Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-6065
Application: Application subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) policy-Equivalency/Data Compensation Assessment
Product: Repute Herbicide
Registration Number: 35280
Active ingredients (a.i.): Clopyralid, Fluroxypyr (present as 1-methylheptyl ester), MCPA (present as 2-ethylhexyl ester)
PMRA Document Number: 3543794

Purpose of Application

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

Chemistry Assessment

Repute Herbicide is formulated as an emulsifiable concentrate containing fluroxypyr (present as 1-methylheptyl ester) at a concentration of 61.56 g/L, clopyralid at a concentration of 42.72 g/L and MCPA (present as 2-ethylhexyl ester) at a concentration of 239.5 g/L. This end-use product has a density of 0.95 g/mL and a pH of 5.3. The required chemistry data for Repute Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Repute Herbicide was considered toxicologically equivalent to the precedent product; therefore no toxicology data were required. Repute Herbicide is slightly toxic by the oral route and of low toxicity by the dermal and inhalation routes. It is mildly irritating to the eyes, moderately irritating to the skin, and is a skin sensitizer.

The use pattern of Repute 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 containing clopyralid, fluroxypyr, and MCPA. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

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No new residue data for clopyralid, fluroxypyr, and MCPA were submitted or were required to support the registration of Repute Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Repute Herbicide label, including the formulation type, target crops, method (ground or aerial), rates, timing of application, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent 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 clopyralid, fluroxypyr, and MCPA is not expected to increase with the registration of Repute 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 of Repute Herbicide are within the currently registered use patterns for fluroxypyr, clopyralid and MCPA. Therefore, no additional risk is expected when Repute Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The formulation of Repute Herbicide was compared to that of the precedent product, and it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, the labelled uses and claims for Repute Herbicide are acceptable since they are also included on the label of the precedent product.

The availability of Repute Herbicide provides growers an additional product to manage common and economically important broadleaved weeds in a variety of crops when applied post-emergence with respect to both crops and weeds.

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 Repute Herbicide.

References

PMRA Document Number	Reference
3407998	2022, Accelerated Storage Stability Study of Fluroxypyr, present as 1-methylheptyl ester 61.56 g/L + Clopyralid 42. 72 g/L + MCPA, present as 2-ethylhexyl ester 239.5 g/L EC, DACO: 3.4.1,3.4.2,3.5.1,3.5.10,3.5.2,3.5.3,3.5.7
3407999	2022, Physico-chemical studies of Fluroxypyr, present as 1-methylheptyl ester 61.56 g/L + Clopyralid 42.72 g/L + MCPA, present as 2-ethylhexyl ester 239.5 g/L EC, DACO: 3.5.11,3.5.12,3.5.13,3.5.14,3.5.6,3.5.8,3.5.9
3408000	2022, Repute - Manufacturing Process, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI