



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-3721
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: Hinge Herbicide
Registration Number: 34352
Active ingredient (a.i.): Rimsulfuron
PMRA Document Number: 3265304

Purpose of Application

The purpose of this application was to register Hinge Herbicide, for control of listed weeds in field corn, tomatoes, caneberries, stone fruit and potatoes, based on a precedent.

Chemistry Assessment

Hinge Herbicide is formulated as water soluble granule containing rimsulfuron at a concentration of 25%. This end-use product has a density of 0.58-0.65 g/mL and pH of 6.12. The required chemistry data for Hinge Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Hinge Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Hinge Herbicide is considered of low toxicity to rats via the oral and dermal route, and is considered slightly toxic via the inhalation route. It is considered minimally irritating to the eye and non-irritating to the skin and is not considered a dermal sensitizer.

The use pattern of Hinge 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 this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for rimsulfuron were submitted or are required to support the registration of Hinge Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Hinge 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 the precedent end-use products.

Based on this assessment, residues are not expected to be greater than that for the currently registered uses and will be covered by the established MRLs. Consequently, dietary exposure to residues of rimsulfuron is not expected to increase with the registration of Hinge Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The application rate and use pattern for Hinge Herbicide is within the currently registered use pattern. Risk to the environment is acceptable when Hinge Herbicide is used according to the label directions.

Value Assessment

Registration of a generic product may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of Hinge Herbicide was compared to the formulations of the cited precedent products. The agronomic equivalence between Hinge Herbicide and the cited precedent products is established based on the formulation comparison. Therefore, all uses and claims found on the precedent product labels are supported for inclusion on the Hinge Herbicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the registration of Hinge Herbicide.

References

PMRA Document Number	References
3146100	2020, Manufacturing Process for Rimsulfuron 250g/kg SG, DACO: 3.2.1,3.2.2 CBI
3146101	2020, Study on the Method Validation of Rimsulfuron 25% Water Soluble Granules, DACO: 3.4.1,3.4.2
3146102	2020, Study on the Accelerated Storage and Packaging Stability of Rimsulfuron 25% Water Soluble Granules, DACO: 3.5.10,3.5.14
3146103	2020, Study on the Physico-chemical Properties, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.7

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