



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-4243
Application: Submission subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) policy - Equivalency/Data Compensation Assessment
Product: FBN Imazamox WDG
Registration Number: 34786
Active ingredient (a.i.): Imazamox
PMRA Document Number: 3384305

Purpose of Application

The purpose of this application was to register a commercial end-use product, FBN Imazamox WDG, for the control of broadleaf and grassy weeds in field peas grown in the Prairie Provinces and Peace River Area of British Columbia, based on a precedent product.

Chemistry Assessment

FBN Imazamox WDG is formulated as water dispersible granules containing imazamox at a concentration of 70%. This end-use product has a density of 0.52 – 0.56 g/mL and pH of 2.79. The required chemistry data for FBN Imazamox WDG have been provided, reviewed and found to be acceptable.

Health Assessments

FBN Imazamox WDG was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. FBN Imazamox WDG is considered to be of low acute toxicity via the oral, dermal and inhalation routes, moderately irritating to the eyes and non-irritating to the skin, and is not considered to be a dermal sensitizer.

The labelled use pattern of FBN Imazamox WDG containing imazamox 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 imazamox were submitted or are required to support the registration of FBN Imazamox WDG. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the FBN Imazamox WDG label, including the target crop field peas, method (ground), rates and timing of application, geographic restrictions, preharvest interval and feeding restriction are comparable to those on the historical label of the precedent end-use product.

Based on this assessment, residues are not expected to be greater than those from the historical use. Consequently, dietary exposure to residues of imazamox is not expected to increase with the registration of FBN Imazamox WDG and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use of FBN Imazamox WDG to control various labelled weeds in field peas does not pose any additional risk to the environment when used according to the label.

Value Assessment

The availability of FBN Imazamox WDG provides farmers with an alternative option to manage broadleaf and grassy weeds in field peas grown in the Prairie Provinces and Peace River Area of British Columbia. Registration of a generic product may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of FBN Imazamox WDG was compared to the formulation of a 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 sufficient to support the registration of FBN Imazamox WDG.

References

PMRA Document Number	Reference
3263371	2021, Applicant's Name and Office Address, Formulating Plant and address, Identity for FBN Imazamox WDG, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.13,3.5.15,3.5.5
3263372	2019, Physico-chemical Properties of Imazamox 70% Water Dispersible Granules, DACO: 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
3263373	2020, Manufacturing process of Imazamox 70% WDG, DACO: 3.2.1,3.2.2 CBI
3263376	2021, Method Validation for the Determination of Imazamox 70% Water Dispersible Granules, DACO: 3.4.1 CBI

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