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Proposed Registration Decision

PRD2015-18

# Fluopicolide

*(publié aussi en français)*

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# Overview

## Proposed Registration Decision for Fluopicolide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Fluopicolide Technical and the end-use products, Fluopicolide 4 SC Fungicide and Presidio Fungicide, containing the technical grade active ingredient fluopicolide, to suppress or control important fungal diseases on vegetable crops and outdoor ornamentals (bedding plants and cut flowers).

Fluopicolide Technical (Registration Number 30049), Presidio Fungicide (Registration Number 30051), and Fluopicolide 4 SC Fungicide (Registration Number 30050) are conditionally registered in Canada. The detailed review can be found in Evaluation Report ERC2011-08, *Fluopicolide*. The current applications were submitted to convert Fluopicolide Technical, Fluopicolide 4 SC Fungicide, and Presidio Fungicide from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Fluopicolide Technical, Fluopicolide 4 SC Fungicide, and Presidio Fungicide.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>1</sup> if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value<sup>2</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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<sup>1</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

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

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

Before making a final registration decision on fluopicolide, the PMRA will consider any comments received from the public in response to this consultation document.<sup>3</sup> The PMRA will then publish a Registration Decision<sup>4</sup> on fluopicolide, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

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

## **What Is Fluopicolide?**

Fluopicolide is the active ingredient present in the end-use products Presidio Fungicide and Fluopicolide 4 SC Fungicide, which belong to a new chemical class (Group 43). Fluopicolide causes rapid destabilization of fungal cell structures. It is a systemic and protectant fungicide applied as a foliar or a drench treatment that is used to control some important diseases on plants.

## **Health Considerations**

### **Can Approved Uses of Fluopicolide Affect Human Health?**

**Fluopicolide is unlikely to affect your health when used according to label directions.**

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

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

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<sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Fluopicolide is of low acute toxicity by oral, dermal and inhalation routes in the rat. It is non-irritating to the skin and minimally irritating to the eyes of rabbits and it is not a dermal sensitizer in guinea pigs. Consequently, no signal words are required on the label. The end-use products Presidio Fungicide and Fluopicolide 4 SC Fungicide are of low acute toxicity by the oral and dermal routes of exposure and slightly toxic by the inhalation route in the rat. They are minimally irritating to the skin and mildly irritating to the eyes of rabbits and are not dermal sensitizer in guinea pigs. The signal words “CAUTION POISON - EYE IRRITANT” are required on the label for the end-use products.

No treatment-related toxicity was observed in rats after repeated exposure with high dose levels of fluopicolide via the dermal route.

Fluopicolide is not genotoxic and is not likely to pose a carcinogenic risk to humans. There was no indication that fluopicolide caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of fluopicolide over long periods of time were decreases in body weight and body weight gain and changes to the kidney, liver and adrenal glands. When fluopicolide was given to pregnant animals, malformations (rats) and abortions (rabbits) were observed at doses that were also toxic to the dams. Due to the nature of these endpoints and their potential implications on the health of the foetus, extra protective factors were applied during the risk assessment to further reduce the allowable level of human exposure to fluopicolide.

The risk assessment was conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children, nursing mothers and women of child bearing age). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

### **Risks in Residential Environments**

**Postapplication risks for individuals contacting outdoor ornamentals (bedding plants and cut flowers) treated with Fluopicolide 4 SC Fungicide or Presidio Fungicide are not of concern.**

There is potential for dermal exposure for individuals through contact with dislodgeable residues following commercial application of fluopicolide on outdoor ornamentals (bedding plants and cut flowers) sold in nurseries for residential areas.

Postapplication risk estimates for individuals contacting treated outdoor ornamentals (bedding plants and cut flowers) are not of concern. Therefore, contact with foliage of treated ornamentals is acceptable once residues have dried.

