

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.10 & 3.11 Application

Application Number: 2009-0317

Application: New EP Product Chemistry-Guarantee, Identity of Formulants, and

Proportion of Formulants.

New to Product Labels-Tank Mixes and New Pests

Product: Trilex AL Concentrate Seed Treatment Fungicide

Registration Number: 29679

Active ingredients (a.i.): Metalaxyl (MTA), Trifloxystrobin (TFY)

PMRA Document Number: 1900412

Purpose of Application

The purpose of this application was to register Trilex AL Concentrate Seed Treatment Fungicide, a new end-use product containing the active ingredients, trifloxystrobin and metalaxyl, for the control of multiple soil- and seed-borne diseases on bean, chickpea, peas, lentils, soybean and corn. The application was also to add tank mix of Stress Shield for Cereals and Soybeans (for use on soybean), Vortex FL Seed Treatment Fungicide and/or Poncho 600 FS Seed Treatment Insecticide to the Trilex Al Concentrate Seed Treatment Fungicide label.

Chemistry Assessment

Trilex AL Concentrate Seed treatment fungicide is formulated as a suspension containing tryfloxystrobin at a nominal concentration of 7.12% and metalaxyl at 5.68% nominal. This enduse product has a density of 1.08 g/mL and pH of 6.66. The chemistry requirements for Trilex AL Concentrate Seed treatment fungicide are complete.

Health Assessments

Trilex AL Concentrate Seed Treatment Fungicide was found to be of low oral toxicity, low toxicity via dermal exposure, and low toxicity via inhalation in rats. It is minimally irritating to the eye and non-irritating to the skin of rabbits. Trilex AL Concentrate Seed Treatment Fungicide is not a dermal sensitizer.

The use of the new end product Trilex AL Concentrate Seed Treatment Fungicide should not result in potential occupational or bystander exposure over the registered uses of trifloxystrobin or metalaxyl. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment as recommended on the label.



No new residue data were required to support the registration of the new end-use product Trilex AL Concentrate Seed Treatment Fungicide. The active ingredients in this product, trifloxystrobin and metalaxyl, are currently registered in Canada for use on all the crops listed on the Trilex AL Concentrate Seed Treatment Fungicide product label. The use of Trilex AL Concentrate Seed Treatment Fungicide on these crops at rates equal or less than the registered ones will not result in residues exceeding their established or proposed MRLs. Consequently, no increase in dietary exposure is anticipated.

Environmental Assessment

An environmental assessment was not conducted because no additional environmental data were required to support the registration of Trilex AL Concentrate Seed Treatment Fungicide. The rate of application of Trilex AL Concentrate Seed Treatment Fungicide is equivalent or lower than current registered rates for the active ingredients and the actives are already registered as a seed treatment for all crops listed on the label.

Value Assessment

Eighteen efficacy trials, including bridging trials, were submitted to support the claim. Based on the data reviewed, Trilex AL Concentrate Seed Treatment Fungicide demonstrated equivalent levels of protection to pulse crops planted in soils infected with soil-borne diseases compared to the current registered product, Trilex AL Concentrate Seed Treatment Fungicide. Data and rationale submitted showed that Trilex AL Concentrate Seed Treatment Fungicide provided control of seed decay/pre-emergence damping-off caused by *Fusarium* spp. on corn, and suppression of seed-borne ascochyta blight caused by *Ascochyta* spp.on chickpea, pea and lentil. Tank mixtures of Trilex AL Concentrate Seed Treatment Fungicide with Stress Shield insecticide on soybean, and with either Vortex FL fungicide and/or Poncho 600 insecticide also demonstrated either higher number of healthy plant roots or lower root rot disease compared to Trilex AL Concentrate Seed Treatment Fungicide alone. The proposed rate of 65 mL/kg seed was applied in all trials. No phytotoxicity was observed in any trial. The claims proposed on the label are fully supported.

Conclusion

Following an assessment of the data provided, the PMRA can support the full registration of the new end-use product Trilex AL Concentrate Seed Treatment Fungicide.

References

Studies/Information Provided by Applicant/Registrant

1712659	2007, Product Chemistry Data Trilex AL Concentrate FS, DACO:
	3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.
	5.2, 3.5.3, 3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
1712661	2008, The corrosion characteristics and storage stability of Trilex Concentrate FS
	end-use product, DACO: 3.5.10,3.5.14 CBI

1712662	2008, Trilex AL Concentrate Seed Treatment Fungicide, DACO:
	3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2,3.5 CBI
1712672	2008, Trilex AL Concentrate Seed Treatment Fungicide: A new formulation for control of seed and seedling diseases on large-seeded legumes, soybean and corn
	- Formulation bridging and demonstration of equivalence with Trilex AL Seed
	Treatment Fungicide, DACO: 10.1, 10.2, 10.2.3.1, 10.2.3.3(D), 10.3, 10.3.1,
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1712667	2008, Stress Shield (Imadacloprid) - Data to support a tank-mixture with Trilex
	AL Seed Treatment Fungicide in soybean, DACO: 10.1, 10.2.3.1, 10.2.3.3(D),
	10.3.1, 10.3.2(B)
1712650	2007, Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.6.2
1712653	2007, Acute Inhalation Toxicity Study in Rats - Limit Test, DACO: 4.6.3
1712654	2007, Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1
1712655	2007, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6
1712656	2007, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
1712657	2007, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5

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