Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-4487
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) Policy - Equivalency/Data Compensation Assessment
Product: Saffola Herbicide
Registration Number: 35269
Active ingredients (a.i.): Imazethapyr and saflufenacil
PMRA Document Number: 3603999

Purpose of Application

The purpose of this application was to register the commercial end-use product, Saffola Herbicide, based on a registered precedent product.

Chemistry Assessment

Saffola Herbicide is formulated as water-dispersible granules containing saflufenacil at a concentration of 17.8% and imazethapyr at a concentration of 50.2%. This end-use product has a density of 0.556–0.594 g/mL and pH of 6.8. The required chemistry data for Saffola Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Saffola Herbicide is considered to be of low acute oral, dermal and inhalation toxicity. It is considered to be mildly irritating eyes and slightly irritating to the skin. It is not considered to be a dermal sensitizer.

The use pattern of Saffola Herbicide is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of these active ingredients. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for imazethapyr or saflufenacil were submitted or were required to support the registration of Saffola Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Saffola Herbicide label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent product.

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Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of imazethapyr and saflufenacil is not expected to increase with the registration of Saffola Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses on the Saffola Herbicide label are within the currently registered uses for saflufenacil and imazethapyr. After a scientific review of the available information, it has been concluded that the environmental risks associated with the use of Saffola Herbicide are acceptable when used according to label directions.

Value Assessment

The availability of Saffola Herbicide provides growers an alternative option to control or suppress labelled weeds pre-plant or pre-emergence to soybeans in Ontario and Quebec. Registration of a generic product may increase competition in the market, which may result in a reduction in purchasing cost of similar products, thus lowering growers' overall input cost.

The formulation of Saffola Herbicide was compared to the formulation of the precedent product. It was concluded that Saffola Herbicide is agronomically equivalent to the precedent product. Therefore, all labelled uses and claims for Saffola Herbicide are acceptable and supported for inclusion since they are also included in the registration of the precedent product.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Saffola Herbicide.

References

PMRA Document Number	Reference
3386580	2022, Additional Product Chemistry for Saffola Herbicide - Parent, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.13,3.5.15,3.5.4,3.5.5
3386584	2022, Manufacturing process of Saflufenacil 178 + Imazethapyr 502 g/kg WDG, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3386592	2022, Determination of Physico-Chemical Properties of Saflufenacil 17.8%+ Imazethapyr 50.2% WDG, DACO: 3.5.11,3.5.12,3.5.6,3.5.8
3386593	2022, Accelerated Storage Stability and Corrosion Characteristcs to Packing Material of Saflufenacil 17.8%+Imazethapyr 50.2% WDG, DACO: 3.4.1,3.4.2,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7
3571886	2024, Response to Notice of Deficiencies for Saffola Herbicide, Submission Number: 2022-4487, DACO: 3.5.10,3.5.5