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Re-evaluation Decision

RVD2018-04

Fludioxonil and Its Associated End-use Products

(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 safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Fludioxonil is a fungicide used as a seed treatment, a foliar spray and a post-harvest dip to control fungal pathogens on a large number of crops. Currently registered products containing fludioxonil are listed in Appendix I.

This document presents the final regulatory decision¹ for the re-evaluation of fludioxonil, including the required risk mitigation measures to protect human health and the environment. All products containing fludioxonil that are registered in Canada are subject to this re-evaluation decision. This re-evaluation decision has undergone a consultation period on the Proposed Re-evaluation Decision PRVD2016-03, *Fludioxonil*,² which ended on 19 March 2016.

The PMRA received additional information relating to the health risk assessment. This information is summarized in Appendix II along with the response by the PMRA. This information did not result in a change to risk assessments. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2016-03. A reference list of data used as the basis for the proposed re-evaluation decision is included in PRVD2016-03, and further data used in the re-evaluation decision is listed in Appendix IV.

Outcome of Science Evaluation

Use of fludioxonil as a seed treatment is important for control of seed- and soil-borne diseases on more than 200 crop species. With respect to human health, no risks of concern were identified. Dietary and occupational exposure from the registered uses is unlikely to affect human health when used according to the revised label directions. Fludioxonil enters the environment when used on field crops and turf. When used according to the revised label directions, fludioxonil is not expected to pose risks of concern to the environment.

¹ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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

Regulatory Decision for Fludioxonil

The PMRA has completed the re-evaluation of fludioxonil. Under the authority of the *Pest Control Products Act*, the PMRA has determined that continued registration of products containing fludioxonil is acceptable. An evaluation of available scientific information found that uses of fludioxonil products meet current standards for protection of human health and the environment when used according to the conditions of registration, which include required amendments to label directions. Label amendments, as summarized below and listed in Appendix III, are required for all technical and end-use products. No additional data are requested.

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.

Human Health

- Advisory label statements to meet current standards.
- Additional label statements restricting pelleting of small seeds to import use only and potato seed piece treatment with dust formulations to on-farm use only.

Environment

- Advisory label statements and best management practices to minimize the potential risk to birds through the ingestion of treated seeds.
- Advisory label statements and spray buffer zones of 1 meter and 1-20 meters to protect non-target terrestrial and aquatic habitats, respectively, from pesticide spray drift.

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. Appendix I lists the products containing fludioxonil that are registered under the authority of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection³ regarding this decision on fludioxonil within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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

Appendix I Registered Fludioxonil Products in Canada¹

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
28399	TGAI	Syngenta Canada	Fludioxonil Technical	Dust	98.1 %
26637	Commercial	Syngenta Canada	Helix Liquid Seed Treatment	Suspension	0.13 % ²
26638	Commercial	Syngenta Canada	Helix XTra Seed Treatment	Suspension	0.13 % ²
26647	Commercial	Syngenta Canada	Maxim PSP Potato Seed Protectant	Dust	0.5 %
27001	Commercial	Syngenta Canada	Maxim 480 FS Colourless Seed Treatment	Solution	40 %
27071	Commercial	Syngenta Canada	Maxim XL Seed Treatment Fungicide	Suspension	21 % ²
27577	Commercial	Syngenta Canada	Apron MAXX RTA Seed Treatment Fungicide	Suspension	0.73 % ²
27650	Commercial	Syngenta Canada	Tribune Seed Treatment Fungicide	Suspension	0.17 % ²
27965	Commercial	Syngenta Canada	Maxim MZ PSP	Dust	0.5 % ²
28189	Commercial	Syngenta Canada	Switch 62.5 WG Fungicide	Soluble Granules	25.0 % ²
28568	Commercial	Syngenta Canada	Scholar 50WP Fungicide	Wettable Powder	50 %
28817	Commercial	Syngenta Canada	Apron Maxx RFC Seed Treatment Fungicide	Suspension	2.31 % ²
28821	Commercial	Syngenta Canada	Cruiser MAXX Beans Seed Treatment	Suspension	1.12 % ²
28861	Commercial	Syngenta Canada	Instrata Fungicide	Suspension	14.5 g/L ²
29110	Commercial	Syngenta Canada	Maxim Liquid PSP	Suspension	40.3 %
29528	Commercial	Syngenta Canada	Scholar 230SC Fungicide	Suspension	230 g/L
29648	Commercial	Syngenta Canada	Astound Fungicide	Wettable Granules	25.0 % ²
29814	Commercial	Syngenta Canada	Proseed Seed Treatment	Solution	40.3 %
29871	Commercial	Syngenta Canada	Maxim Quattro Seed Treatment	Suspension	3.32 % ²
30185	Commercial	Syngenta Canada	Cyproflu Fungicide	Wettable Granules	25.5 % ²
30388	Commercial	Syngenta Canada	A18046A Seed Treatment	Suspension	12.9 g/L ²