## **Occupational Risks From Handling Fluopicolide 4 SC Fungicide or Presidio Fungicide**

**Occupational risks are not of concern when Fluopicolide 4 SC Fungicide or Presidio Fungicide are used according to the label directions, which include protective measures.**

Farmers, custom applicators, or ornamental nursery operators who mix, load or apply Fluopicolide 4 SC Fungicide or Presidio Fungicide, as well as field workers re-entering treated fields and nurseries, can come in direct contact with fluopicolide residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Fluopicolide 4 SC Fungicide or Presidio Fungicide must wear a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes. The label also requires that workers do not enter treated fields or other treated sites for specific activities in some crops for 1 to 16 days after application. For all other uses, a restricted-entry interval (REI) of 12 hours is specified. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to workers handling Fluopicolide 4 SC Fungicide or Presidio Fungicide is not of concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

## **Residues in Water and Food**

**Dietary risks from food and drinking water are not of health concern.**

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation that may ingest the most fluopicolide relative to body weight, are expected to be exposed to less than 37% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from fluopicolide is not of concern for all population sub-groups.

The acute aggregate (food and water) dietary intake estimate for women aged 13-49 years was less than 16% of the reference dose, which is not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk. The fluopicolide MRLs specified under the *Pest Control Products Act* may be found at Health Canada's MRL Database.

## **Environmental Considerations**

### **What Happens When Fluopicolide Is Introduced Into the Environment?**

**When used according to label directions fluopicolide is not expected to pose an unacceptable risk to the environment.**

When fluopicolide is released into the environment some of it can be found in soil and surface water. In the terrestrial environment, fluopicolide is expected to be persistent and residues may carry over into the following growing season. Fluopicolide is shown to bind weakly to soils, however, there is evidence that adsorption to soil may increase over time as the product is used. The major transformation product, 2,6-dichlorobenzamide (BAM), is expected to be mobile in soils. Both fluopicolide and BAM are expected to leach through soil and have the potential to reach groundwater.

In aquatic environments, fluopicolide is expected to be persistent and to partition from the water phase to the sediment; BAM has been shown to partition mainly into the water phase. Fluopicolide residues are not expected in the air because of its low volatility and it has a low potential for bioaccumulation in biota. BAM is not expected to be a concern to terrestrial and aquatic life.

Fluopicolide may pose a potential risk to aquatic organisms. In order to minimize the potential exposure of aquatic organisms to fluopicolide, an unsprayed area (spray buffer zone) is needed between the sprayer and downwind sensitive habitats. The width of these spray buffer zones is specified on the product label.

## **Value Considerations**

### **What Is the Value of Fluopicolide 4 SC Fungicide and Presidio Fungicide?**

Fluopicolide, the active ingredient in Fluopicolide 4 SC Fungicide and Presidio Fungicide, controls or suppresses economically important diseases on vegetable crops and outdoor ornamentals (bedding plants and cut flowers).

Presidio Fungicide and Fluopicolide 4 SC Fungicide are products formulated as a foliar or a drench treatment against important diseases on vegetable crops and outdoor ornamentals (bedding plants and cut flowers). Presidio Fungicide and Fluopicolide 4 SC Fungicide are active against certain pathogens by affecting the normal cell division cycle. They have systemic and curative properties and offer additional tools for disease and resistance management, particularly for the control of downy mildew on various vegetable crops as well as late blight on potato and tomato. Presidio Fungicide and Fluopicolide 4 SC Fungicide are most effective when applied in a regularly scheduled spray program and are to be used as a tank-mix with other registered fungicides with a different mode of action.

Additional value information was submitted and deemed sufficient to fulfill the value conditions for Fluopicolide 4 SC Fungicide and Presidio Fungicide.



## **Measures to Minimize Risk**

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Fluopicolide 4 SC Fungicide and Presidio Fungicide to address the potential risks identified in this assessment are as follows.

