Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-0678
Application: Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PPIP) policy - Equivalency/Data Compensation Assessment
Product: Venim Herbicide
Registration Number: 34394
Active ingredient (a.i.): Imazamox
PMRA Document Number : 3257644

Purpose of Application

The purpose of this application was to register Venim Herbicide, a new end-use product for use in the Prairie Provinces and the interior of British Columbia to control grasses and broadleaf weeds in various crops, based on a registered precedent.

Chemistry Assessment

Venim Herbicide is formulated as a solution containing imazamox (present as ammonium salt) at a concentration of 350 g/L. This end-use product has a density of 1.088-1.110 g/mL and pH of 5.5-6.0. The required chemistry data for Venim Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Venim Herbicide was considered toxicologically equivalent to the precedent products; therefore, no toxicology data were required. Venim Herbicide is considered to be of low acute toxicity by the oral and dermal routes and of slight acute toxicity by the inhalation route. It is considered to be moderately irritating to eyes and slightly irritating the skin. It is not considered to be a potential skin sensitizer.

The use pattern of Venim Herbicide is comparable to the registered use pattern of the precedent products. Therefore, potential exposure for mixers, loaders, applicators, 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 Venim Herbicide. Previously reviewed residue data were re-assessed in the framework of this petition. The use directions on the Venim Herbicide label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest

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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 Venim 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 of Venim Herbicide is within those currently registered for the precedent products. The registration of Venim Herbicide to control grass and broadleaf weeds in soybeans, field peas, dry beans, imidazolinone-tolerant lentils, and imidazolinone-tolerant sunflowers in the Prairie Provinces and the British Columbia interior is not expected to pose any additional environmental risks when used in accordance with label directions.

Value Assessment

The availability of Venim Herbicide provides farmers with another option to control both grasses and broadleaf weeds in soybean, field pea, dry bean, and select imidazolinone-tolerant crops. Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

Value information from replicated field trials demonstrated that the performance, in terms of efficacy and crop tolerance, of Venim Herbicide can be expected to be agronomically equivalent to that of the cited precedent products. Therefore, all labelled uses and claims found on the precedent product labels are supported for inclusion on the Venim Herbicide label.

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 Venim Herbicide.

References

PMRA Document Number	Reference
3092820	2016, Technical Package for CLAW 350SL, DACO: 3.2.1, 3.2.2, 3.5.4, 3.5.5 CBI
3092821	2019, Claw 350: Enforcement Analytical Method for the Determination of Imazamox by High Performance Liquid Chromatography , DACO: 3.4.1
3092822	2019, Claw 350: Physical and Chemical Characteristics, DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9
3092823	2019, Claw 350: Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10, 3.5.14

PMRA Document Number	Reference
3092825	2020, A rationale based on trial data to support the equivalence of Venim Herbicide to the precedent product Davai 80SL, DACO: 10.2.3.3(B) and 10.3.2(A)
3150860	2020, In response to Part 10 Deficiency, DACO: 10.2.3.3 and 10.3.2(A)
3150861	2020, Venim Herbicide – trial reports, DACO: 10.2.3.3 and 10.3.2(A)