Proposed Registration Document PRD2014-01

Penthiopyrad

(publié aussi en français)

3 January 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-23/2014-01E (print version)
H113-23/2014-01E-PDF (PDF version)

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Overview

Proposed Registration Decision for Penthiopyrad

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 Penthiopyrad Technical Fungicide and DuPont Penthiopyrad 250 FS Fungicide Seed Treatment containing the technical grade active ingredient penthiopyrad, for use as a seed treatment on canola, rapeseed, mustard (oil and condiment types), corn and soybean to control or suppress various soil-borne and seed-borne fungal diseases.

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 section provides detailed technical information on the human health, environmental and value assessments of Penthiopyrad Technical Fungicide and DuPont Penthiopyrad 250 FS Fungicide Seed Treatment.

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[1] 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[2] when used according to the 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 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.

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

2 "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."

Before making a final registration decision on penthiopyrad, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on penthiopyrad, 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 section of this consultation document.

What Is Penthiopyrad?

Penthiopyrad is a systemic fungicide that can be applied as a seed treatment to control or suppress various soil-borne and seed-borne fungal diseases on canola, rapeseed, oil and condiment varieties of mustards, corn and soybean. This active ingredient is currently registered for use in other products applied as foliar or in-furrow treatments.

Health Considerations

Can Approved Uses of Penthiopyrad Affect Human Health?

Product containing penthiopyrad is unlikely to affect your health when used according to label directions

Potential exposure to Penthiopyrad Technical Fungicide may occur through the diet (food and water), or when handling and applying the product or when entering treated sites. 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 penthiopyrad products are used according to label directions.

In laboratory animals, the acute toxicity of the active ingredient penthiopyrad was low via the oral, dermal and inhalation routes of exposure. Penthiopyrad was minimally irritating to the eyes, non-irritating to the skin and did not cause an allergic skin reaction.

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

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

The acute toxicity of the end-use product DuPont Penthiopyrad 250 FS Fungicide Seed Treatment was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the skin and did not cause an allergic skin reaction. DuPont Penthiopyrad 250 FS Fungicide Seed Treatment was mildly irritating to the eyes; consequently, the hazard signal words "CAUTION – EYE IRRITANT" are required on the label.

Health effects in animals given repeated doses of penthiopyrad included changes in the liver, thyroid, adrenals and kidneys. Penthiopyrad did not cause birth defects in animals and there were no effects on the ability to reproduce. When penthiopyrad was given to pregnant or nursing animals, effects on the developing fetus and juvenile animal (reduced survival, pup and litter weights, body size, thymus weight, altered thymus development and/or delayed sexual development) were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to penthiopyrad than the adult animal. Penthiopyrad caused temporary functional effects, possibly related to the nervous system; however, there was no indication that penthiopyrad caused damage to the nervous system. There was no evidence to suggest that penthiopyrad damaged genetic material. Penthiopyrad did, however, cause thyroid tumours in rats. There was also evidence of an effect on the immune system at high doses.

The risk assessment protects against the effects of penthiopyrad by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and infants less than one year old, the subpopulation that would ingest the most penthiopyrad relative to body weight, are expected to be exposed to less than 19% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from penthiopyrad is not of health concern for all population subgroups. There were no cancer risks of concern.

Acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups were less than 6% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was infants less than one year old.

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.

MRLs to cover residues of penthiopyrad in/on rapeseeds (canola), mustard seeds (oilseed type), soybean, field corn, sweet corn cobs plus kernels with husks removed, and popcorn grain have been established based on residue data generated following foliar applications. The seed treatment use of penthiopyrad on these crops is not expected to result in residues exceeding the established MRLs. The MRL for this active ingredient on mustard seeds (condiment type) can be found in the Science Evaluation section of this document.

Occupational Risks From Handling DuPont Penthiopyrad 250 FS Fungicide Seed Treatment

Occupational risks are not of concern when DuPont Penthiopyrad 250 FS Fungicide Seed Treatment is used according to the proposed label directions, which include protective measures.

Workers treating seed with DuPont Penthiopyrad 250 FS Fungicide Seed Treatment in commercial seed treatment facilities and workers planting treated seed can come into direct contact with penthiopyrad residues on the skin and through inhalation. Therefore, the label specifies that workers treating and handling treated seed must wear the following personal protective equipment (PPE). In commercial seed treatment facilities, workers mixing, loading, calibrating, treating, bagging, sewing, stacking, and forklifting treated seed must wear a long-sleeved shirt and long pants and chemical-resistant gloves. In addition, workers cleaning treatment equipment in commercial seed treatment facilities must wear coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. Workers planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves. Closed transfer is required for treating seeds in commercial seed treatment facilities and a closed cab tractor is required when planting treated seed. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals is not a 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.

Environmental Considerations

What Happens When Penthiopyrad Is Introduced Into the Environment?

When used as a seed treatment for canola, rapeseed, mustard, corn and soybeans to control plant diseases, penthiopyrad is not likely to move a great distance downward into soil and contaminate groundwater. Once in soil, studies show that penthiopyrad breaks down quickly. It is unlikely to evaporate from the seeds after the seeds are planted.

Birds and small mammals will not be at risk if they happen to eat the seeds that are treated with penthiopyrad. Similarly, earthworms and insects will not be at risk if they come into contact with penthiopyrad in the soil or come into contact with the treated seed.

Value Considerations

What Is the Value of DuPont Penthiopyrad 250 FS Fungicide Seed Treatment?

DuPont Penthiopyrad 250 FS Fungicide Seed Treatment is a flowable suspension (FS) product for soil-borne and seed-borne disease management in canola, rapeseed, mustard, corn and soybean seeds.

Penthiopyrad has demonstrated efficacy against diseases with potentially severe economic impact on major Canadian field crops. Seed treatments are an effective and targeted means of early disease control requiring a single application in a closed environment and relatively small amounts of active ingredients compared to soil or foliar applications in the field.

