RD2009-10

Registration Decision

Trifloxystrobin

Trilex AL Seed Treatment Fungicide
Trilex FL Seed Treatment Fungicide

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Registration Decision for Trifloxystrobin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting amended full registration for the sale and use of Trifloxystrobin Technical Fungicide (Registration Number 27526) and full registration for the sale and use of Trilex AL Seed Treatment Fungicide (Registration Number 29160) and Trilex FL Seed Treatment Fungicide (Registration Number 29161) containing the technical grade active ingredient trifloxystrobin to control fungal diseases on canola, rapeseed, mustard, bean, chickpea, pea, lentil and soybean seeds and seedlings.

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.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2009-02, *Trifloxystrobin*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for trifloxystrobin and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-02. This decision is consistent with the proposed registration decision stated in PRD2009-02.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-02, *Trifloxystrobin* that contains a detailed evaluation of the information submitted in support of this registration.

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[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies 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 (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For

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.*

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

4 "Value" as defined by subsection 2(1) of *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".

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.

What is Trifloxystrobin?

Trifloxystrobin is a fungicide that is currently registered as a foliar use on grapes, pome fruits, wheat, spring barley, oats, turf and ornamentals.

Trifloxystrobin is the active ingredient in the end-use product Trilex FL Seed Treatment Fungicide. This product is used for the control of seed and seedling diseases on canola, rapeseed, mustard, bean, chickpea, pea, lentil, soybean and corn.

Trilex AL Seed Treatment Fungicide is a ready-to-use seed treatment product for use on bean, chickpea, pea, lentil and soybean, for control of various seed and seedling diseases. It is a mixture of the fungicides trifloxystrobin and metalaxyl.

Health Considerations

Can Approved Uses of Trifloxystrobin Affect Human Health?

Trifloxystrobin is unlikely to affect your health when used according to the label directions.

Potential exposure to trifloxystrobin 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 at which 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 trifloxystrobin products are used according to label directions.

Trifloxystrobin was of low toxicity by the oral, dermal and inhalation routes in rats. It was mildly irritating to the skin and eyes of rabbits. Trifloxystrobin was negative for dermal sensitization according to the Buehler method, but positive according to the Maximization test.

Trifloxystrobin did not cause cancer in animals and was not genotoxic. There was also no indication that trifloxystrobin caused damage to the nervous system, and there were no

effects on reproduction. Repeated dermal administration to rats over 28 days was tolerated by females without any local or systemic reactions at high doses; increased liver and kidney weights were observed in males of the high-dose group. The first signs of toxicity in animals given daily oral doses of trifloxystrobin over longer periods of time were decreased body-weight gain and food consumption as well as effects in the liver. Additional effects in the liver were also observed after longer term exposure to trifloxystrobin. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When trifloxystrobin was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is not more sensitive to trifloxystrobin than the adult animal. Because of this observation, extra protective measures were not retained during the risk assessment.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation who would ingest the most trifloxystrobin relative to body weight, are expected to be exposed to less than 69% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from trifloxystrobin is not of concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of trifloxystrobin is not likely to cause acute health effects in the general population (including infants and children).

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.

Radiotracer studies conducted in canola, corn and soybean indicated it is unlikely there would be any quantifiable residues of trifloxystrobin in crops harvested from seed treated according to the approved label rates. As per Regulatory Directive DIR2003-02, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United Sates*, MRLs are being proposed for the parent compound trifloxystrobin at the limit of quantitation of the established enforcement method AG-659A. The MRLs for this active ingredient can be found in the Science Evaluation of the Proposed Registration Decision PRD2009-02, *Trifloxystrobin*.

Risks in Residential and Other Non-Occupational Environments

Occupational Risks From Handling Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide are not of concern when the label directions are followed.

Farmers and custom applicators have potential for exposure to trifloxystrobin during mixing, loading and application, during seed treatment as well as during bagging, loading and planting treated seed. The occupational exposure for these use scenarios are not of concern when the products are used according to the label directions.

In addition to the standard personal protective equipment for seed treatment the following statement is found on the bags of treated seed to protect workers from the dust that may come from bags of treated seed.

> This seed has been treated with [product name] fungicide containing [List of active ingredients]. Use chemical-resistant gloves when handling treated seed.

Environmental Considerations

What Happens When Trifloxystrobin Is Introduced Into the Environment?

The expected release of trifloxystrobin to the environment through the use of treated seeds will be less than the currently registered foliar use and poses negligible risk to animals, birds and aquatic organisms. For details on the fate and toxicity of trifloxystrobin to the environment, please refer to Regulatory Note REG2004-03 and Proposed Registration Decision PRD2008-01 for details.

Value Considerations

What Is the Value of Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide?

The value of registering Trilex AL Seed Treatment and Trilex FL Seed Treatment is that they contain a systemic fungicide (trifloxystrobin) that will replace an older contact fungicide, thiram. They can also be used simultaneously with liquid seed inoculants.

