

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1, 3.10, 3.11, and 3.12 Application

Application Number: 2010-2395
Application: B.2.1 - New / Changes EP Product Chemistry-Guarantee
B.2.3 - New / Changes EP Product Chemistry-Identity of Formulants
B.2.4 - New / Changes EP Product Chemistry-Proportion of Formulants
B.2.5 - New / Changes EP Product Chemistry-Formulation Type
B.3.1 - New or Changes to Product Labels-Application Rate Increase
B.3.10 - New or Changes to Product Labels-Tank Mixes
B.3.11 - New or Changes to Product Labels-New Pests
B.3.12 - New or Changes to Product Labels-New Site or Host

Product: GF-1352 Herbicide
Registration Number: 30162
Active ingredients (a.i.): Florasulam
PMRA Document Number English PDF: 2066562

Purpose of Application

The purpose of this application was to register a new product, GF-1352 Herbicide, based on precedent product Florasulam Suspension Concentrate Herbicide (Registration Number 26891) with a change in formulation type, an increase in rate and a request for Master Product status. In addition, the application is adding a new pest (summer fallow), a new tank mix partner and a new crop, winter wheat.

Chemistry Assessment

GF-1352 Herbicide is a granular solid containing the active ingredient florasulam at a nominal concentration of 25 %. This product has a density of 0.9 g/mL and pH of 5.0 for a 1 % solution in water. The chemistry requirements for GF-1352 Herbicide have been completed.

Health Assessments

GF-1352 Herbicide is of low acute toxicity by the oral, dermal, and inhalation routes in rats. It is moderately irritating to the eye in rabbits. GF-1352 is not irritating to the skin in rabbits, nor is it a dermal sensitizer in guinea pigs.

Since the use is early postemergent application, and the application rate is within the rate for florasulam, the use of GF-1352 Herbicide is not expected to increase the magnitude of florasulam residues in/on wheat, barley and oats. Therefore the use of GF-1352 Herbicide is not expected to increase and will not pose an unacceptable risk in terms of dietary exposure to any segment of the population, including infants, children, adults and seniors.

A risk assessment for mixers, loaders and applicators was performed. The use of GF-1352 Herbicide should not result in unacceptable exposure to the active ingredient, florasulam. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

The use of GF-1352 Herbicide will not result in increased environmental exposure relative to the existing registered product Florasulam SC Herbicide (Reg. No. 26891). Thus, an acceptable environmental risk is expected. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

The efficacy of GF-1352 Herbicide applied to cereals for control of labelled broadleaf weeds was directly compared to that of Florasulam Suspension Concentrate Herbicide (Reg. No. 26891) applied at the rate of 5 g a.i./ha. The submitted data support the claim that the products are agronomically equivalent from an efficacy perspective. The submitted data do not support the requested control claim for narrow-leaved hawk's beard for GF-1352 applied alone.

Crop injury to spring wheat, durum wheat, winter wheat, barley and oats (pre-plant only) treated with GF-1352 Herbicide was usually low or absent, and was similar to the level of injury observed with Florasulam Suspension Concentrate. Grain yield data in general corroborated the crop injury data. The submitted data support the claim that the products are agronomically equivalent from a crop tolerance perspective.

Conclusion

The PMRA has completed an assessment of this application and has found the information to be sufficient to support full registration of GF-1352 Herbicide.

References

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- 1909026 2005, Analytical Method and Validation for the Analysis of Florasulam in Formulation GF-1352, DACO: 3.4.1 **CBI**
- 1909027 2005, Determination of Physico-Chemical Properties and Accelerated Storage Stability for GF-1352, DACO: 3.5 **CBI**
- 1909031 2008, Packaging Stability Study to Assess the Compatibility of GF-1352 with 0.25 L PET, 0.25 L HDPE and 100 g Plastic-lined Foil Containers, DACO: 3.5.10 **CBI**
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