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 DuPont Penthiopyrad 250 FS Fungicide Seed Treatment 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 penthiopyrad on the skin or through inhalation of spray mists, anyone mixing, loading and applying DuPont Penthiopyrad 250 FS Fungicide Seed Treatment must wear the following PPE: In commercial seed treatment facilities, workers mixing, loading, calibrating, treating, bagging, sewing, stacking, and forklifting treated seed must wear a long-sleeved shirt and long pants and chemical-resistant gloves. In addition, workers cleaning treatment equipment in commercial seed treatment facilities must wear coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. Workers planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves. Closed transfer is required for treating seeds in commercial seed treatment facilities and a closed cab tractor is required when planting treated seed.

Environment

As the environmental risks are very small with the planting of seeds treated with penthiopyrad, no additional precautions or risk-reduction measures are required that are not already indicated on the product label.

Next Steps

Before making a final registration decision on penthiopyrad, the PMRA will consider all 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 note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. 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

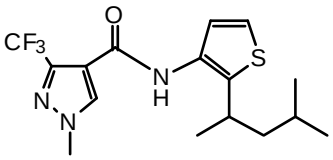
When the PMRA makes its registration decision, it will publish a Registration Decision on penthiopyrad (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the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

Science Evaluation

Penthiopyrad

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Penthiopyrad
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(*RS*)-*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide
2. Chemical Abstracts Service (CAS)	*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1*H*-pyrazole-4-carboxamide
CAS number	183675-82-3
Molecular formula	$C_{16}H_{20}F_3N_3OS$
Molecular weight	359.4 g/mol
Structural formula	
Purity of the active ingredient	99.5%

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Penthiopyrad Technical

Property	Result
Colour and physical state	White solid
Odour	Odourless
Melting range	108.7°C ± 0.2°C
Boiling point or range	Not applicable
Relative density at 20°C	1.256
Vapour pressure at 25°C	6.43×10^{-6} Pa
Ultraviolet (UV)-visible spectrum	$\lambda_{max} \approx 226$ nm under neutral, acidic and basic conditions

Property	Result	
Solubility in water at 20°C	pH	Solubility (mg/L)
	4	2.535
	7	1.375
	10	1.657
Solubility in organic solvents at 20°C	Solvent	Solubility (g/L)
	Acetone	557
	Dichloromethane	531
	Methanol	402
	Ethyl acetate	349
	Ethanol	234.5
	Toluene	67.0
	Xylene	42.7
	Hexane	0.75
	Heptane	0.74
n-Octanol-water partition coefficient (K_{ow})	pH	log K_{ow}
	4	4.36
	7	4.62
	10	4.54
Dissociation constant (pK_a)	$pK_a = 10.0 \pm 0.16$	
Stability (temperature, metal)	Thermally stable in air under the test conditions (25 to 150°C at 10°C/min).	

End-Use Product—DuPont Penthiopyrad 250 FS Fungicide Seed Treatment

Property	Result
Colour	Off-white
Odour	Mild Odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	Penthiopyrad: 250 g/L nominal
Container material and description	1 L to bulk, metal or plastic Jug/tote/drum/tank
Density	1.08 g/cm^3
pH of 1% dispersion in water	7 -9
Oxidizing or reducing action	Product is not expected to have oxidizing properties
Storage stability	Stable in fluorinated HDPE containers for at least 12 months
Corrosion characteristics	Not corrosive to fluorinated HDPE containers
Explodability	Not expected to be explosive

1.3 Directions for Use

DuPont Penthiopyrad 250 FS Fungicide Seed Treatment may be applied at a rate of 80 to 200 mL of product per 100 kg of seed on canola, rapeseed, and mustard seeds or at 0.015 to 0.045 mg of active ingredient per seed on corn and soybean. The seed treatment can be used on all of these crops to control early season diseases, including damping-off, seedling blight, seed rot and root rot caused by certain fungal pathogens. In the case of canola, rapeseed and mustard, DuPont Penthiopyrad 250 FS Fungicide Seed Treatment may also be applied to suppress blackleg and alternaria. Consult the complete DuPont Penthiopyrad 250 FS Fungicide Seed Treatment label for details regarding use directions and restrictions.

1.4 Mode of Action

Penthiopyrad inhibits spore germination and mycelial growth by binding to certain enzymes within fungal cells, thereby interfering with the normal respiration process. As a systemic fungicide, penthiopyrad can act on pathogenic fungi that are found within the seed and prevent damage to emerging seedlings.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Not required for this submission as acceptable methods were previously submitted by the applicant and reviewed by PMRA.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Please refer to the Proposed Regulatory Decision PRD2011-26, *Penthiopyrad*, for the analytical methods on penthiopyrad residues in plant and animal matrices for data generation and enforcement purposes.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

For the review of the technical active please refer to PRD2011-26.

The acute toxicity of the end-use product DuPont Penthiopyrad 250 FS Fungicide Seed Treatment was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the skin and did not cause an allergic skin reaction. It was mildly irritating to the eyes. See Appendix I, Table 1 for more details.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set period. Information on how to report a pesticide incident can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. Incidents from Canada and the United States were searched and reviewed for penthiopyrad. As of 18 September 2013 no incident reports were identified for products containing penthiopyrad.

3.1.1 *Pest Control Product Act* Hazard Characterization

Please refer to PRD2011-26 for details.

3.2 Determination of Acute Reference Dose

The acute reference dose was estimated to be 1.25 mg/kg bw of penthiopyrad (refer to PRD2011-26).

3.3 Determination of Acceptable Daily Intake

The acceptable daily intake was calculated to be 0.09 mg/kg bw/day of penthiopyrad (refer to PRD2011-26).

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to penthiopyrad is characterized as short- to intermediate-term in duration and is predominantly by the dermal and inhalation routes.

3.4.1.1 Dermal Absorption

Dermal absorption data were not submitted for DuPont Penthiopyrad 250 FS Fungicide Seed Treatment. Previously, a weight-of-evidence approach was used to estimate dermal absorption for penthiopyrad.

