshead Minnow, *Cyprinodon variegatus*, Under Flow-Through Conditions. ABC Study No. 65140; BASF Study No.: 375482; BASF Report ID: 2010/7012691. 94 p. DACO 9.5.3.1.
2885744	Mitchell, G.C., Barker, C.L., Boeri, R.L., Magazu, J. P., Ward, T.J. 1997. Acute Toxicity of AC 336379 (Dimethomorph) to the Sheepshead Minnow (*Cyprinodon variegatus*) Under Flow-Through Test Conditions. Report Number: ECO 96-306. American Cyanamid Company Lab ProjectID: 954-96-306; TR Wilbury Laboratories Lab ProjectID: 1182-AC. 107 p. DACO 9.5.2.4.
2885747	Jatzek. 2001. BAS 550 F - Determination of the inhibitory effect on the cell multiplication of unicellular green algae. BASF DocID: 2001/1019489. Lab projectID: 01/0271/60/1. 27 p. DACO 9.8.2.
2885749	Hughes, J.S., Williams, T.L., Conder, L.A. and Canez, V.M. 1997. Effects of a 9%/60% WP co-formulation of AC 336,379 (dimethomorph) and mancozeb on the Growth of *Anabaena flos-aquae*. Report Number: ECO 96-111. American Cyanamid Company Lab ProjectID: 954-96-111; Carolina Ecotox ProjectID: 12-09-2. 79 p. DACO 9.8.6.
2885750	Hughes, J.S., Williams, T.L., Conder, L.A. and Canez, V.M. 1997. Effects of a 9%/60% WP co-formulation of AC 336,379 (dimethomorph) and mancozeb on the Growth of *Navicula pelliculosa*. Report Number: ECO 96-113. American Cyanamid Company Lab ProjectID: 954-96-113; Carolina Ecotox ProjectID: 12-09-3. 79 p. DACO 9.8.6.

References Considered Following Publication of PRVD2019-03

Information submitted by the registrant considered in responding to comments related to occupational/residential exposure

PMRA#	Reference
2463743	2013. Ross, J.H., Driver, J.H. Estimated Transfer Coefficient for Hops Harvest. Agriculture Re-entry Task Force.

Additional information considered in responding to comments related to occupational/ residential exposure

PMRA#	Reference
2859858	2015. U.S. EPA. Review of “Estimated Transfer Coefficient for Hops Harvest”. EPA: Washington, DC.