



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-3282
Application: Application Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Topple Herbicide
Registration Number: 35126
Active ingredient (a.i.): Topramezone
PMRA Document Number: 3490923

Purpose of Application

The purpose of this application was to register the new end-use product, Topple Herbicide, for control of grasses and broadleaf weeds, based on a registered precedent product.

Chemistry Assessment

Topple Herbicide is formulated as a suspension containing topramezone at a concentration of 336 g/L. This end-use product has a density of 1.112 – 1.116 g/mL and a pH of 4.23. The required chemistry data for Topple Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Topple herbicide is of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is minimally irritating to the eyes, slightly irritating to the skin and it is not considered a dermal sensitizer.

The use pattern of Topple Herbicide containing topramezone 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 topramezone were submitted or are required to support the registration of Topple Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Topple Herbicide label, including the target crops, method, rates and timing of application, preharvest intervals, feeding restrictions, 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 topramezone is not expected to increase with the registration of Topple 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 Topple Herbicide label are within the currently registered use pattern of the active ingredient topramezone. Therefore, no additional risk is expected when Topple Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The availability of Topple Herbicide provides growers an alternative option for the control of labelled weeds in field corn and sweet corn. 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 Topple Herbicide was compared to the formulation of the precedent product. It was concluded that Topple Herbicide is agronomically equivalent to the precedent product since the differences in their formulations would be unlikely to result in any significant impact on product performance, either in terms of efficacy or crop tolerance. Therefore, the labelled uses and claims for Topple Herbicide are acceptable 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 Topple Herbicide.

References

PMRA

Document

| Number | Reference |
|---------|---|
| 3372946 | 2022, Additional Product Chemistry for Topple Herbicide - Parent, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.15,3.5.4,3.5.5 |
| 3372950 | 2022, Manufacturing process to Topramezone 336 g/L SC, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI |
| 3372951 | 2022, Accelerated Storage Stability Test by Heating by at 54 +/- 2C of Torpamezone 29.7% w/w SC, DACO: 3.5.1,3.5.10,3.5.2,3.5.3,3.5.7 |
| 3372952 | 2022, Physicochemical Properties of Torpamezone 29.7% w/w SC, DACO: 3.5.11,3.5.12,3.5.13,3.5.14,3.5.6,3.5.8,3.5.9 |
| 3385654 | 2021, Acute Oral Toxicity Study of Topramezone 29.7% w/w SC in Wistar Rats, DACO: 4.6.1 |
| 3385655 | 2021, Acute Dermal Toxicity Study of Topramezone 29.7% w/w SC in Wistar Rats, DACO: 4.6.2 |
| 3385656 | 2021, Acute Inhalation Toxicity Study of Topramezone 29.7% w/w SC in Wistar Rats, DACO: 4.6.3 |
| 3385659 | 2021, Acute Eye Irritation/ Serious eye damage Study of Topramezone 29.7% w/w SC in New Zealand White Rabbits, DACO: 4.6.4 |
| 3385657 | 2021, Acute Dermal Irritation/Corrosion Study of Topramezone 29.7% w/w SC in New Zealand white Rabbits, DACO: 4.6.5 |
| 3385658 | 2021, Skin Sensitisation Potential of Topramezone 29.7% w/w SC in Guinea pigs (GPMT), DACO: 4.6.6 |

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