The physical and chemical properties of penthiopyrad are such that refinement of the dermal absorption value was possible. Based on the molecular mass (359.4 g/mol), water solubility (1.375 mg/L at pH 7 and 20°C) and the octanol water partition coefficient (log P_{ow} of 4.62 at pH 7 and 20°C), the dermal absorption of penthiopyrad is expected to be low to moderate. A dermal absorption value of 50% was used during the assessment of dermal exposure for penthiopyrad.

3.4.2 Occupational Exposure and Risk

Canola, rapeseed, mustard, corn and soybean can be treated with DuPont Penthiopyrad 250 FS Fungicide Seed Treatment in commercial seed treatment facilities and planted using conventional seeding equipment.

3.4.2.1 Commercial Seed Treatment Exposure and Risk Assessment

Individuals have potential for exposure to penthiopyrad while treating seed in commercial seed treatment facilities. Chemical specific data for assessing human exposure during commercial seed treatment were not submitted. As such, surrogate exposure data were used to estimate risk to workers in commercial seed treatment facilities.

3.4.2.1.1 Canola, Rapeseed, Mustard, Corn and Soybean Seed

DuPont Penthiopyrad 250 FS Fungicide Seed Treatment is for use in commercial seed treatment facilities capable of treating canola (rapeseed, mustard), corn and soybean seeds. Worker exposure was assessed for treating seed with closed transfer systems only.

For assessing exposure during seed treatment in commercial operations, a surrogate passive dosimetry study measuring the exposure of mixers, loaders, calibrators, baggers and cleaners at eleven small to large commercial facilities treating cereal seed with Jockey Fungicide was used. Thirty seven trials were conducted with mixers, loaders, calibrators (7 operators) and baggers (22 operators) wearing a single layer and gloves and cleaners (8 operators) wearing Tyvek coveralls over a single layer and gloves. Dermal exposure for each worker was measured by passive dosimetry using a combination of an inner whole body dosimeter, hand rinses, and face/neck wipes. Inhalation exposure for each worker was measured by means of a personal air sampling pump. Exposure values for mixers, loaders, calibrators and baggers were normalized for the amount of active ingredient handled. Exposure values for cleaners were normalized for the application rate used in the study. The arithmetic mean was used for all activities since there were an adequate number of replicates and the recoveries were sufficient.

The submitted dust-off study compared the dust generated from the proposed product (in tank mix with a variety of other formulations) on canola with the surrogate study formulations on

their respective crop seeds (Jockey on wheat and Gaucho on corn). Based on dust generated per 100 kg of seed, canola had the highest dust produced followed by wheat and then corn with the least dust generated. No untreated controls were performed during the study. In addition, while the tank mix combination used in the study may be the intended treatment regimen, testing Penthiopyrad 250 FS Fungicide Seed Treatment alone on canola, corn and soybeans and also on the surrogate study crop seeds would have helped support the use of the surrogate studies to assess exposure from the proposed uses.

Table 3.4.2.1.1 presents the risk estimates for the commercial seed treatment of canola (rapeseed, mustard), corn and soybean seeds with DuPont Penthiopyrad 250 FS Fungicide Seed Treatment. The calculated margins of exposure (MOEs) were above the target MOE of 100. As such, there are no occupational risks of concern for treating canola (rapeseed, mustard), corn and soybean seeds with DuPont Penthiopyrad 250 FS Fungicide Seed Treatment in closed transfer commercial facilities when workers wear the PPE worn in the surrogate study. Given the high MOEs, it was determined that further confirmatory dust-off data for canola (rapeseed, mustard), corn and soybean seeds were not required.

Table 3.4.2.1.1 Risk Assessment for Commercial Treating of Seeds with Penthiopyrad

Canola (Rapeseed, Mustard), Corn, Soybean – JOCKEY STUDY							
Scenario – Canola	**Amount Handled per Day [1]**	**Unit Exposure**		**Exposure [2,4] (mg/kg bw/day)**		**MOE [3]**	
		Dermal	**Inhalation**	**Dermal**	**Inhalation**	**Dermal**	**Inhalation**
Single layer plus gloves							
kg a.i. andled/day		**µg/kg a.i. handled**					
Treater/Applicator	33.5	0.88	0.016	1.8×10^{-4}	6.7×10^{-6}	410,000	6,000,000
Bagger/Sewer/ Stacker		17.67	0.89	3.7×10^{-3}	3.7×10^{-4}	20,000	110,000
Coveralls over single layer							
g a.i./100 kg seed		**µg/g a.i./100 kg seed**					
Cleaner	50	18.46	0.64	5.8×10^{-3}	4.0×10^{-4}	13,000	100,000
Cleaner + Treater [5]		n/a	n/a	6.0×10^{-3}	4.1×10^{-4}	13,000	98,000

[1] kg a.i. handled per day = kg seed treated per day × application rate (kg a.i./kg seed), canola value used for calculation as it is the highest amount of active handled per day and highest application rate.

[2] For treater/applicators and bagger/sewer/stackers:

$$\text{Exposure (mg/kg bw/day)} = \frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day}}{\text{80 kg bw} \times \text{1000 µg/mg}}$$

[3] Dermal NOAEL = 75 mg/kg bw/day; dermal absorption = 50%; Inhalation NOAEL = 40 mg/kg bw/day; target MOE = 100

[4] For cleaning personnel, unit exposures are normalized for application rate. Exposure was calculated using the highest application rate proposed therefore:

$$\text{Exposure (mg/kg bw/day)} = \frac{\text{Unit exposure (µg a.i./g a.i./100 kg seed)} \times \text{application rate (g a.i./100 kg seed)}}{\text{80 kg bw} \times \text{1000 µg/mg}}$$

[5] Cleaner task was <1 hour per day therefore it was assumed other tasks such as treating may be performed.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

Individuals have potential for exposure to DuPont Penthiopyrad 250 FS Fungicide Seed Treatment while planting treated seed. Chemical specific data for assessing human exposure during planting of treated seed were not submitted. As such, surrogate exposure data were used to estimate risk to workers planting treated seed.

