

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-2092
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide (PIIP) Data Policy – Equivalency/Data Compensation Assessment
Product: FBN Bromoxynil 240 EC
Registration Number: 35241
Active ingredient (a.i.): Bromoxynil, present as octanoate ester
PMRA Document Number : 3480668

Purpose of Application

The purpose of this application was to register the commercial class end-use product FBN Bromoxynil 240 EC, for selective post-emergence control of broadleaf weeds in labelled crops, based on a registered precedent product.

Chemistry Assessment

FBN Bromoxynil 240 EC is formulated as an emulsifiable concentrate containing bromoxynil (present as octanoate ester) at a concentration of 240 g/L. This end-use product has a density of 1.05 g/mL and pH of 4.45. The required chemistry data for FBN Bromoxynil 240 EC have been provided, reviewed and found to be acceptable.

Health Assessments

FBN Bromoxynil 240 EC is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. FBN Bromoxynil 240 EC is considered to be moderately toxic by the oral route and of low acute toxicity by the dermal and inhalation routes. Additionally, it is considered to be non-irritating to the skin, but moderately irritating to the eyes, and not a skin sensitizer.

The registered use pattern of FBN Bromoxynil 240 EC 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 bromoxynil. 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 were submitted or were required to support the registration of FBN Bromoxynil 240 EC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the FBN Bromoxynil 240 EC label, including the target crops, method (ground), rates and timing of application, geographic restrictions, 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 bromoxynil is not expected to increase with the registration of FBN Bromoxynil 240 EC, and will not pose health risks of concern to any segment of the population, including infants, children, adults, and seniors.

Environmental Assessment

The registered use pattern of FBN Bromoxynil 240 EC is within the registered use pattern of bromoxynil. Therefore, no additional risk is anticipated when FBN Bromoxynil 240 EC is used in accordance with the label directions, which includes statements to mitigate risks to the environment.

Value Assessment

The availability of FBN Bromoxynil 240 EC provides farmers with an alternative option for selective post-emergence control of broadleaf weeds in a variety of crops grown throughout Canada. Registration of a generic product, such as FBN Bromoxynil 240 EC, may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of FBN Bromoxynil 240 EC was compared to the formulation of the precedent product. It was concluded that differences in the formulations would be unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance.

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 FBN Bromoxynil 240 EC.

References

PMRA Document Number	Reference
3355963	2022, Data for FBN Bromoxynil 240 EC EP, DACO: 3.1.1,3.1.3,3.1.4,3.2.3, 3.3.1,3.5.15,3.5.4,3.5.5
3355965	2022, Physico-chemical Properties of Bromoxynil 240 EC, DACO: 3.4.1, 3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3355966	2021, Manufacturing Process of Bromoxynil 240g/L EC, DACO: 3.2.1,3.2.2 CBI
3470121	2023, Manufacturing Process of Bromoxynil 240g/L EC, DACO: 3.2,3.2.1, 3.2.2 CBI

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