



Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, and 3.13 Application

Application Number: 2009-2515
Application: New / Changes EP or MA Product Chemistry - Guarantee, Identity and Proportion of Formulants and New or Changes to Product Labels - Precautions
Product: Fluroxypyr EC Herbicide
Registration Number: 30389
Active ingredients (a.i.): Fluroxypyr
PMRA Document Number: 2028164

Purpose of Application

The purpose of this application was to register a new end-use product, Fluroxypyr EC Herbicide (guarantee 348 g/L fluroxypyr), for post-emergent control of annual broadleaf weeds in spring wheat, durum wheat, and spring barley in the Prairie Provinces and Peace River Region of British Columbia. Fluroxypyr EC Herbicide is based on the registered precedent products Starane Herbicide (Registration number 24815) and Starane II Herbicide (Registration number 29463), which have the same uses and rates.

Chemistry Assessment

Fluroxypyr EC Herbicide is formulated as an emulsifiable concentrate containing fluroxypyr-methyl at a nominal concentration of 348 g/L. This end-use product has a density of 1.1025 g/mL and pH of 5.66. The chemistry requirements for Fluroxypyr EC Herbicide are complete.

Health Assessments

Fluroxypyr EC is of low acute toxicity by the oral, dermal, and inhalation routes in rats. It is mildly irritating to the rabbit eye and is moderately irritating to the rabbit skin. The formulation is not a skin sensitizer in guinea pigs.

No new food residue chemistry data were submitted in support of the current application. The use directions for Fluroxypyr EC Herbicide are similar to the registered uses. Therefore, dietary exposure to residues of fluroxypyr in/on wheat and barley treated according to the label directions is not expected to increase for any segment of the population.

Similarly, the use of Fluroxypyr EC Herbicide on spring wheat, durum wheat, and spring barley fits within the registered use pattern for fluroxypyr, and exposure to fluroxypyr is not expected to increase over the currently registered use pattern.

Environmental Assessment

The use of Fluroxypyr EC Herbicide for post-emergent control of annual broadleaf weeds in spring wheat, durum wheat, and spring barley would not result in an increase in environmental impact/risk relative to the existing registered Starane products (Registration numbers 24815 & 29463). Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

The formulation of Fluroxypyr EC Herbicide was compared to the formulation of the cited precedent product, Starane II Herbicide. It was considered that the formulation changes to Fluroxypyr EC Herbicide should not result in any effects on product efficacy and crop safety compared to the Starane Herbicide formulations.

Confirmatory data from a total of 28 field trials conducted in Alberta, Manitoba, Michigan, North Dakota, and Saskatchewan in 2008 and 2009 were submitted to support registration of Fluroxypyr EC Herbicide. Efficacy and crop safety of Fluroxypyr EC Herbicide were directly compared to Starane Herbicide in these trials.

The efficacy of Fluroxypyr EC Herbicide for control of cleavers, kochia, volunteer flax, and wild buckwheat was visually assessed 1-3 times during the growing season. The level of control of these weeds following the application of Fluroxypyr EC Herbicide was comparable to that of Starane Herbicide.

Tolerance of 5 spring wheat varieties in 8 trials, 4 spring barley varieties in 5 trials, and 2 durum wheat varieties in 2 trials to Fluroxypyr EC Herbicide was reported 1-3 times during the growing season. Crop injury following the application of Fluroxypyr EC Herbicide was either slight or not detectable over locations and years, and comparable to the Starane Herbicide treatment. Yield data collected confirmed that spring wheat, durum wheat, and spring barley exhibited an adequate margin of crop safety to Fluroxypyr EC Herbicide applied in accordance with the label.

Conclusion

The PMRA has conducted a review of the available data to register Fluroxypyr EC Herbicide and has concluded that this new end-use product is acceptable for full registration.

References

- 1780356 2009, Product Chemistry Data to Support the Registration of Fluroxypyr EC Herbicide., DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5,3.5.4,3.5.5 CBI
- 1780357 2008, Product Identity and Composition, Description of Materials Used to Produce the product, Description of Formulation process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2 CBI
- 1780358 2008, Physical Properties of Obtain EC, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
- 1780359 Product Chemistry Protocol. Storage Stability of Obtain EC with Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
- 1780360 2009, Interim Analysis (6-months) Obtain EC, DACO: 3.5.10,3.5.14 CBI
- 1851905 2010, Fluroxypyr EC Herbicide Product Chemistry Summary Response to Deficiencies, DACO: 3.5,3.5.12,3.5.13,3.5.15
- 2045249 2011, Method Validation for Fluroxypyr-meptyl, DACO: 3.4.1
- 2045251 2011, Obtain EC Herbicide: Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
- 1851928 2010, Value Data to Support the Registration of Fluroxypyr EC Herbicide, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.3.2
- 1780361 22009, Value Data to Support the Registration of Fluroxypyr EC Herbicide, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.3.2
- 1780365 2009, Obtain EC - Acute Toxicology Data to Support the Registration of Fluroxypyr EC Herbicide, DACO: 4.1
- 1780366 2008, Obtain EC - Acute Oral Toxicity Up And Down Procedure in Rats, DACO: 4.2.1
- 1780367 2008, Obtain EC - Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.2.2
- 1780368 2008, Obtain EC - Acute Inhalation Toxicity Study in Rats - Limit Test, DACO: 4.2.3
- 1780369 2008, Obtain EC - Primary Eye Irritation Study in Rabbits, DACO: 4.2.4
- 1780370 2008, Obtain EC - Primary Skin Irritation Study in Rabbits, DACO: 4.2.5
- 1780371 2008, Obtain EC - Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.2.6

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