3.4.2.2.1 Canola, Rapeseed, Mustard, Corn and Soybean Seed

Commercially treated canola (rapeseed, mustard), corn and soybean seed is generally bagged. During planting, workers load the treated seeds from bags into the planter. To address planting exposure from bagged seed, the Gaucho planting study was used as a surrogate. In the study, 15 replicates were monitored while planting treated corn seed from bags. The workers in the study loaded treated seed from bags into the planter and sowed the seed using a closed cab tractor. Dermal exposure for each worker was measured by passive dosimetry using a combination of an inner whole body dosimeter, hand rinses, and face/neck wipes. The inner dosimeter was worn underneath worker clothing consisting of a single layer and chemical-resistant gloves. Inhalation exposure was monitored using personal air sampling pumps. The study was of good quality and had only minor limitations. As such, the arithmetic mean values from the study were adequate for risk assessment purposes.

The submitted dust-off study compared the dust generated from the proposed product (in tank mix with a variety of other formulations) on canola with the surrogate study formulations on their respective crop seeds (Jockey on wheat and Gaucho on corn). Based on dust generated per 100 kg of seed, canola had the highest dust produced followed by wheat and then corn with the least dust generated. No untreated controls were performed during the study. In addition, while the tank mix combination used in the study may be the intended treatment regimen, testing Penthiopyrad 250 FS Fungicide Seed Treatment alone on canola, corn and soybeans and also on the surrogate study crop seeds would have helped support the use of the surrogate studies to assess exposure from the proposed uses.

Table 3.4.2.2.1 presents the risk estimates for the planting of canola (rapeseed, mustard), corn and soybean seeds treated with DuPont Penthiopyrad 250 FS Fungicide Seed Treatment. The calculated MOEs were above the target MOE of 100. As such, there are no occupational risks of concern for planting treated canola (rapeseed, mustard), corn and soybean seeds with DuPont Penthiopyrad 250 FS Fungicide Seed Treatment with closed cab equipment when workers wear the PPE worn in the surrogate study. Given the high MOEs, it was determined that further confirmatory dust-off data for canola (rapeseed, mustard), corn and soybean seeds were not required.

Table 3.4.2.2.1 Exposure Estimates for Planting of Penthiopyrad Treated Seed Using a Closed Cab Tractor

Exposure scenario	Amount of a.i. handled per day (kg)	Unit Exposure (µg/kg a.i. handled)		Exposure (µg/kg bw/day) [2]		MOE [3]	
		Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
Closed cab dermal and inhalation	2.70	1515.0	82.83	25.6	2.80	2,930	14,300
Closed cab dermal, Open cab inhalation	2.70	1515.0	116.75	25.6	3.94	2,930	10,200

[1] Amount of a.i. handled was calculated by multiplying the amount of seed that could be planted per day (Maximum seed handled example: 9000 kg soybean seed/day) by the application rate.

[2] For planting exposure:

$$\text{Exposure (mg/kg bw/day)} = \frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day}}{80 \text{ kg bw} \times 1000 \text{ µg/mg}}$$

[3] Dermal NOAEL = 75 mg/kg bw/day; dermal absorption = 50%; Inhalation NOAEL = 40 mg/kg bw/day; target MOE= 100.

3.4.3 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal when planting treated seed.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

Penthiopyrad is currently registered for foliar application on various crops including canola, soybean and corn. Please refer to PRD2011-26 for the residue definition for risk assessment and enforcement purposes, for the field trial data on various crops resulting from foliar applications, and for the frozen storage stability of penthiopyrad in plant and animal foodstuffs.

Based on foliar applications, MRLs for penthiopyrad were established at 1.5 ppm for commodities of Crop Group 20 (Oilseeds), 0.4 ppm for dry soybeans, and 0.01 ppm for field corn, popcorn grain, and sweet corn kernels plus cob with husks removed. The seed treatment use of penthiopyrad on these crops at lower rates and longer PHIs are not expected to result in residues exceeding the established MRLs. Supervised residue trials with foliar applications conducted throughout North America using end-use products containing penthiopyrad in or on oilseeds are sufficient to support the proposed maximum residue limit on mustard seeds (condiment type).

3.5.2 Dietary Risk Assessment

Refined acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.16), 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.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

Aggregate chronic exposure to penthiopyrad from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to penthiopyrad from food and drinking water is 7.1% (0.006393 mg/kg bw/day) of the acceptable daily intake (ADI) for the total population. The highest exposure and risk estimate is for all infants less than one year old, at 18.3% (0.016426 mg/kg bw/day) of the ADI. Please refer to PRD2011-26 for details.

3.5.2.2 Acute Dietary Exposure Results and Characterization

The aggregate acute dietary exposure (food and drinking water) for all supported penthiopyrad registered commodities is estimated to be 3.1% (0.038877 mg/kg/day) of the ARfD for total population (95^{th} percentile, deterministic). The highest exposure and risk estimate is for infants less than one year old, at 6.0% (0.075542 mg/kg bw/day) of the ARfD. Please refer to PRD2011-26 for details.

3.5.3 Aggregate Exposure and Risk

The aggregate risk for penthiopyrad consists of exposure from food and drinking water sources only. Aggregate risks were calculated based on acute and chronic endpoints. Please refer to PRD2011-26 for details.

3.5.4 Maximum Residue Limits

Table 3.5.1 Proposed Maximum Residue Limit

Commodity	Recommended MRL (ppm)
Mustard seeds (condiment type)	1.5

No revision is required for the established MRLs. Please refer to PRD2011-26 for detailed discussion of the nature of the residues in animal and plant matrices, analytical methodologies, field trial data, and acute and chronic dietary risk estimates.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Please refer to PRD2011-26, *Penthiopyrad* for details.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. In this case, the risk assessment was conducted only for terrestrial organisms as the exposure to aquatic organisms resulting from seed treatment is negligible. This integration is achieved by comparing

exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food and soil. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints.

