



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-5318
Application: Submission subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) policy - Equivalency/Data Compensation Assessment
Product: Bonita Herbicide
Registration Number: 34924
Active ingredient (a.i.): Trifluralin
PMRA Document Number: 3472210

Purpose of Application

The purpose of this application was to register a commercial end-use product, Bonita Herbicide, for use in the Prairie Provinces and the Peace River region and interior of British Columbia for pre-emergent control of grassy and broadleaf weeds in labelled field crops, based on a precedent product.

Chemistry Assessment

Bonita Herbicide is formulated as granules containing trifluralin at a concentration of 10%. This end-use product has a density of 0.917 – 0.958 g/mL and pH of 4.99 – 5.44. The required chemistry data for Bonita Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Bonita Herbicide is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Bonita Herbicide is considered to be of low acute toxicity by the oral, dermal and inhalation routes of exposure. It is not considered to be an eye or skin irritant. It is considered to be a skin sensitizer.

The labelled use pattern of the end-use product, Bonita 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 active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for trifluralin were submitted or are required to support the registration of Bonita Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Bonita Herbicide label, including the target crops, application method (soil by ground equipment), rates, timing of application (once, preemergent), geographic

restrictions, 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 trifluralin is not expected to increase with the registration of Bonita 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 Bonita Herbicide is within the registered use pattern of the precedent product, therefore, no additional risk is expected from its use. The label includes all the required environmental precautions and directions for use information which adequately mitigate risks to the environment. Risk from use of Bonita Herbicide is acceptable from the environmental perspective when used according to 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 Bonita Herbicide was compared to the formulation of the precedent product. Although formulation differences between the products were observed, they are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance when taking into consideration the nature of the product and the labelled Directions for Use. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Bonita Herbicide label.

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 Bonita Herbicide.

References

PMRA

Document

Number

Reference

3274437	2021, Additional Product Chemistry for Bonanza 10 G, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.15,3.5.4,3.5.5,3.5.9
3274447	2021, Physico-Chemical Characterization of Trifluralin 10% GR, DACO: 3.1.4,3.4.1,3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7,3.5.8
3309586	2022, Composition of Trifluralin 100 GR, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3458180	2023, Responses to Chemistry Clarifications for Sub. #2021-5318 - Trifla Herbicide, DACO: 3.2.2,3.2.3,3.5.10,3.5.13

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