### **Key Risk-Reduction Measures**

#### **Human Health**

Because there is a concern with users coming into direct contact with fluopicolide on the skin, anyone mixing, loading, applying, and involved in clean-up or repair activities with Fluopicolide 4 SC Fungicide or Presidio Fungicide must wear the recommended personal protective equipment. In addition, standard label statements to protect against drift during application are included on the label. The label also requires REIs of 8 days for hand pruning, thinning, tying and leaf pulling in grapes, 16 days for cane turning and girdling in table grapes, and 1 day for hand pruning and irrigation in brassica vegetables. A 12-hour REI is required for all other re-entry activities.

#### **Environment**

Precautionary statements and spray buffer zones for non-target aquatic habitats are required as a result of the environmental risk assessment. To reduce the potential for runoff of fluopicolide to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are required. Fluopicolide residues could have a high leaching potential, therefore, a label statement is required advising that use may result in contamination of groundwater, particularly in areas where soils are permeable and/or the depth to the water table is shallow. Fluopicolide is persistent and may carry over into the following growing season, therefore a label statement is required advising that products containing fluopicolide should not be used in areas treated with fluopicolide during the previous season.

#### **Next Steps**

Before making a final registration decision on fluopicolide, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

## **Other Information**

When the PMRA makes its registration decision, it will publish a Registration Decision on fluopicolide (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).



## Science Evaluation

An evaluation report, ERC2011-08, *Fluopicolide*, provides a summary of data reviewed and the rationale for the regulatory decision. The information captured herein relates to new information provided to the Agency in support of a conversion from conditional to full registration.

### Fluopicolide

#### 1.0 The Active Ingredient, Its Properties and Uses

For full details on the active ingredient and its properties and uses, please refer to ERC2011-08, *Fluopicolide*.

#### 2.0 Methods of Analysis

For full details on the methods of analysis for fluopicolide and its associated end-use products, please refer to ERC2011-08, *Fluopicolide*.

#### 3.0 Impact on Human and Animal Health

For full details on the toxicological summary, determination of acute reference doses and acceptable daily intake, as well as occupational and residential risk assessments, please refer to ERC2011-08, *Fluopicolide*.

##### 3.1 Food Residues Exposure Assessment

For full details, please refer to ERC2011-08, *Fluopicolide*.

###### 3.1.1 Residues in Plant and Animal Foodstuffs

Additional freezer storage stability data demonstrated that residues of fluopicolide, 2,6-dichlorobenzamide (BAM), and 3-chloro-5-(trifluoromethyl)-2-pyridinecarboxylic acid (PCA), when stored at approximately -20°C, were stable for at least 38 months in lettuce and 45 months in cabbage (Appendix I, Table 1). The information is adequate to support the storage intervals from the crop field trials and the field accumulation studies.

###### 3.1.2 Dietary Risk Assessment

Acute and chronic (non-cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.14), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994-1996 and 1998.

### **3.1.2.1 Chronic Dietary Exposure Results and Characterization**

The following criteria were applied to the refined chronic non-cancer analysis for fluopicolide: 100% crop treated, default and experimental processing factors (where available), residues in various crops based on supervised trial median residue values, and anticipated residues for the processed commodities and animal commodities (where applicable). The refined chronic dietary exposure from all supported fluopicolide food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 5% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to fluopicolide from food and drinking water is 13% (0.008626 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for all infants (< 1 year), which is less than 37% (0.024349 mg/kg bw/day) of the ADI.

### **3.1.2.2 Acute Dietary Exposure Results and Characterization**

The following assumptions were applied in the refined acute analysis for fluopicolide: 100% crop treated, default processing factors, maximum residues or highest average field trial in/on crops, and anticipated residues for animal commodities. The refined acute dietary exposure (food alone) for all supported fluopicolide registered commodities is estimated to be 11% (0.021172 mg/kg bw/day) of the acute reference dose (ARfD) for females 13–49 years old (95<sup>th</sup> percentile, deterministic). Aggregate exposure from food and drinking water is considered acceptable as it was less than 16% of the ARfD for females 13–49 years old, the only sub-population for which an ARfD is required to be established. Refer to Appendix I, Table 2 for the outcomes of the acute and chronic (non-cancer) risk assessments.

