

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-1313
Application: Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PPIP) policy - Equivalency/Data Compensation Assessment
Product: Thumb Herbicide
Registration Number: 34380
Active ingredients (a.i.): Bromoxynil and 2,4-D (present as low volatile esters)
PMRA Document Number: 3238685

Purpose of Application

The purpose of this application was to register a new end-use product, Thumb Herbicide, based on a precedent.

Chemistry Assessment

Thumb Herbicide is formulated as an emulsifiable concentrate containing bromoxynil (present as mixed octanoate and heptanoate esters) at a concentration of 280 g/L and 2,4-D (present as the 2-ethylhexyl ester) at a concentration of 280 g/L. This end-use product has a density of 1.15 – 1.20 g/cm³ and pH of 6.60 – 6.65. The required chemistry data for Thumb Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Thumb Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Thumb Herbicide is considered to be of moderate acute toxicity via the oral route, slight acute toxicity via the dermal route and low acute toxicity via the inhalation route. It is considered to be mildly irritating to the eyes and slightly irritating to the skin. It is not considered to be a dermal sensitizer.

The use pattern of Thumb Herbicide is comparable to the use pattern of the precedent product. The potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of the 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 bromoxynil or 2,4-D were submitted or are required to support the registration of Thumb Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Thumb Herbicide label, including the target crops, method (air and ground), rates and timing of application, preharvest intervals, feeding restrictions, and withdrawal intervals were compared to the precedent product.

Based on this assessment, residues are not expected to be greater than that for registered uses and will be covered by the established MRLs. Consequently, dietary exposure to residues of bromoxynil and 2,4-D is not expected to increase with the registration of Thumb Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Thumb Herbicide is within that of the registered precedent product. The registration of Thumb Herbicide is not expected to pose any additional environmental risks when used in accordance with 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 Thumb Herbicide was compared to the formulation of the cited precedent product. The agronomic equivalence between Thumb Herbicide and the cited precedent product can be established. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Thumb Herbicide label subject to the required label amendments/updates.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register Thumb Herbicide.

References

PMRA

Document

Number	Reference
3110293	2020, Description of Process Formulation to 2,4-D 2-ethylhexyl ester 280 g/L (as acid) and Bromoxynil (hepta+octanoate) ester 280 g/L (as ester) EC Sharda, DACO: 3.2,3.2.2 CBI
3110288	2019, Validation of Analytical Method for Determination of Active Content of 2,4-D (as Ethyl-Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g a.e./L EC, DACO: 3.4.1 CBI
3110280	2019, Appearance (Colour, Physical State and Odour) of 2,4-D (as Ethyl-Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g a.e./L EC, DACO: 3.5.1,3.5.2,3.5.3 CBI
3110277	2019, Relative Density of 2,4-D (as Ethyl Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g.a.e./L EC, DACO: 3.5.6 CBI
3110281	2019, pH of 2,4-D (as Ethyl-Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g a.e./L EC, DACO: 3.5.7 CBI
3110287	2019, Oxidizing Properties of 2,4-D (as Ethyl-Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g a.e./L EC, DACO: 3.5.8 CBI
3110284	2019, Viscosity of 2,4-D (as Ethyl-Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g a.e./L EC, DACO: 3.5.9 CBI
3110290	2019, Accelerated Storage Stability and Corrosion Characteristics of 2,4-D (as Ethyl-Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g a.e./L EC, DACO: 3.5.10,3.5.14 CBI
3110285	2019, Flash Point of 2,4-D (as Ethyl-Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g a.e./L EC, DACO: 3.5.11 CBI
3110291	2019, Determination of Explosive Properties of 2,4-D (as Ethyl-Hexyl Ester) 280 g a.e./L + Bromoxynil (Mixed as Heptanoate and Octanoate Ester) 280 g a.e./L EC, DACO: 3.5.12 CBI

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