Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3 & 2.4 Application

Application Number: 2013-1929
Application: New EP Product Chemistry-Identity of Formulants, Proportion of Formulants
Product: Evergol Xtend C Seed Treatment Fungicide
Registration Number: 31404
Active ingredients (a.i.): Penflufen and Trifloxystrobin
PMRA Document Number: 2417370

Purpose of Application

The purpose of this application was to register a new end-use product, EverGol Xtend C Seed Treatment Fungicide, based on a precedent product, EverGol Xtend Seed Treatment (Registration Number 30365).

Chemistry Assessment

EverGol Xtend C Seed Treatment Fungicide is formulated as a suspension containing penflufen at a nominal concentration of 154 g/L and trifloxystrobin at a nominal concentration of 154 g/L. The end-use product has a density of 1.08 g/mL at 20ºC and pH of 6.0-7.5. The chemistry requirements for this product have been fulfilled.

Health Assessments

Evergol Xtend C Seed Treatment is of low acute oral, dermal, and inhalation toxicity in rats. It is minimally irritating to the eye and non-irritating to the skin in rabbits. It is not a dermal sensitizer in the mouse.

No new residue data were submitted in support of the registration of the new end-use product EverGol Xtend C Seed Treatment Fungicide. Since it has identical guarantee and use pattern for both actives compared to the registered end-use product EverGol Xtend Seed Treatment Fungicide, the use of EverGol Xtend C Seed Treatment Fungicide is not expected to increase the magnitude of trifloxystrobin and penflufen residues in/on the treated crops. Therefore, the use of EverGol Xtend C Seed Treatment Fungicide will not increase the dietary exposure and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Canada

The use of the new end-use product, EverGol Extend C for seed treatment use on corn (field, sweet and popcorn), Crop Group 6 (beans and peas including soybeans), and alfalfa to control various disease fits within the registered use pattern for penflufen and trifloxystrobin. Exposure for commercial treaters and planters is not expected to increase when compare to the registered uses for penflufen and trifloxystrobin. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

An environmental assessment was not conducted because no additional environmental data were required to support EverGol Xtend C Seed Treatment Fungicide as the guarantee and use pattern is the same as the precedent product.

Value Assessment

A data waiver rationale based on the precedent product EverGol Xtend Seed Treatment was submitted to support the registration of EverGol Xtend C Seed Treatment Fungicide.

EverGol Xtend C Seed Treatment Fungicide and EverGol Xtend have the same guarantee (154 g penflufen + 154 g trifloxystrobin/L) and use pattern. Further, both fungicides deliver the same amount of active ingredients per 100 kg seed. The changes in identity and proportion of formulants are not expected to significantly impact product efficacy.

Conclusion

The PMRA has conducted a review of the information in support of this application and has determined that the registration of EverGol Xtend C Seed Treatment Fungicide can be supported.

References

PMRA Document Number	Reference
2288532	2013, Description of Materials Used to Produce EverGol Xtend C end use product, DACO: 3.2.1 CBI
2288533	2013, Description of the Formulation Process For EverGol Xtend C end use product, DACO: 3.2.2 CBI
2288534	2013, Product Identity and Certified Limits For EverGol Xtend C end use product, DACO: 3.3.1 CBI
2288535	2009, HPLC Determination of BYF 14182 (Penflufen)+ Trifloxystrobin Formulations, DACO: 3.4.1 CBI
2288536	2011, Validation of the Analytical Method AM006207KF4 for Determination of PENTRI308FS (Penflufen and Trifloxystrobin 308 g/L SC), PEN 240FS, PENRED 240FS, and Penflufen Technical by Liquid Chromatography (HPLC), DACO: 3.4.1 CBI
2288537	2013, Summary of Product Chemistry Reports for EverGol Xtend C, DACO: 3.5,3.7 CBI
2288538	2011, Determination of Safety-Relevant Data of penflufen + trifloxystrobin FS 308 (154+154 g/L), DACO: 3.5.11,3.5.12,3.5.8,3.7 CBI
2288539	2012, Storage Stability and corrosion characteristics of penflufen + trifloxystrobin FS 308 (154+154 g/L), DACO: 3.5.10,3.5.14 CBI
2288541	2011, Physical, chemical and technical properties of penflufen + trifloxystrobin FS 308 (154+154 g/L), DACO: 3.5,3.5.1,3.5.11,3.5.12,3.5.13,3.5.15,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7,3.5.8,3.5.9,3.7 CBI
2288526	EverGol Xtend C Seed Treatment Fungicide - General Bridging Rational Supporting New Formulation, DACO: 0.17.1
2288527	EverGol Xtend C Seed Treatment Fungicide - General Bridging Rationale Supporting New Formulation, DACO: 0.17.1
2288542	2011, PENFLUFEN+TRIFLOXYSTROBIN FS 154 + 154 G/L (colorless): Acute Oral Toxicity Study in Rats, DACO: 4.6.1
2288544	2011, Acute Dermal Toxicity Study in Rats with PENFLUFEN+TRIFLOXYSTROBIN FS 154 + 154 G/L (colorless), DACO: 4.6.2
2288545	2012, Acute Inhalation Toxicity Study (Nose-only) in the Rat with Penflufen + Trifloxystrobin FS 154+154 G/L (colorless), DACO: 4.6.3
2288546	2011, PENFLUFEN+TRIFLOXYSTROBIN FS 154 + 154 G/L (colorless): Acute Eye Irritation Study in Rabbits, DACO: 4.6.4
2288547	2011, Acute Skin Irritation Study in Rabbits with PENFLUFEN+TRIFLOXYSTROBIN FS 154 + 154 G/L (colorless), DACO: 4.6.5
2288548	2011, Penflufen & Trifloxystrobin FS 154 + 154 (colorless) Evaluation of potential skin sensitization in the local lymph node assay in the mouse, DACO: 4.6.6

ISSN: 1911-8082