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
30599	Commercial	Syngenta Canada	Maxim D	Suspension	19.4 g/L ²
30627	Commercial	Syngenta Canada	Apron Advance Seed Treatment	Suspension	25 g/L ²
30763	Commercial	Syngenta Canada	Palladium Fungicide	Wettable Granules	25 % ²
31024	Commercial	Syngenta Canada	Cruiser MAXX Potato Extreme	Suspension	62.5 g/L ²
31050	Commercial	Syngenta Canada	Stadium Fungicide	Suspension	143 g/L ²
31408	Commercial	Syngenta Canada	Vibrance Quattro	Suspension	7.6 g/L ²
31453	Commercial	Syngenta Canada	Cruiser Vibrance Quattro	Suspension	7.7 g/L ²
31454	Commercial	Syngenta Canada	Helix Vibrance	Suspension	1.7 g/L ²
31528	Commercial	Syngenta Canada	Medallion Fungicide	Suspension	125 g/L
31531	Commercial	Syngenta Canada	Instrata II A Fungicide (a component of Instrata II Fungicide Tank-mix)	Suspension	125 g/L
31564	Commercial	Syngenta Canada	Academy Fungicide	Suspension	147 g/L ²
32272	Commercial	Syngenta Canada	Vibrance MAXX RFC	Suspension	25 g/L ²
32624	Commercial	Syngenta Canada	Vibrance Flexi Canola	Suspension	4.2 g/L ²
32625	Commercial	Syngenta Canada	Vibrance Flexi Cereals	Suspension	4.2 g/L ²
32712	Commercial	Syngenta Canada	Instrata II A Fungicide	Suspension	125 g/L
32725	TGAI	ADAMA Agricultural Solutions Canada	Adama Fludioxonil Technical Fungicide	Solid	98.9 %
32728	Commercial	ADAMA Agricultural Solutions Canada	Fludioxonil 50 WDG	Wettable Granules	50 %
32765	Commercial	ADAMA Agricultural Solutions Canada	Quali-Pro Intaglio Fungicide	Suspension	17.4 g/L ²

¹ As of 15 October 2017, excluding discontinued products or products with a submission for discontinuation.

² Co-formulated with other active ingredients, which are not listed in the table.

TGAI: technical grade active ingredient

Appendix II Comment and Response

1. Comment Related to Occupational/Residential Exposure

Since there are insufficient data available to assess the pelleting treatment for small seeds using a liquid formulation, and commercial treatment of potato seed pieces using a dust formulation, PRVD2016-03 proposed label wording to clarify that these uses are not permitted. During the consultation period, the registrant provided additional information in order to maintain the use for pelleting small seeds.

PMRA's Response

One study was received and reviewed to estimate commercial seed treatment exposure for pelleting, priming, film-coating, and encrusting small seeds in an open mixing/loading scenario. This study is not considered to be acceptable for use as a stand-alone study for risk assessment purposes due to a number of major limitations, such as a very small sample size (n=4), and that baggers/packers were not monitored. Other limitations were that different levels of personal protective equipment were worn, and the field fortifications did not bracket the levels detected in the field.

While this study could be combined with those from other similar pelletization seed treatment studies in the future, currently, it is the only study the PMRA has to estimate exposure from this type of seed treatment. Since it is not considered to be acceptable for use as a stand-alone study for risk assessment purposes, there are no changes to the outcome of the occupational exposure assessment as described in PRVD2016-03; label statements restricting pelleting of small seeds are required.

Appendix III Label Amendments for Products Containing Fludioxonil

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

1. For Technical Grade Products

Add the following statement under a new section titled **ENVIRONMENTAL PRECAUTIONS**:

“TOXIC to aquatic organisms.”

Add the following statement under **PRECAUTIONS**:

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

2 For Commercial-Class Products

Add the following statement under **STORAGE**:

“To prevent contamination, store this product away from food or feed.”

2.1 For Seed Treatment Products

Add the following statement to the principal and secondary label panels of seed treatment products (except potato seed piece treatment products):

“For use with commercial seed treaters (facilities and mobile treaters).”

Add the following statement to the principal and secondary label panels of dust-formulated potato seed piece treatment products:

“For on-farm use only.”

Add the following statement to labels (under **PRECAUTIONS**) and tags of bags containing fludioxonil-treated seed for sale or use in Canada:

“Keep out of reach of children and animals.”

Add the following statements under **ENVIRONMENTAL PRECAUTIONS**:

“TOXIC to aquatic organisms.”

