Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-5767
Application: Submissions subject to Protection of Proprietary Interests in Pesticide Data policy-Equivalency/Data Compensation Assessment
Product: FBN Zethmox 70 WDG
Registration Number: 34895
Active ingredients (a.i.): Imazethapyr and Imazamox
PMRA Document Number: 3456368

Purpose of Application

The purpose of this application was to register a new end-use product, FBN Zethmox 70 WDG, to control labelled weeds, as an early post-emergence treatment in field pea, fenugreek (seed uses only), fenugreek (forage), Clearfield lentils, Clearfield sunflowers, soybeans, seedling and established alfalfa grown for seed, seedling clover (red, alsike and sweet) grown for seed, bird's foot trefoil (seed production), and fababeans in the Prairie Provinces and Peace River Region of British Columbia only, based on a registered precedent.

Chemistry Assessment

FBN Zethmox 70 WDG is formulated as a water dispersible granule containing imazethapyr and imazamox each at a concentration of 35 %. This end-use product has a density of 0.62 g/mL and pH of 2.91 (1% solution). The required chemistry data for FBN Zethmox 70 WDG have been provided, reviewed and found to be acceptable.

Health Assessments

FBN Zethmox 70 WDG was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. FBN Zethmox 70 WDG is considered to be of low acute toxicity via the oral, dermal and inhalation routes, minimally irritating to the eyes of rabbits and mildly irritating to the skin of rabbits, and is not considered to be a dermal sensitizer.

The use pattern of FBN Zethmox 70 WDG is comparable to the registered use pattern of the precedent product. Therefore, potential exposures for mixers, loaders, applicators, bystanders and postapplication workers are not expected to exceed the current exposures 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 for imazethapyr and imazamox were submitted or are required to support the registration of FBN Zethmox 70 WDG. Previously reviewed residue data were re-assessed to support this application.

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The use directions on the FBN Zethmox 70 WDG label, including the target crops, method, rates and timing of application, preharvest and grazing intervals, and crop rotation restrictions are comparable to the precedent end-use product.

Based on this assessment, residues are not expected to be greater than that for the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of imazethapyr and imazamox is not expected to increase with the registration of the new end-use product FBN Zethmox 70 WDG and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

As the use patterns, application methods, and application rates are comparable to the precedent product, the registration of FBN Zethmox 70 WDG will not pose any additional risks to the environment. When used according to label directions, the environmental risks are acceptable for FBN Zethmox 70 WDG.

Value Assessment

Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of FBN Zethmox 70 WDG was compared to the formulation of the cited precedent product. The differences between the formulations were considered minor, which are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the FBN Zethmox 70 WDG label; subject to the required label update/amendments.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of FBN Zethmox 70 WDG.

References

PMRA Document Number	Reference
3282502	2020, Declaration, DACO: 3.2.1 CBI
3282505	2020, Information for FBN Imazamox + Imazethapyr EP, 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
3282509	2019, Physico-chemical Properties of 35% Imazamox and 35% Imazethapyr Water Dispersible Granules, DACO: 3.4.1,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8 CBI
3282517	2021, Method Validation for the Determination of 35% Imazamox and 35% Imazethapyr Water Dispersible Granules, DACO: 3.4.1 CBI
3441731	2023, Storage stability of 35% imazethapyr+35% imazamox WDG in sealed soluble bag +aluminum foil bag, DACO: 3.5.10
3441732	2023, Method Validation for the Determination of 35% Imazethapyr+35% Imazamox WDG, DACO: 3.4.1,3.5.10
3441733	2023, Manufacturing Process of 35% Imazethapyr + 35% Imazamox WDG, DACO: 3.2.2 CBI