



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-1622
Application: Application subject to the Protection of Proprietary Interests in Pesticide Data Policy
Product: Primero Herbicide
Registration Number: 34948
Active ingredient (a.i.): Nicosulfuron
PMRA Document Number: 3463064

Purpose of Application

The purpose of this application was to register Primero Herbicide to control quackgrass and annual grasses in field and sweet corn as well as seed corn inbreds (Eastern Canada only), based on a registered precedent product.

Chemistry Assessment

Primero Herbicide is formulated as water dispersible granules containing nicosulfuron at a concentration of 75%. This end-use product has a density of 0.58 – 0.67 g/mL and pH of 5.56. The required chemistry data for Primero Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Primero Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Primero Herbicide is considered to be of low acute toxicity via oral, inhalation, and dermal routes. Primero Herbicide is considered to be mildly irritating to the eye and minimally to slightly irritating to the skin and is not considered to be a dermal sensitizer.

The use pattern of Primero 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 of this 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 nicosulfuron were submitted or are required to support the registration of Primero Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Primero Herbicide label, including the target crops, method (ground), rates and timing of application, 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 of nicosulfuron are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposure to residues of nicosulfuron is not expected to increase with the registration of Primero Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults, and seniors.

Environmental Assessment

The registration of Primero Herbicide for control of quackgrass and annual grasses in field and sweet corn as well as seed corn inbreds (Eastern Canada only) does not pose any additional risk to the environment when used according to label directions.

Value Assessment

The availability of Primero Herbicide provides growers with an alternative option to manage grass weed species in field and sweet corn as well as seed corn inbreds (Eastern Canada only). Registration of a generic product may increase competition in the market, which may result in a reduction in purchasing cost of similar products, thus lowering growers overall input cost.

The formulation of Primero Herbicide was compared to the formulation of the cited product. It was concluded that the differences in formulations would be unlikely to result in any significant impact on performance, in regards to efficacy and crop tolerance. Therefore, all uses and claims found on the cited precedent product label are supported for the inclusion on the Primero 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 Primero Herbicide.

References

PMRA

Document

Number	Reference
3343947	2022, Manufacturing Process of Nicosulfuron 750 g/kg WG, DACO: 3.2.1,3.2.2, 3.2.3,3.3.1 CBI
3343948	2015, Study on the physico-chemical properties of nicosulfuron 750 g/kg water dispersible granule, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8
3343950	2019, Certificate of analysis of nicosulfuron 750 g/kg water dispersible granules, DACO: 3.4.1,3.5.1,3.5.2,3.5.3
3343966	2022, Additional Product Chemistry for Primero Herbicide - Parent, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.13,3.5.15,3.5.4,3.5.5,3.5.9

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