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 labels of Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In addition to the standard personal protective equipment for seed treatment the following statement is found on the bags of treated seed to protect workers from the dust that may come from bags of treated seed.

> This seed has been treated with [product name] fungicide containing [list of active ingredients]. Use chemical-resistant gloves when handling treated seed.

Environment

Standard seed treatment label statements will apply.

Other Information

The relevant test data on which the decision is based (as referenced in 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.

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration 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 Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

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

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

1.1 The Active Ingredient, Its Properties and Uses

PMRA Document Number: 1068839
Reference: 2005, The physical characteristics of GUS 7082-00 seed treatment end-use products. Confidential, PC/04-005, Edition Number: M-253872-01-1, Data Numbering Code: 3.5 Confidential Business Information

PMRA Document Number: 1068840
Reference: 2005, The method validation of GUS 7082-00 end-use product. confidential, PC/04-005MV, Edition Number: M-253915-01-1, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1241319
Reference: 2005, The corrosion characteristics and storage stability of GUS 7082-02 end-use product, PC/04-005SS, MRID: N/A, Data Numbering Code: 3.5.10,3.5.14 Confidential Business Information

PMRA Document Number: 1069195
Reference: 2005, The corrosion characteristics and storage stability of RTU Trifloxystrobin Metalaxyl end-use product. confidential, PC/03-008SS, Edition Number: M-253869-01-1, Data Numbering Code: 3.5.10,3.5.14 Confidential Business Information
PMRA Document Number: 1069196 2003, The physical characteristics of RTU Trifloxystrobin Metalaxyl end-use product. confidential, PC/03-008, Edition Number: M-253868-01-1, Data Numbering Code: 3.5 Confidential Business Information

PMRA Document Number: 1069197
Reference: 2005, Jazz FL seed treatment fungicide - PART 3 Chemistry requirements for the registration of a manufacturing concentrate (MA) or an end-use product (EP). confidential. also filed: 12.7.3 /01, 05041DC, Edition Number: M-254415-01-1, Data Numbering Code: 12.7,3.5 Confidential Business Information

PMRA Document Number: 1069465
Reference: 2003, The corrosion characteristics and storage stability of Trifloxystrobin flowable end-use product. confidential, PC/02-003SS - Edition Number: M-253867-01-1, Data Numbering Code: 3.5.10,3.5.14 Confidential Business Information

PMRA Document Number: 1069466
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PMRA Document Number: 1069467
Reference: 2005, Trilex FL seed treatment fungicide - PART 3 Chemistry requirements for the registration of a manufacturing concentrate (MA) or an enduse product (EP). confidential. also filed: 12.7.3 /01, 05042DC - dition Number: M-254430-01-1, Data Numbering Code: 12.7,3.5 Confidential Business Information

1.2 Methods of Analysis

2.0 Human and Animal Health

Toxicology:

PMRA Document Number: 1068841
Reference: 2003, GUS 7082 00 (Flint Clothianidin (400 g Clothianidin/100 kg)) Acute oral toxicity up and down procedure in rats., 15567, Edition Number: M 252966 01 1, Data Numbering Code: 4.6.1

PMRA Document Number: 1068842
Reference: 2009, GUS 7082 00 (Flint Clothianidin (400 g Clothianidin/100 kg)) Acute dermal toxicity study in rats Limit test., 15572, Edition Number: M 252993 01 1, Data Numbering Code: 4.6.2

PMRA Document Number: 1068843
Reference: 2004, GUS 7082 00 (Flint Clothianidin (400 g Clothianidin/100 kg)) Acute inhalation toxicity study in rats Limit test., 15568, Edition Number: M 252971 01 1, Data Numbering Code: 4.6.3

PMRA Document Number: 1068844
Reference: 2004, GUS 7082 00 (Flint Clothianidin (400 g Clothianidin/100kg)) Primary eye irritation study in rabbits., 15569, Edition Number: M 252983 01 1, Data Numbering Code: 4.6.4

PMRA Document Number: 1068845
Reference: 2004, GUS 7082 00 (Flint Clothianidin (400 g Clothianidin/100kg)) Primary skin irritation study in rabbits., 15570, Edition Number: M 252988 01 1, Data Numbering Code: 4.6.5

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PMRA Document Number: 1069198
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PMRA Document Number: 1069200
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PMRA Document Number: 1069201
Reference: 2003, Primary Eye Irritation Study in Rabbits. Product Safety Laboratories. Laboratory Study Report Number 14205. Applicant Report No. M 252953 01 1. Study report date: 20 November 2003. pp. 1 15. Data Numbering Code 4.6.4. PMRA received date: 01 September 2005.

