

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-0316
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: Lone Wolf Herbicide
Registration Number: 34517
Active ingredient (a.i.): Imazamox
PMRA Document Number : 3330334

Purpose of Application

The purpose of this application was to register a new end-use product, Lone Wolf Herbicide, for use to control weeds in Clearfield or Imazamox tolerant wheat and field peas, based on a precedent product.

Chemistry Assessment

Lone Wolf Herbicide is formulated as a solution containing imazamox at a concentration of 120 g/L. This end-use product has a density of 1.05 g/mL and pH of 5.33. The required chemistry data for Lone Wolf Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Lone Wolf Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Lone Wolf Herbicide is considered to be of low acute toxicity via the oral, dermal, and inhalation route. Lone Wolf Herbicide is considered to be non-irritating to the eyes and skin, and not a potential dermal sensitizer.

The use pattern of Lone Wolf 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 imazamox were submitted or are required to support the registration of Lone Wolf Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Lone Wolf Herbicide label, including the target crops, method, rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, 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 MRLs. Consequently, dietary exposure to residues of imazamox is not expected to increase with the registration of Lone Wolf 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 Lone Wolf Herbicide is within the registered use pattern of the precedent product and imazamox, and therefore, no additional risk is expected from the use of Lone Wolf Herbicide.

The label includes all the required environmental precautions, directions for use and spray buffer zone information which adequately mitigate risks to the environment when used according to label directions.

Value Assessment

The availability of Lone Wolf Herbicide would provide farmers with an alternative option to manage broadleaf and grassy weeds in Clearfield wheat and field peas grown in the Prairie Provinces and Interior 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 Lone Wolf Herbicide 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 it sufficient to support the registration of Lone Wolf Herbicide.

References

PMRA Document Number	References
3194082	2020, AG36424 1 SL Herbicide, Physical and Chemical Properties - Product Chemistry, Group A: Product Identity and Composition, DACO: 3.2.1, 3.2.2, 3.2.3,3.3.1 CBI
3194084	2020, AG36424 1 SL Herbicide, Physical and Chemical Properties - Waiver Requests of Product Chemistry Data, DACO: 3.5.10,3.5.11,3.5.12,3.5.13, 3.5.14,3.5.15
3194085	2020, Physical and Chemical Characteristics of AG36424 1 SL, DACO: 3.5.1, 3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9

3194086 2021, Storage Stability and Corrosion Characteristics of AG36424 1 SL, DACO:
3.4.1,3.5.10,3.5.14

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