“Treated seed is TOXIC to birds. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil or other surfaces.”

Add the following statement under **USE RESTRICTIONS**:

“All bags containing treated seed for sale or use in Canada must be labeled or tagged as follows: “Treated seed is TOXIC to birds. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.”

Add the following statements under **DIRECTIONS FOR USE**:

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

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

Add the following statements and table under **DIRECTIONS FOR USE**, in a new section titled **FOR IMPORTATION OF TREATED SEEDS**:

“DO NOT treat in Canada.”

“DO NOT prime, film-coat, encrust, and/or pellet small seeded vegetables with fludioxonil in Canada.”

For Import Use Only			
Crop*	Diseases Controlled	Use Rate per 100 kg seed	Notes
Beets (garden, sugar)	Seed-borne and soil-borne diseases caused by <i>Fusarium</i> spp. (including seedling disease due to <i>F. graminearum</i>), <i>Rhizoctonia</i> spp., <i>Aspergillus</i> spp. and <i>Penicillium</i> spp.	5.2 – 10.4 mL	One application as a seed treatment before planting. Do not graze or feed livestock on seeded area for 30 days.
Cauliflower			

*Remaining import crops to be specified on product labels.

2.2 For Products with Post-harvest Uses

Add the following statement under **ENVIRONMENTAL PRECAUTIONS**:

“TOXIC to aquatic organisms. DO NOT apply directly to water, or to areas where surface water is present.”

Add the following statements under **DIRECTIONS FOR USE**:

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

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

2.3 For Products with Greenhouse Uses

Add the following statement under **DIRECTIONS FOR USE**:

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

2.4 For Products with Field Uses (Except Turf)

Add the followings statement under **ENVIRONMENTAL PRECAUTIONS**:

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

“Fludioxonil is persistent and may carryover. It is recommended that any products containing fludioxonil not be used in areas treated with this product during the previous season.”

“To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.”

“Avoid application when heavy rain is forecast.”

“Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.”

Add the following statements under **DIRECTIONS FOR USE**:

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

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

“DO NOT apply this product through any type of irrigation system.” (This statement does not apply to products registered for use by chemigation, such as Medallion Fungicide, Reg. No. 31528)

“Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) fine classification. Boom height must be 60 cm or less above the crop or ground.”

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

“**DO NOT** apply by air.” (This statement does not apply to products registered for aerial application, such as Astound Fungicide, Reg. No. 29648)

Add the following buffer zones and corresponding statements under **DIRECTIONS FOR USE**:

“Use of the following spray methods or equipment DOES NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.”

“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	Crop	Buffer Zones (metres) Required for the Protection of Freshwater Habitat of Depths		
		Less than 1 m	Greater than 1 m	
Field sprayer	Canola	2	0	
	Crop Group 1B (root vegetables, except sugar beet; excluding carrots and ginseng), grapes, spinach	4	1	
	Crop Group 3-07 (bulb vegetables), Crop Group 5B (leafy brassica greens), Crop Group 13-07 (berries and small fruits), carrots, chickpeas, dry beans, dry peas, field peppers, field tomatoes, ginseng, lentils, turnip greens, outdoor ornamentals	5	1	
Airblast	Grapes	Early growth stage	15	1
		Late growth stage	10	1
	Crop Subgroups: 13-07A (caneberries), 13-07B (bushberries) 13-07F (small fruiting vines), outdoor ornamentals	Early growth stage	20	2
		Late growth stage	10	1
Aerial	Canola	Fixed wing	10	0
		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 spray drift 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.”

For Palladium Fungicide (Reg. No. 30763), under **DIRECTIONS FOR USE**, add a maximum spray volume of 500 L/ha for outdoor ornamentals.

2.5 For Products with Turf Uses

Add the following statement under **ENVIRONMENTAL PRECAUTIONS**:

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

Add the following buffer zones and corresponding statements under **DIRECTIONS FOR USE**:

“Use of the following spray methods or equipment DOES NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.”

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

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:				Terrestrial habitat
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Turf		4	1	1	1	1
	Outdoor ornamentals		1	1	0	0	0
Airblast	Outdoor ornamentals	Early growth stage	20	2	0	0	0
		Late growth stage	10	1	0	0	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 spray drift buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.”

2.6 For Products Registered for Aerial Application (such as Astound Fungicide, Reg. No. 29648)

Add the following statement under **DIRECTIONS FOR USE**:

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

Appendix IV Additional References

A. List of Studies/Information Submitted by Registrant

Human Health

PMRA Document Number	Reference
2481146	2006, Determination of operator exposure to imidacloprid during treatment of sugar beet seeds with Imprimo® in France, DACO 5.4.