### **3.1.3 Aggregate Exposure and Risk**

The aggregate risk for fluopicolide consists of exposure from food and drinking water sources only. Contribution to the aggregate risk from residential exposure due to potential contact with treated ornamentals was considered minimal and not of concern.

### **3.1.4 Maximum Residue Limits**

Refer to Evaluation Report ERC2011-08, *Fluopicolide*.

The fluopicolide maximum residue limits (MRLs), captured in Evaluation Report ERC2011-08, *Fluopicolide* and regulated under the *Pest Control Products Act*, may be found on Health Canada's MRL Database.

## **4.0 Impact on the Environment**

For full details on the impact of fluopicolide on the environment, please refer to ERC2011-08, *Fluopicolide*.

## 5.0 Value

### 5.1 Effectiveness Against Pests

Efficacy was reviewed and established for the supported claims. For more details, refer to ERC2011-08, *Fluopicolide*. The claims discussed below were conditionally supported and additional value information was submitted to confirm the efficacy.

#### 5.1.1 Acceptable Efficacy Claims

##### 5.1.1.1 Control of downy mildew (*Peronospora parasitica*) on brassica head and stem vegetables and brassica root vegetables

This claim was conditionally supported, pending additional value information on cabbage, radish and/or turnip to confirm the efficacy. Additional experimental trials were provided (two on broccoli, one on mustard green and one on Chinese broccoli). A scientific rationale was also submitted to extrapolate the efficacy of fluopicolide to root brassica vegetables. The experimental trials demonstrated an average efficacy of 75% control (55 to 86% control) of downy mildew severity when Presidio Fungicide was applied at 219 to 292 L product/ha with one to four applications. In one trial, Presidio Fungicide was tank-mixed and applied in alternation with other commercial standards and obtained 23% increase in control compared to the same tank mix without Presidio Fungicide.

A scientific rationale was submitted in lieu of efficacy trials on brassica root vegetables: “The epidemiology and behaviour of brassica downy mildew caused by *P. parasitica* on brassica head and stem vegetables (cabbage, cauliflower, broccoli, Brussels sprouts, mustard greens) and root brassica vegetables (radish, rutabaga, horseradish, turnip) is identical. Monitoring, disease forecasting and management of this disease on brassica vegetable crops is identical”. The scientific rationale was deemed acceptable. The claim of control of downy mildew (*P. parasitica*) on brassica head and stem vegetables and brassica root vegetables is fully supported and the conditions attached to this claim have been fulfilled.

##### 5.1.1.2 Suppression of phytophthora blight/crown rot (*Phytophthora capsici*) on cucurbit vegetables

This claim was conditionally supported, pending additional value information on pumpkin to confirm the efficacy. Three additional experimental trials were provided on pumpkin, one of which tested the efficacy of Presidio Fungicide against *P. capsici*. The experimental trial demonstrated 46 to 65% disease severity reduction at the low and high rate, respectively, under moderate disease pressure. This level of disease reduction is in line with a claim of suppression.

The claim of suppression of *Phytophthora* blight/crown rot caused by *P. capsici* on cucurbits vegetables is fully supported and the conditions attached to this claim have been fulfilled.

### **5.1.1.3 Suppression of phytophthora crown and root rot (*Phytophthora* spp.) on field and container grown outdoor ornamentals (bedding plants and cut flowers)**

This claim was conditionally supported, pending additional value information from two additional trials on ornamental plants infected by *P. ramorum* and *P. parasitica* to confirm efficacy.

A scientific rationale and a value summary from the IR-4 Horticulture Program were submitted to fulfil the above condition. Previous results demonstrated that Presidio Fungicide reduced severity of *P. cryptogea*, *P. drechsleri* and *P. nicotianae* (syn. *P. parasitica*) at the suppression level on gerbera, snapdragon and poinsettia. It was also noted that Presidio Fungicide showed similar effect on *P. capsici* on pepper, tomato and pumpkin as reviewed under the claims of fruiting vegetables and cucurbit vegetables. The IR-4 value summary demonstrated that fluopicolide provided variable levels of control on the different ornamental plants tested, i.e. good to excellent control of *P. nicotianae* (syn. *P. parasitica*) and tended to provide good efficacy on *P. ramorum*. The level of control also varied depending on the type of plant (for example, good to excellent control of *P. cinnamomi* on azalea but variable control on rhododendron).

The claim of suppression of *Phytophthora* crown and root rot (*Phytophthora* spp.) on field and container grown outdoor ornamentals (bedding plants and cut flowers) is fully supported and the conditions attached to this claim have been fulfilled.

## **5.2 Non-Safety Adverse Effects**

Refer to ERC2011-08, *Fluopicolide* in the section Phytotoxicity to Host Plants for a summary of non-safety adverse effects.

## **5.3 Consideration of Benefits**

Refer to ERC2011-08, *Fluopicolide* for information on the social and economic impact, compatibility with current management practices including integrated pest management, occurrence or possible occurrence of the development of resistance, and contribution to risk reduction.

### **5.3.1 Survey of Alternatives**

Refer to Appendix I, Table 3 for a summary of the active ingredients currently registered for the same uses as Presidio Fungicide and Fluopicolide 4 SC Fungicide.

## **5.4 Supported Uses**

For full details on the supported uses, please refer to ERC2011-08, *Fluopicolide* and Appendix 1, Table 4.

## **6.0 Pest Control Product Policy Considerations**

### **6.1 Toxic Substances Management Policy Considerations**

For full details on the Toxic Substances Management Policy considerations for fluopicolide, please refer to ERC2011-08, *Fluopicolide*.

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

For full details on formulants and contaminants of human or environmental concern for fluopicolide, please refer to ERC2011-08, *Fluopicolide*.

## **7.0 Summary**

### **7.1 Human Health and Safety**

For full details on the human health and safety of fluopicolide, please refer to ERC2011-08, *Fluopicolide*.

The use of fluopicolide on crops listed on the labels and the import of fluopicolide-treated commodities does not constitute an unacceptable chronic or acute dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors.

### **7.2 Environmental Risk**

For full details on the environmental risk of fluopicolide, please refer to ERC2011-08, *Fluopicolide*.

### **7.3 Value**

The submitted value information is sufficient to meet the conditions for full registration. Refer to Appendix I, Table 4 for a list of supported uses.

## **8.0 Proposed Regulatory Decision**

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Fluopicolide Technical and the end use products Fluopicolide 4 SC Fungicide and Presidio Fungicide, containing the technical grade active ingredient fluopicolide, to suppress or control important fungal diseases on vegetable crops and outdoor ornamentals (bedding plants and cut flowers).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.





**List of Abbreviations**

°C	degrees Celsius
µg	microgram
ADI	acceptable daily intake
ARfD	acute reference dose
BAM	2,6-dichlorobenzamide
bw	body weight
FRAC	Fungicide Resistance Action Committee
ha	hectare(s)
kg	kilogram
L	litre
mg	milligram
MRL	maximum residue limit
PCA	3-chloro-5-(trifluoromethyl)-2-pyridinecarboxylic acid
PMRA	Pest Management Regulatory Agency
REI	restricted-entry interval
SC	soluble concentrate
spp.	species



## Appendix I Tables and Figures

**Table 1 Integrated Food Residue Chemistry Summary**

<b>FREEZER STORAGE STABILITY</b>	<b>PMRA #s 2312292 and 2312294</b>
<p><b>Plant matrices: lettuce and cabbage</b>            The freezer storage stability data indicate that residues of fluopicolide, BAM and PCA are stable at -20°C for 38 months in lettuce and 45 months in cabbage.</p>	