4.2.1 Risks to Terrestrial Organisms

Please refer to PRD2011-26 for a summary of the ecotoxicology for terrestrial organisms and the environmental risk associated with foliar application.

For assessing the impact of seed treatment on birds and small mammals, the highest calculated risk was based on ingestion of treated canola seed (Appendix I, Table 2). For birds, the toxicity endpoints considered for acute and reproductive effects were 206.6 and 718.7 mg a.i./kg bw/day, respectively. For small mammals, the acute and reproductive endpoints were 200 and 250 mg a.i./kg bw/day, respectively. On the basis of these endpoints and the estimated daily exposure values for consumption of treated canola seed, the resulting RQ are less than 1.0. Thus, the LOC is not exceeded and the risk to birds and small mammals is negligible through the ingestion of penthiopyrad-treated seed (Appendix I, Table 2).

From the initial assessment of penthiopyrad (see PRD2011-26), where the exposure is based on substantially higher application rates (900–3375 g a.i./ha), the risk to earthworms was determined to be negligible (RQ <1). In beneficial arthropods, there was a low risk in which a 19% and 12% reduction in population was observed in the predatory mite exposed to application rates of 448 and 720 g a.i./ha, respectively. By comparison with the maximum proposed seed treatment rate of 22.2 g a.i./ha, the risk to soil-dwelling beneficial arthropods is therefore expected to be negligible. For bees, the risk was negligible (RQ<1) with foliar application of penthiopyrad; hence, a negligible risk is also anticipated with seed treatment. For non-target terrestrial plants, a risk was identified (RQ = 2) for exposure to a seasonal cumulative rate of 3.1

kg a.i./ha. By comparison with the exposure expected with the highest seed treatment rate of 22.2 g a.i./ha, the risk to non-target terrestrial plants is expected to be negligible (RQ <1).

4.2.2 Risks to Aquatic Organisms

As exposure to the aquatic environment is not anticipated with the intended use of penthiopyrad-treated seed, a negligible risk is expected for aquatic organisms.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

5.1.1.1 Control of damping-off, seedling blight, seed rot and root rot caused by *Fusarium*

Data from seven efficacy trials on canola, two from greenhouse and five from field, were provided to demonstrate the efficacy of penthiopyrad as a seed treatment to control seed and seedling disease caused by *Fusarium* in canola, rapeseed, and mustard. Inoculations with known species of *Fusarium* were made in most trials to ensure pathogen identity. In some trials, only small increases in emergence counts resulting from penthiopyrad seed treatments were observed; however, the lack of a large response was attributed to the fact that disease pressure was quite low in these trials. Conversely, in trials where disease pressure was considered extreme, penthiopyrad treated seedlings showed larger increases in emergence relative to the untreated controls along with reduced disease severity and greater plant height.

Nine additional trials were provided to show effectiveness of penthiopyrad against *Fusarium* diseases on soybean seedlings. Four different *Fusarium* species were identified among these trials. Significant improvements in stand count, disease severity and incidence along with some yield increases resulting from penthiopyrad seed treatments were observed under disease pressures ranging from low to very high.

Four trials testing penthiopyrad efficacy against *Fusarium* on corn seeds and seeding were also reviewed; however, because of experimental limitations (for example, low disease pressure and co-application of treatment with other fungicides), little support for the claim in question could be derived from this data. Nevertheless, evidence obtained from other crop trials was extrapolated to the corn claim given the similarities in seed size and disease progression between corn and soybean and the range of *Fusarium* species shown to be sensitive to penthiopyrad.

5.1.1.2 Control of damping-off, seedling blight, seed rot and root rot caused by *Rhizoctonia*

Across six field trials conducted on canola to demonstrate penthiopyrad efficacy against seed and seedling diseases caused by *Rhizoctonia*, significant improvements were noted in parameters measured to assess disease severity and incidence. Seed treatments with penthiopyrad at or near the recommended rates provided higher plant stand counts and lower levels of seed rot, seedling

blight, and root rot when compared to the untreated seeds. Plant biology and *Rhizoctonia* seedling disease susceptibility and development in mustard, rapeseed and canola are sufficiently similar to allow for extrapolation of efficacy evidence across these different crops.

Eleven field trials were conducted to show penthiopyrad efficacy against the same diseases on corn. Certain trials could not be considered in support of this claim given inadequate disease pressure. Nevertheless, sufficient evidence was obtained from the remaining trials in the form of increased stand counts and good to excellent control of disease severity and incidence resulting from seed treatments with penthiopyrad at or near the recommended application rates.

Efficacy data from thirteen trials were obtained in support of penthiopyrad efficacy against soybean seedling diseases caused by *Rhizoctonia*. Similarly to the trials conducted on corn and canola, large increases in stand counts were observed even under very high disease pressure. In addition, large yield increases attributed to penthiopyrad seed treatment (up to 154% more bushels per hectare) were also noted in comparison with the untreated control plants.

5.1.1.3 Suppression of blackleg

Data from three greenhouse trials and one field trial were presented to demonstrate penthiopyrad efficacy against blackleg in canola, rapeseed and mustard. Most of the evidence relied on indirect assessments of efficacy in the form of improved plant vigor and crop stand; however, these two parameters can be impacted by other seed and soil borne diseases other than blackleg. The greater weight of evidence for this claim was obtained through direct assessments of blackleg symptoms where, under moderate disease pressure, penthiopyrad was significantly improved disease ratings on seedlings. Given the remaining levels of blackleg disease on seedlings following penthiopyrad treatment and the resulting potential for later season secondary infection in maturing plants, the efficacy behind this claim was shown to be in line with expectations of disease suppression.

