



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-0776
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Intensa
Registration Number: 35041
Active ingredient (a.i.): Sulfentrazone
PMRA Document Number: 3471367

Purpose of Application

The purpose of this application was to register a new herbicide end-use product, Intensa, for use on labelled terrestrial food and feed crops, based on a registered precedent product.

Chemistry Assessment

Intensa is formulated as a suspension concentrate containing sulfentrazone at a concentration of 480 g/L. This end-use product has a density of 1.228 g/mL and pH of 6.11. The required chemistry data for Intensa have been provided, reviewed and found to be acceptable.

Health Assessments

Intensa is considered to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is considered to be minimally irritating to the eye and is not considered to be irritating to the skin. It is not considered to be a dermal sensitizer.

The registered use pattern of Intensa 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 sulfentrazone. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.*

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

The use directions on the Intensa label, including the target crops, method, rates and timing of application, preharvest intervals, and crop rotation restrictions are comparable to those on the label of the precedent end-use product.

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 sulfentrazone is not expected to increase with the registration of Intensa 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 Intensa label are within the currently registered use pattern of sulfentrazone. After a scientific review of the available information, the PMRA has concluded that the environmental risks associated with the use of Intensa are acceptable when used according to label directions.

Value Assessment

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

The formulation of Intensa was compared to the formulation of the precedent product. The differences between the formulations were considered minor, which is unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Intensa label.

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 Intensa.

References

PMRA

Document

Number

Reference

3322474	2022, DER for Intensa, DACO: 12.7.3,3.1.2,3.5.4,Document J,Document M
3322475	2022, Applicant's Name and Address; Formulating Plant Name and Address; Product Identification, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.13, 3.5.15, 3.5.5
3322477	2022, Physicochemical Properties of Sulfentrazone 480 G/L SC, DACO: 3.5.11, 3.5.12,3.5.13,3.5.14,3.5.6,3.5.8,3.5.9
3322478	2021, Accelerated Storage Stability Test by Heating at 54 +- 2C of Sulfentrazone 480 G/L SC, DACO: 3.4.1,3.5.1,3.5.10,3.5.2,3.5.3,3.5.7 CBI
3322486	2022, Manufacturing Process, DACO: 3.2,3.2.1,3.2.2 CBI
3365387	2022, Five batch analysis of sulfentrazone technical, DACO: 2.13.4 CBI

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