**Table 2 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment**

<b>DIETARY RISK FROM FOOD AND WATER</b>			
	<b>POPULATION</b>	<b>ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)</b>	
		<b>Food Alone</b>	<b>Food and Water</b>
<p><b>Refined chronic non-cancer dietary exposure analysis</b>   <b>ADI = 0.067 mg/kg bw/day</b>   <b>Estimated chronic drinking water concentration = 0.323 µg/L</b></p>	<b>All Infants (&lt;1 year old)</b>	3.0	36.3
	<b>Children 1-2 years old</b>	5.0	20.1
	<b>Children 3-5 years old</b>	4.1	18.3
	<b>Children 6-12 years old</b>	2.8	12.6
	<b>Youth 13-19 years old</b>	2.1	9.4
	<b>Adults 20-49 years old</b>	2.6	12.1
	<b>Adults 50+ years old</b>	2.6	12.6
	<b>Females 13-49 years old</b>	2.6	12.1
	<b>Total population</b>	2.7	12.9
<p><b>Refined acute dietary exposure analysis, 95<sup>th</sup> percentile</b>   <b>ARfD = 0.2 mg/kg bw</b>   <b>Estimated acute drinking water concentration = 0.326 µg/L</b></p>	<b>POPULATION</b>	<b>ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)</b>	
		<b>Food Alone</b>	<b>Food and Water</b>
	<b>Females 13-49 years</b>	10.59	15.63

**Table 3 Registered Alternatives (As of May, 2014)**

<b>Crop</b>	<b>Disease</b>	<b>Active ingredient and FRAC Fungicide Group</b>
Brassica (head and stem) vegetables	Downy mildew ( <i>Peronospora parasitica</i> )	<i>Bacillus subtilis</i> (44) Boscalid (7) (Suppression) Chlorothalonil (M5) (on broccoli, brussels sprouts, cabbage and cauliflower) Fosetyl AL (33) (on broccoli and bok choy) Mandipropamid (40) Zineb (M3) (on broccoli, brussels sprouts, cabbage and cauliflower) Fenamidone (11) (Suppression) Dimethomorph (40) (Suppression) Cyazofamid (21) (Suppression) Pyraclostrobin (11) + Boscalid (7) (Suppression) Ametoctradin (45) + Dimethomorph (40) Ametoctradin (45) (Suppression) Mono- and dibasic sodium, potassium, and ammonium phosphites (33) (Suppression)
Brassica root vegetables	Downy mildew ( <i>Peronospora parasitica</i> )	Fosetyl AL (33) (for rutabaga)
Cucurbit vegetables	Downy mildew ( <i>Pseudoperonospora cubensis</i> )	<i>Bacillus subtilis</i> (44) Chlorothalonil (M5) Copper oxychloride (M1) Cyazofamid (21) Fenamidone (11) Folpet (M4) Mancozeb (M3) Mandipropamid (40) (Suppression) Propamocarb (28) Pyraclostrobin (11) Zineb (M3) Ametoctradin (45) + Dimethomorph (40) Ametoctradin (45)
	Phytophthora blight/crown rot ( <i>Phytophthora capsici</i> )	Ametoctradin (45) + Dimethomorph (40) Ametoctradin (45) (Suppression)

Crop	Disease	Active ingredient and FRAC Fungicide Group
Fruiting vegetables	Late blight ( <i>Phytophthora infestans</i> )	Captan (M4) (on tomato) Chlorothalonil (M5) (on tomato) Copper hydroxide (M1) (on tomato) Copper oxychloride (M1) (on tomato) Cymoxanil (27) (on tomato) Famoxadone (11) (on tomato) Mancozeb (M3) (on tomato) Mandipropamid (40) (on tomato) Metiram (M3) (on tomato) Pyraclostrobin (11) Zineb (M3) (on tomato, eggplant and pepper) Ametoctradin (45) + Dimethomorph (40)
	Phytophthora blight ( <i>Phytophthora capsici</i> )	Mandipropamid (40) (Suppression on pepper) Ametoctradin (45) + Dimethomorph (40) (Suppression)
Grapes	Downy mildew ( <i>Plasmopara viticola</i> )	Azoxystrobin (11) Boscalid (7) Captan (M4) Copper oxychloride (M1) Folpet (M4) Kresoxim-methyl (11) Mancozeb (M3) Mandipropamid (40) Metalaxyl-M (4) Metiram (M3) Pyraclostrobin (11) Zoxamide (22) Fosetyl AL (33) Dimethomorph (40) Ametoctradin (45) + Dimethomorph (40) Tea tree oil (Suppression)
Leafy vegetables (except brassica vegetables)	Downy mildew ( <i>Bremia lactucae</i> , <i>Peronospora farinosa</i> )	Azoxystrobin (11) (on spinach) <i>Bacillus subtilis</i> (44) (on lettuce) Boscalid (7) (Suppression on spinach) Fosetyl AL (33) (on greenhouse and field lettuce) Mandipropamid (40) (for <i>Bremia lactucae</i> ) Metalaxyl-M (4) (on spinach) Zineb (M3) (on lettuce) Fenamidone (11) (Suppression on

