Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.3.1, 3.12, 3.13, 4.6 Application

Application Number: 2015-2215
Application: New EP Product Chemistry:
Product: Intego Solo Fungicide
Registration Number: 31324
Active ingredients (a.i.): ethaboxam
PMRA Document Number: 2664002

Background

Intego Solo Fungicide was granted full registration in Canada on August 7th, 2014. This agricultural end-use product contains ethaboxam as its active ingredient and is used a seed treatment for the control or suppression of various seed and seedling diseases in a range of crops.

Purpose of Application

The purpose of this submission was to include a higher rate to the currently registered use of Intego Solo Fungicide on legume vegetables (Crop Group 6), add a new use for the sunflower crop group (Crop Subgroup 20B), and fulfill outstanding conditions for full registration of this end-use product.

Chemistry Assessment

Intego Solo Fungicide is formulated as a suspension containing ethaboxam at a nominal concentration of 383 g/L. This end-use product has a density of 1.10-1.14 g/mL and pH of 7.6-8.3. The conditions of registration for this product included the provision of corrosion characteristics and storage stability studies. Data to fulfill these conditions were provided, reviewed, and found to be acceptable. As such, the chemistry requirements for Intego Solo Fungicide have been fulfilled.

Health Assessments

Residue data from soybean field trials, a radiotracer study on sunflower seed and storage stability data were reviewed to support the domestic use of Intego Solo Fungicide on Crop Group 6 (Legume Vegetables) and Crop Subgroup 20B (sunflower subgroup). Ethaboxam was applied as a seed treatment to soybean at exaggerated rates and harvested according to label directions. Ethaboxam was applied as a seed treatment to sunflower seed at or greater than the treatment rate, and harvested according to label direction.

Canada

Maximum Residue Limits (MRLs)

The recommendation for MRLs for ethaboxam was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of ethaboxam in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities.

Table 1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits MRLs

Commodity	Application Method/ Total Application Rate (g a.i./100 kg seed)	PHI (days)	Ethaboxam Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Soybean seeds	Seed treatment 75 g a.i./100 kg seed	130-138	<0.01	<0.01	No quantifiable residues were observed at exaggerated rates	0.01 Crop Group 6 (except field pea and cowpea)	0.01 Dry cowpea seeds, succulent shelled cowpeas and dry field peas
Sunflower	Seed treatment 0.0945-0.202 mg a.i./seed	105	<0.005	<0.005	No quantifiable residues were observed at exaggerated rates	--	0.01 Crop Subgroup 20B (sunflower subgroup)
	Seed Treatment 0.185-0.192 mg a.i./seed	105	<0.005	0.005			

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

MRLs are recommended to cover residues of ethaboxam. Residues in these crop commodities at the MRLs proposed in Table 1 will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

An occupational risk assessment was performed for commercial and on-farm treaters and planters that may be exposed to Intego Solo Fungicide. The proposed changes to the product should not result in health risks of concern to the active ingredient, ethaboxam. No health risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

An environmental risk assessment was conducted to determine the potential for risk to non-target organisms posed by the increase in application rate of Intego Solo Fungicide to legume vegetable seed and the addition of sunflower seed treatments. Risks to birds and small, wild mammals were identified. As such, label statements to identify hazards and mitigate risk from ingestion of treated seed are required for product labels.

Value Assessment

Intego Solo Fungicide treatments have demonstrated an acceptable level of *Phytophthora* control based on stand establishment and yield benefits in soybean. Intego Solo Fungicide is recommended for control of phytophthora root rot on legumes in several states in the US, including Kansas, Ohio and Michigan. Intego Solo Fungicide is registered in the USA for the control of early season phytophthora root rot on all legume vegetables at the same rate as the labelled Canadian rate. With the value information provided, the registrant has fulfilled the data requirements for this use. A rate range of 19.6 - 39.1 mL/100 kg seed was supported for all legume vegetables. With the addition of the high rate, an upgrade of the claim against *Phytophthora*, from suppression to control, was supported.

To support the proposed claims for Intego Solo Fungicide on the sunflower crop subgroup (Crop Group 20B), the registrant provided efficacy data from five trials against downy mildew on sunflower. The data demonstrated that Intego Solo Fungicide, at rates of 260 – 391 mL/100 kg seed, significantly reduced downy mildew infection. Rationales were provided to support extrapolation of this evidence to support all crops under Crop Group 20B that can be grown under Canadian field conditions and include a claim for control of *Pythium* seed rot/pre-emergence damping-off.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Intego Solo Fungicide, and has found the information sufficient to include a higher rate to the currently registered use of Intego Solo Fungicide on legume vegetables, add a new use for the sunflower crop subroup, and fulfill outstanding conditions for full registration.

References

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