5.1.1.4 Suppression of *Alternaria*

Data from two greenhouse trials were presented to demonstrate penthiopyrad efficacy against alternaria disease in canola, rapeseed and mustard. Improvements attributable to penthiopyrad seed treatments were observed in certain seedling parameters including root and shoot length, although it is noted that these are not direct measures of disease development. Visual ratings of emerging seedlings also showed a reduction in disease severity in the penthiopyrad treatment relative to the untreated control seedlings. It is also noted that other claims against various pathogens in the *Alternaria* genus are currently registered on other foliar-applied penthiopyrad products. The level efficacy demonstrated against *Alternaria brassicae* is consistent with expectations of disease suppression.

5.2 Phytotoxicity

Phytotoxicity was assessed visually in all of the canola, corn and soybean trials. Phytotoxicity resulting from the recommended rates of penthiopyrad applied as a seed treatment was not observed.

5.3 Economics

Not assessed

5.4 Sustainability

5.4.1 Survey of Alternatives

The chemical and other non-conventional/biological fungicidal active ingredients listed in Appendix I, Table 3 are found in products that are registered for the management of the diseases appearing on the DuPont Penthiopyrad 250 FS Fungicide Seed Treatment label.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

DuPont Penthiopyrad 250 FS Fungicide Seed Treatment applications on labelled crops will not interfere with any preventative measures employed to reduce disease pressure and, when used in accordance with label directions is fully compatible with integrated pest management (IPM) strategies.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Penthiopyrad is part of the succinate dehydrogenase inhibitor (SDHI) class of fungicides (Fungicide Resistance Action Committee [FRAC] group 7; carboxamides). No cross resistance to any compound of a different fungicide class is expected. Cross-resistance may occur within the same fungicide class. SDHI fungicides are currently considered by FRAC to present medium to high risk of disease resistance development. In cases where pathogens with medium to high resistance risks are concerned, it is recommended to use penthiopyrad in mixtures with an appropriate partner that is active in its own right against current field populations of the target pathogen at the applied dose. Treatments of penthiopyrad alone can be used in cases where pathogens with low resistance risk are concerned such as *Rhizoctonia*. FRAC has not reported resistance to any of the diseases on the labelled crops. In addition, the limitation to one application with a seed treatment alleviates the risk of disease resistance development associated with repeated applications of single active ingredients.

5.4.4 Contribution to Risk Reduction and Sustainability

The use of DuPont Penthiopyrad 250 FS Fungicide Seed Treatment is fully compatible with IPM strategies. Since penthiopyrad is intended here for use in seed treatments, the amount of product that will be applied is small relative to other methods of application such as ground or foliar sprays. Fungicide seed treatments allow for targeted applications of effective active ingredients to reduce or prevent early season disease development and potentially alleviate later disease pressure due to secondary infections. Penthiopyrad provides an effective management tool for seed and soil-borne diseases of serious economic impact to major crops in Canadian agriculture.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Please refer to PRD2011-26 for details.

6.2 Formulants and Contaminants of Health or Environmental Concern

Impurities and formulants of human health or environmental concern as identified in the Canada Gazette[5], Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances and allergens known to cause anaphylactic-type reactions, are not expected to be present in the end-use product or carried through from the technical grade active ingredient. The end-use product may contain toluene and petroleum distillates at up to 0.3% and 0.16 %, respectively. Other formulants and impurities of human health or environmental concern as identified in the PMRA formulants database, Section 2.13.4 of DIR98-04[6] and Appendix II of DIR99-03[7] (excluding those identified in the Canada Gazette) are not expected to be present in the product or carried through from the technical grade active ingredient.

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5 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

6 DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product.*

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

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for penthiopyrad is adequate to define the majority of toxic effects that may result from exposure. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies. Penthiopyrad is not neurotoxic but there was evidence of immunotoxicity in adults. In short-term and chronic studies on laboratory animals, the primary target was the liver. Effects also occurred in the thyroid and adrenal glands as well as in the gall bladder of the dog. In the chronic rat study, the most sensitive target was the kidney. Although penthiopyrad is not evidently genotoxic, there was weak evidence of oncogenicity in rats after chronic dosing. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Workers treating seed with DuPont Penthiopyrad 250 FS Fungicide Seed Treatment and workers planting treated seed are not expected to be exposed to levels of penthiopyrad that will result in an unacceptable risk when DuPont Penthiopyrad 250 FS Fungicide Seed Treatment is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

The proposed seed treatment use of penthiopyrad on canola, rapeseed, mustard, soybean and corn does not constitute a risk of concern for chronic or acute dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. No revision is required for the established MRLs. The PMRA recommends that the following MRL be specified for residues of penthiopyrad.

Commodity	Recommended MRL (ppm)
Mustard seeds (condiment type)	1.5

7.2 Environmental Risk

Please refer to PRD2011-26 for a summary of the environmental fate and behaviour of penthiopyrad.

Overall, there are negligible environmental risks associated with the planting of penthiopyrad-treated seeds. As exposure to the aquatic environment is not anticipated with the intended use of penthiopyrad-treated seed, a negligible risk is expected for aquatic organisms. Although, birds and small mammals may be exposed to penthiopyrad through ingestion of treated seed on agricultural fields, the risk was determined to be negligible on an acute and chronic exposure basis. Earthworms and soil-dwelling arthropods could be exposed to penthiopyrad in the soil; however, this exposure is likely to exhibit a negligible risk given the much lower application rates associated with treated seed. For bees, the risk was negligible with foliar application of penthiopyrad; hence, a negligible risk is also anticipated with the lower seed treatment rates.

Similarly, with the lower application rates associated with seed treatment, the risk to non-target terrestrial plants is expected to be negligible.

7.3 Value

The value information, which includes efficacy data and scientific rationales, submitted to register DuPont Penthiopyrad 250 FS Fungicide Seed Treatment was sufficient in supporting the value of the products' uses for control or suppression of seed and soil-borne diseases in canola, rapeseed, mustard, corn and soybean.