Crop	Disease	Active ingredient and FRAC Fungicide Group
		spinach) Dimethomorph (40) (Suppression on lettuce, head and leaf) Cyazofamid (21) (Suppression on lettuce, head and leaf) Ametoctradin (45) + Dimethomorph (40) Ametoctradin (45) (Suppression) Mono- and dibasic sodium, potassium, and ammonium phosphites (33) (Suppression)
Potato	Late blight ( <i>Phytophthora infestans</i> )	Azoxystrobin (11) Boscalid (7) Chlorothalonil (M5) Copper hydroxide (M1) Copper oxychloride (M1) Cyazofamid (21) Cymoxanil (27) Dimethomorph (40) Famoxadone (11) Fenamidone (11) Fluazinam (29) Mancozeb (M3) Mandipropamid (40) Metalaxyl-M (4) Metiram (M3) Propamocarb (28) Pyraclostrobin (11) Zineb (M3) Zoxamide (22)
Outdoor ornamentals	Downy mildew ( <i>Peronospora</i> spp.)	Dimethomorph (40) Cyazofamid (21)
	Phytophthora crown and root rot ( <i>Phytophthora</i> spp.)	Metalaxyl-M (4) (on foliage plants, bedding plants and flowers) Propamocarb (28) Fosetyl AL (33) (For Suppression of Sudden Oak Death caused by <i>Phytophthora ramorum</i> ) Cyazofamid (21) <i>Bacillus subtilis</i> (44)

**Table 4 List of Supported Uses**

For a complete list of supported uses refer to ERC2011-08, *Fluopicolide*.

Use Claim	Comments
1. <u>Control</u> of downy mildew ( <i>Peronospora parasitica</i> ) on Brassica (head and stem) vegetables and Brassica Root vegetables	Value information was sufficient to fulfill conditions.
2. <u>Suppression</u> of <i>Phytophthora</i> blight/crown rot caused by <i>P. capsici</i> on cucurbits vegetables	Value information was sufficient to fulfill conditions.
3. <u>Suppression</u> of <i>Phytophthora</i> crown and root rot ( <i>Phytophthora</i> spp.) on outdoor ornamentals (field and container grown) bedding plants and cut flowers	Value information was sufficient to fulfill conditions.





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## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Chemistry

2415514 2014, Batch Data, Material Accountability of Fluopicolide, DACO: 2.13.3

#### 2.0 Human and Animal Health

2312292 2013, Fluopicolide: Freezer Storage Stability of Fluopicolide, BAM, and PCA in Leafy Vegetables, DACO: 7.3

2312294 2013, Fluopicolide: Freezer Storage Stability of Fluopicolide, BAM, and PCA on Cabbage, DACO: 7.3

#### 3.0 Value

2415535 2014, Summary of Value for Presidio Fungicide, containing Fluopicolide Addressing Conditions of Registration, DACO: 10.1, 10.2.3.3

2415538 2010, IR-4 Ornamental Horticulture Program Phytophthora Efficacy, DACO: 10.2.3.3