Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-1992
Application: Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PPIP) policy-Equivalency/Data Compensation Assessment
Product: Brilliant
Registration Number: 34383
Active ingredients (a.i.): Bromoxynil (present as mixed octanoate and heptanoate esters) and MCPA (present as the 2-ethylhexyl ester)
PMRA Document Number: 3261156

Purpose of application

The purpose of this application was to register a new herbicide, Brilliant, based on a registered precedent product.

Chemistry assessment

Brilliant is formulated as an emulsifiable concentrate containing bromoxynil (present as mixed octanoate and heptanoate esters) at a concentration of 280 g/L and MCPA (present as the 2-ethylhexyl ester) at a concentration of 280 g/L. This end-use product has a specific gravity of 1.1615 – 1.1668 and pH of 4.04. The required chemistry data for Brilliant have been provided, reviewed and found to be acceptable.

Health assessments

Brilliant was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Brilliant is considered to be of moderate acute toxicity by the oral route and of low acute toxicity by the dermal and inhalation routes. It is not considered to be a skin or eye irritant, nor is it a skin sensitizer.

The use pattern of Brilliant 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 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 were submitted in support of the registration of Brilliant. The use pattern of Brilliant was determined to be equivalent to that of the registered product. Therefore, the previously reviewed data were reassessed in the framework of this application and it was confirmed that the use of Brilliant is not expected to result in an increase in

the magnitude of both bromoxynil and MCPA residues in/on the treated crops. Therefore, the registration of Brilliant will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental assessment

The registration of Brilliant will not pose any additional risks to the environment. The environmental risks associated with the use of Brilliant are acceptable when the product is used according to the 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 Brilliant was compared to the formulation of the cited precedent product. The differences between the two formulations were considered minor, which are unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance. The agronomic equivalence between Brilliant 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 Brilliant 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 Brilliant.

References

PMRA Document Number	Reference
3123427	2020, Description of Process Formulation to MCPA (as 2-ethylhexyl ester) 280 g a.e./L and Bromoxynil (as heptanoate + octanoate esters) 280 g/L EC Sharda, DACO: 3.2,3.2.1,3.2.2 CBI
3123408	2019, Validation of Analytical Method for Determination of Active Ingredient of MCPA (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
3123410	2019, Specific Gravity of MCPA (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
3123414	2019, pH of MCPA (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
3123412	2018, Oxidizing Properties of MCPA (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
3123418	2019, Viscosity of MCPA (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
3123415	2019, Accelerated Storage Stability and Corrosion Characteristics of MCPA (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
3123411	2019, Flash Point of MCPA (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
3123419	2018, Determination of Explosive Properties of MCPA (as Ethyl Hexyl Ester) 280 g.a.e./L + Bromoxynil (mixed as octanoate and heptanoate ester) 280 g.a.e./L EC, DACO: 3.5.12 CBI
3123406	2019, Relative Density of MCPA (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
3123409	2019, Appearance (Colour, Physical State and Odour) of MCPA (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