Registration of this new seed treatment provides users with an additional option with a demonstrated potential to increase yields and reduce early-season impact of seed and seedling diseases on crop stand establishment. Proper stand establishment is reported to be one of the most important early production factors for insuring profitable crop yield.

Seed treatments are effective and targeted means of early disease control requiring a single application under controlled conditions of relatively smaller amounts of active ingredients compared to soil or foliar applications in the field.

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 Penthiopyrad Technical Fungicide and DuPont Penthiopyrad 250 FS Fungicide Seed Treatment containing the technical grade active ingredient penthiopyrad, for use as a seed treatment on canola, rapeseed, mustard (oil and condiment types), corn and soybean to control or suppress various soil-borne and seed-borne fungal diseases.

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

µg	microgram
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
AD	administered dose
bw	body weight
cm	centimetre
DACO	Data Code
EDE	estimated daily exposure
EEC	expected environmental concentration
FRAC	Fungicide Resistance Action Committee
FS	flowable suspension
g	gram
ha	hectare(s)
HDPE	High density polyethylene
IPM	Integrated Pest Management
kg	kilogram(s)
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOC	level of concern
L	litre(s)
MOE	margin of exposure
MAS	maximum average score for 24, 48 and 72 hours
MIS	maximum irritation score (subscript in hours indicates time after dosing)
MRL	maximum residue limit
mg	milligram(s)
mL	millilitre(s)
MRL	maximum residue limit
n/a	not applicable
nm	nonametre
NC	not classified
NOAEL	no observable adverse effect level
NZW	New Zealand White
Pa	Pascal
ppm	parts per million
PPE	personal protective equipment
PCPA	*Pest Control Product Act*
PMRA	Pest Management Regulatory Agency
PHI	preharvest interval
PRD	Proposed Registration Decision
RQ	risk quotient
SDHI	Succinate Dehydrogenase Inhibitor
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Toxicity Profile of DuPont Penthiopyrad 250 FS Fungicide Seed Treatment Containing Penthiopyrad

Study Type/Animal/PMRA #	Study Results	PMRA #
Acute oral toxicity Wistar rats	LD_{50} > 5000 mg/kg bw Low toxicity	2277883
Acute dermal toxicity Sprague-Dawley rats	LD_{50} > 5000 mg/kg bw Low toxicity	2277884
Acute inhalation toxicity (nose-only) Wistar rats	LC_{50} > 6.2 mg/L Low toxicity	2277885
Dermal irritation NZW rabbits	MAS = 0, MIS = 0.2/8.0 Minimally irritating	2277887
Eye irritation NZW rabbits	MAS (24–72 hours) of 15.7/110 Mildly irritating	2277886
Dermal sensitization Local Lymph Node Assay (LLNA) CBA/JHsd mice	Non-sensitizer	2277888

Table 2 Screening Level Risk Assessment for Birds and Mammals Exposed to Penthiopyrad-Treated Canola Seed.

Organism	Study Endpoint (mg a.i./kg bw/day)	EDE (mg a.i./kg bw/day)	RQ
Small bird (0.02 kg)			
Acute	206.60	126.969	0.61
Reproduction	718.70	126.969	0.18
Medium bird (0.10 kg)			
Acute	206.60	99.736	0.48
Reproduction	718.70	99.736	0.14
Large bird (1.00 kg)			
Acute	206.60	29.077	0.14
Reproduction	718.70	29.077	0.04
Small mammals (0.015 kg)			
Acute	200.00	72.559	0.36
Reproduction	250.00	72.559	0.29
Medium mammals (0.035 kg)			
Acute	200.00	62.401	0.31
Reproduction	250.00	62.401	0.25
Large mammals (1.00 kg)			
Acute	200.00	34.359	0.17
Reproduction	250.00	34.359	0.14

EDE = estimated daily exposure; RQ = risk quotient

Table 3 Active Ingredients in Alternative Fungicide Seed Treatment Products Registered for Use on Canola, Rapeseed, Mustard, Soybean, and/or Corn for the Management of Soil and Seed-Borne and Soil-Borne Diseases (Correct to October, 2013)

Crops	Active Ingredient (FRAC Resistance Management Group)
Canola	azoxystrobin (11) [b]
	Bacillus subtilis, strain GB03(44) [ab]
	Bacillus subtilis, strain MBI 600 (44) [ab]
	boscalid (7) + pyraclostrobin (11) [ab]
	carbathiin (7) + ipconazole (3) [abc]
	carbathiin (7)+ thiram (M3) [bcd]
	carbathiin (7)+ trifloxystrobin (11) +metalaxyl (4) [bcd]
	difenoconazole (3) +metalaxyl (4) + fludioxonil (12) [abcd]
	ipconazole (3) [ab]
	iprodione (2) + thiram (M3) [bcd]
	iprodione (2) [b]
	metalaxyl (4) + thiram (M3) + carbathiin (7) [abd]
	penflufen (7) +trifloxystrobin (11) + metalaxyl (4) [abcd]
	penflufen (7) [ab]
	pyraclostrobin (11) [abcd]
	sedaxane (7) [b]
	trifloxystrobin (11) [b]
Soybean	azoxystrobin (11) [b]
	Bacillus subtilis GB03 (44) [a]
	Bacillus subtilis, strain MBI 600 (44) [ab]
	boscalid (7) + pyraclostrobin (11) [ab]
	carbathiin (7) + thiram (M3) [ab]
	fludioxonil (12) + metalaxyl (4) [ab]
	fluxapuroxad (7) [a]
	metalaxyl (4) + fludioxonil (12)+ azoxystrobin (11) [ab]
	metalaxyl (4) + fludioxonil (12) [b]
	penflufen (7) + trifloxystrobin (11) [ab]
	penflufen (7) +prothioconazole (3) + metalaxyl (4) [ab]
	penflufen (7) [ab]
	propiconazole (3) [b]
	prothioconazole (3) [a]
	pyraclostrobin (11) [ab]
	saponins of *Chenopodium quinoa* (NC) [b]
	sedaxane(7) [b]
	Trichoderma harzianum Rifai strain KRL-AG2 (NC) [ab]
	trifloxystrobin (11) + metalaxyl (4) [ab]
Corn	azoxystrobin (11) [b]
	difenoconazole (3) + metalaxyl (4) [a]
	fludioxonil (12) + metalaxyl (4) +azoxystrobin (11) + thiabendazole (3) [ab]
	fludioxonil (12) + metalaxyl (4) [ab]

