

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-0702
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy-Equivalency/Data Compensation Assessment
Product: TruSlate Pro Herbicide
Registration Number: 34546
Active ingredients (a.i.): Clopyralid, Fluroxypyr (present as 1-methylheptyl ester), MCPA (present as esters)
PMRA Document Number : 3324028

Purpose of Application

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

Chemistry Assessment

TruSlate Pro Herbicide is formulated as an emulsifiable concentrate containing MCPA, present as 2-ethylhexyl ester at a concentration of 210 g/L, fluroxypyr, present as 1-methylheptyl ester at a concentration of 77 g/L and clopyralid at a concentration of 60 g/L. This end-use product has a density of 1.065 g/mL and pH of 2.54. The required chemistry data for TruSlate Pro Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

TruSlate Pro Herbicide is of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is severely irritating to the eye, mildly irritating to the skin, and is not considered to be a dermal sensitizer.

The requested use pattern of TruSlate Pro 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 product 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 clopyralid, fluroxypyr and MCPA were submitted or are required to support the registration of TruSlate Pro Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the TruSlate Pro Herbicide label, including the target crops, method (ground and aerial), rates and timing of application, preharvest intervals, feeding/grazing restrictions, and crop rotation restrictions are comparable to the precedent end-use product.

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 clopyralid, fluroxypyr and MCPA is not expected to increase with the registration of TruSlate Pro Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

When used in accordance with label directions, the environmental risks associated with the use of TruSlate Pro Herbicide for the control of broadleaf weeds in spring, winter, and durum wheat, spring barley, and oats, as well as special uses in seedling and established tall fescue grown for seed, canaryseed, and improved pastures containing only forage grasses, are acceptable.

Value Assessment

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

The TruSlate Pro Herbicide formulation was compared to the cited precedent product formulation. The differences between the formulations are unlikely to result in any significant impact on product performance, in terms of efficacy and crop tolerance. This was corroborated with data from replicated field trials, which were conducted in Alberta and Manitoba in 2019. Therefore, uses and claims, which are found on the precedent product label, are supported for inclusion on the TruSlate Pro Herbicide label.

Conclusion

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

References

PMRA Document No.	Reference
3093466	2020, DACO 3_Product Chemistry Summary_FINAL, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
3304425	2021, DACO 3.2.2 Description of the Formulation Process Deficiency Response, DACO: 3.2.2 CBI
3304426	2021, DACO 3.2.2 Description of the Formulation Process Deficiency Response - [CBI removed], DACO: 3.2.2 CBI

- 3304427 2021, NUP-08035: Enforcement Analytical Method for the Determination of MCPA 2EHE, Fluroxypyr MHE and Clopyralid by Gas Chromatography or High Performance Liquid Chromatography, DACO: 3.4.1 CBI
- 3304429 2008, Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscosity and Density/Relative Density, DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
- 3304430 2009, Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
- 3304431 2008, Physical and Chemical Characteristics: Flammability, DACO: 3.5.11 CBI
- 3304432 2021, DACO 3.5.12 - 3.5.13 Explodability & Miscibility Waiver Request, DACO: 3.5.12,3.5.13 CBI
- 3093468 2008, Acute Oral Toxicity Up And Down Procedure in Rats, DACO: 4.6.1
- 3093469 2008, Acute Dermal Toxicity Study in Rats – Limit Test, DACO: 4.6.2
- 3093470 2008, Acute Inhalation Toxicity Study in Rats – Limit Test, DACO: 4.6.3
- 3093471 2008, Primary Eye Irritation Study in- Rabbits, DACO: 4.6.4
- 3093472 2008, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
- 3093473 2008, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6

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