Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2019-2765
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy (PPIP) – Equivalency/Data Compensation Assessment
Product: Clorvante 50 g/L
Registration Number: 34431
Active ingredient (a.i.): Florasulam
PMRA Document Number : 3143087

Purpose of Application

The purpose of this application was to register Clorvante 50 g/L Herbicide, an end-use product containing florasulam for the control of hard-to-kill annual broadleaf weeds in spring wheat (including durum), winter wheat, spring barley, and oats (tank mixes only) not underseeded with legumes, based on a precedent.

Chemistry Assessment

Clorvante 50 g/L Herbicide is formulated as a suspension containing florasulam at a concentration of 50 g/L. This end-use product has a density of 1.020 g/mL and pH of 4.27 (1% w/w). The required chemistry data for Clorvante 50 g/L Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Clorvante 50 g/L Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Clorvante 50 g/L Herbicide is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is considered non-irritating to the skin and minimally irritating to the eyes, and is not considered to be a dermal sensitizer.

The use pattern of Clorvante 50 g/L Herbicide fits within the registered use pattern of the precedent product. As such, exposure to florasulam is not expected to exceed that of the registered use. There are no health risks of concern for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for florasulam in spring wheat (including durum), winter wheat, spring barley, and oats were submitted to support the use of this active ingredient on the Clorvante 50 g/L Herbicide label. The use pattern of Clorvante 50 g/L Herbicide, including the target crops, method, rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions, was determined to be equivalent to that of the precedent end-use product. The previously reviewed data were re-assessed in

the framework of the current submission and it was confirmed that the use of Clorvante 50 g/L Herbicide is not expected to result in an increase in the magnitude of florasulam residues in/on the treated crops. Florasulam residues in wheat, barley and oats will be covered under the established MRLs. Therefore, the registration of Clorvante 50 g/L Herbicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use patterns for Clorvante 50 g/L Herbicide fit within those of currently registered products containing florasulam. No additional risk to the environment is expected from the registration of this product.

Value Assessment

The availability of Clorvante 50 g/L Herbicide will provide farmers with an alternative option to manage broadleaf weeds in wheat (spring, durum and winter), spring barley and oats grown in the Prairie Provinces and Peace River region 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 Clorvante 50 g/L 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 the information sufficient to support the registration of Clorvante 50 g/L Herbicide.

References

PMRA Document Number	References
3003406	2018, Additional Product Chemistry for Clorvante 50 g/L Herbicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.4,3.5.5
3003407	2018, Additional Product Chemistry for Clorvante 50 g/L Herbicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.4,3.5.5 CBI
3003408	2018, Clorvante 50 g/L Product Identity and Composition, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3003409	2018, Florasulam 50 g/L: Enforcement Analytical Method for the Determination of Florasulam by High Performance Liquid Chromatography, Florasulam 50 g/L: Enforcement Analytical Method for the Determination fo Florasulam by High Performance Liquid Chromatography, DACO: 3.4.1
3003410	2018, Florasulam 50 g/L: Physical and Chemical Characteristics: Color, Physical

State, Odor, Oxidation/Reduction, pH, Viscosity and Density/Relative Density, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9

3100249 2020, Storage Stability and Corrosion Characteristics of Florasulam 50 g/L SC, DACO: 3.5.10,3.5.14