Crops	Active Ingredient (FRAC Resistance Management Group)
	ipconazole (3) [ab]
	penflufen (7) + prothioconazole (3) + metalaxyl (4) [ab]
	penflufen (7) + trifloxystrobin (11) [ab]
	penflufen (7) [b]
	prothioconazole (3) [a]
	pyraclostrobin (11) [b]
	sedaxane (7) [b]
	trifloxystrobin (11) + metalaxyl (4) [a]
	trifloxystrobin (11) [a]

[a] registered for management of seed and/or seedling diseases caused by *Fusarium*
[b] registered for management of seed and/or seedling diseases caused by *Rhizoctonia*
[c] registered for management of blackleg
[d] registered for management of seed-borne *Alternaria*

Table 4 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed use claim	Supported Use
Damping-off, seedling blight, seed rot and root rot caused by *Fusarium* spp. on canola, rapeseed, mustards (oil and condiment varieties), at a rate of 20–50 g a.i./100 kg seed, and on corn and soybeans at a rate of 0.015–0.045 mg a.i./seed as a seed treatment before planting.	Supported with proposed use pattern for disease control
Damping-off, seedling blight, seed rot and root rot caused by *Rhizoctonia solani* on canola, rapeseed, mustards (oil and condiment varieties), at a rate of 20–50 g a.i./100 kg seed, and on corn and soybeans at a rate of 0.015–0.045 mg a.i./seed as a seed treatment before planting.	Supported with proposed use pattern as proposed for disease control
Blackleg caused by soil-borne and seed-borne *Leptosphaeria maculans* on canola, rapeseed, mustards (oil and condiment varieties) at a rate of 20–50 g a.i./100 kg seed as a seed treatment before planting.	Supported with proposed use pattern for disease suppression
Alternaria caused by seed-borne *Alternaria* spp. on canola, rapeseed, mustards (oil and condiment varieties) at a rate of 20–50 g a.i./100 kg seed as a seed treatment before planting.	Supported with proposed use pattern for disease suppression against *Alternaria brassicae*

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

The maximum residue limit (MRL) proposed for penthiopyrad in/on mustard seeds (condiment type) in Canada is not being promulgated in the United States, due to differences in the pesticide use pattern. American tolerances for penthiopyrad in/on other crops are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs[8] listed for penthiopyrad in or on any commodity on the Codex Alimentarius Pesticide Residues in Food website.

Table 1 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Mustard seeds (condiment type)	1.5	Not Established	Not Established

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Under the North American Free Trade Agreement, Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

[8] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA #	Reference
2250464	2012, Product Identity and Composition of End-Use Product Penthiopyrad (DPX-LEM 17) 250 g/L FS Seed Treatment formulation, DACO: 3.2,3.2.1,3.2.2,3.3.1 CBI
2250461	2250461 2012, Determination of Penthiopyrad (DPX-LEM 17), Chlorothalonil (DPX-V2757), and Cyproconazole (DPX-YG177) in End-Use products, DACO: 3.4.1
2250462	2012, Validation of the analytical method for determination of Penthiopyrad (DPX-LEM 17) in DPX-LEM 17 g/L FS formulated product, DACO: 3.4.1
2250466	2012, Penthiopyrad 250 g/L FS Seed treatment formulation (DPX-LEM 17): Laboratory study of Physical and chemical characteristics, DACO: 3.5, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2314184	2013, Penthiopyrad 250 g/L FS Seed Treatment formulation (DPX-LEM 17): Laboratory Study of Storage Stability and Corrosion Characteristics, DACO: 2.14.14

2.0 Human and Animal Health

PMRA #	Reference
2250453	2011, Penthiopyrad (DPX-LEM 17) 250 g/L FS: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.2.1,4.6.1
2250454	2011, Penthiopyrad (DPX-LEM 17) 250 g/L FS: Acute Dermal Toxicity in Rats, DACO: 4.2.2,4.6.2
2250455	2012, Penthiopyrad (DPX-LEM 17) 250 g/L FS: Inhalation medium lethal concentration (LC_{50}) Study in Rats, DACO: 4.2.3,4.6.3
2250456	2011, Penthiopyrad (DPX-LEM 17) 250 g/L FS: Primary Eye Irritation in Rabbits, DACO: 4.2.4,4.6.4
2250457	2011, Penthiopyrad (DPX-LEM 17) 250 g/L FS: Primary Skin Irritation in Rabbits, DACO: 4.2.5,4.6.5
2250459	2012, Penthiopyrad (DPX-LEM 17) 250 g/L FS: Local Lymph Node Assay (LLNA) in mice, DACO: 4.2.6,4.6.6
2250473	2009, Fluquinconazole and Prochloraz: Determination of operator exposure during cereal seed treatment with Jockey fungicide in Germany, United Kingdom and France, DACO: 5.4
2250474	2007, Determination of operator exposure to imidacloprid during loading/sowing of Gaucho treated maize under realistic field conditions in Germany and Italy, SeedTropex Steering Group, DACO: 5.4
2250472	2011, Heubach Dust Test: DPX-HGW86 Containing Seed Treatment on Canola/Oilseed Rape, DACO: 5.4

3.0 Environment

None

4.0 Value

PMRA #	Reference
2250468	2012. Biological Assessment Dossier for DuPont Penthiopyrad 250 FS Fungicide Seed Treatment - Canada, 2012. 1080 pp. DACO 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5.3, 10.5.4.