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PMRA Document Number: 1069203
Reference: 2003, Dermal Sensitization Study in Guinea Pigs (Buehler Method). Product Safety Laboratories. Laboratory Report No. 14207. Applicant Report No. M 252958 01 1. Study report date: 21 November 2003. pp. 1 22. Data Numbering Code 4.6.6. PMRA received date: 01 September 2005.

Occupational Exposure Assessment:

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Reference: GAUCHO 480 SC – Worker Exposure During On-farm and Commercial Seed Treatment of Cereals., November 20, 2006, Bayer CropScience Environmental Research Bayer Research Park, Unpublished.

PMRA Document Number: 1335562.
Reference: 1Laboratory Dust-off Study of Canola and Pulse seeds treated with Trifloxystrobin based seed treatment formulations. November 23, 2006. Bayer CropScience. Unpublished.

PMRA Document Number: 1672418.
Reference: 1Exposures of Workers to Isofenphos During Planting of Oftanol-Treated Canola Seeds. 1MRID 422519-01; Report Number 99799.

PMRA Document Number: 1069477.
Reference: 1Dermal absorption study with (Glyoxyl-phenyl-U-14C) CGA 279202 formulated as A-9604 A in rats. Bayer CropScience AG, December 10, 1997. Report No.: 470955. GLP, unpublished.

PMRA Document Number: 1069475.
Reference: 1Occupational Exposure & Safety Assessment for Trifloxystrobin Fungicide During Commercial and On-Farm Seed Treatment and Planting of Canola, Corn and Legumes. Bayer CropScience, July 22, 2005. Report No.: 201360. GLP, unpublished.

Food Residue Exposure Assessment:

PMRA Document Number: 1069480
Reference: 2003, Determination of the total radioactive residue in soybean raw agricultural commodities after seed treatment with [benzeneaceticphenyl- UL 14C] Trifloxystrobin., 200425 - Edition Number: M-087646-01-1, Data Numbering Code: 7.4.1

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Reference: 2005, Trifloxystrobin: Data Numbering Code 7.4.1 - Canola, Rapeseed, Mustard Rationale to Register TRILEX Daco Part 7: Food, Feed and Tobacco Residue Studies (EP) USC #5., CRW RSI Triflox-05 - Edition Number: M-255501-01-1, Data Numbering Code: 7.4.1

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PMRA Document Number: 1069489
Reference: 2005, Trifloxystrobin: Data Numbering Code 7.4.1 - Legume Vegetables Rationale to Register TRILEX and JAZZ., M-255531-01-1, Data Numbering Code: 7.4.1

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Reference: 2002, Analytical method for the determination of residues of trifloxystrobin (Flint) and trifloxystrobin acid in/on tomatoes and peppers by LC-MS/MS, 200177, Data Numbering Code: 7.2.1

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Reference: 2003, Flint 50WG - Magnitude of the Residue in Soybean - Flint Working Method FL030919, Data Numbering Code: 7.2.1

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4.0 Value

Trilex AL:

PMRA Document Number: 1069191
Reference: 2005. Jazz FL seed treatment fungicide for control of seed and seedling diseases on large-seeded legumes. Bayer CropScience. CANBYS015, Edition Number: —256354-01-1. Data Numbering Code 10.1

PMRA Document Number: 1069206
Reference: Jazz FL seed treatment fungicide - Data Numbering Code 12.7.10.3 Tier II summary of non-safety adverse effects. 2005. Bayer CropScience Inc. —256346-01-1. Data Numbering Code 10.3.2,12.7

PMRA Document Number: 1069207
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PMRA Document Number: 1335551
Reference: Jazz FL Seed Treatment Fungicide for Control of Seed and Seedling Diseases on Large-seeded Legumes and Soybean - Deficiency Response. 2006. Bayer CropScience. Project No. CANBYS015. Data Numbering Code 10.2.3.1,10.2.3.3(D)

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Trilex FL:

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Reference: Trilex FL Seed Treatment Fungicide for Seed and Seedling Protection Against Damping-Off and Seed Rot Caused by *Rhizoctonia solani* and *Fusarium* spp. on Canola, Rapeseed, Mustard, Corn and Large-seeded Pulse Crops, Volume 1. 2005. Bayer CropScience. —255642-01-1 . Data Numbering Code 10.1

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PMRA Document Number: 1069522
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PMRA Document Number: 1335559
Reference: Trilex FL Seed Treatment Fungicide for Control of Seed and Seedling Diseases on Large-seeded Legumes and Soybean - Deficiency Response. 2006. Bayer CropScience. Data Numbering Code 10.2.3.1,10.2.3.3(D)

B. Additional Information Considered

i) Published Information

Reference: Trifloxystrobin Regulatory Note REG2004-03

Reference: Trifloxystrobin Proposed Registration Decision Document PRD2008-01

1.0 Chemistry

2.0 Human and Animal Health

Reference: DIR98-02 Residue Chemistry guidelines

Reference: DIR2003-02 Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States