Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-0701
Application: Application subject to the Protection of Proprietary Interests in Pesticide Data Policy
Product: Sharmina 660 EC
Registration Number: 34240
Active ingredient (a.i.): 2,4-D (present as low volatile esters)
PMRA Document Number: 3234196

Purpose of Application

The purpose of this application was to register Sharmina 660 EC for control of broadleaf weeds in cropland, pasture and rangeland, golf course, and industrial non-crop areas as a broadcast treatment and for control of woody brush and young trees as a basal bark and stump treatment, based on a precedent product.

Chemistry Assessment

Sharmina 660 EC is formulated as an emulsifiable concentrate containing 2,4-D at a concentration of 660 g/L (present as the 2-ethylhexyl ester). This end-use product has a density of 1.1487 g/ mL and pH of 3.46. The required chemistry data for Sharmina 660 EC have been provided, reviewed and found to be acceptable.

Health Assessments

Sharmina 660 EC was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Sharmina 660 EC is considered to be of high acute toxicity by the oral route, and low acute toxicity by the dermal and inhalation routes of exposure in rats. In rabbits, it is minimally irritating to the eyes and moderately irritating to the skin. It is considered to be a dermal sensitizer.

The use pattern of Sharmina 660 EC is the same as that of the registered 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 2,4-D (present as volatile esters) were submitted or are required to support the registration of Sharmina 660 EC. Previously reviewed residue data were re-assessed in the framework of this petition.

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The use directions on the Sharmina 660 EC label, including the formulation type, target crops, method (ground and/or aerial), rates and timing of application, preharvest intervals, and feeding restrictions were compared to the precedent 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 2,4-D is not expected to increase with the registration of Sharmina 660 EC 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 Sharmina 660 EC was compared to that of the registered precedent product. No additional risk to the environmental is expected from the registration of this product when label directions are followed.

Value Assessment

The availability of Sharmina 660 EC Herbicide would provide farmers with another option for control of broadleaf weeds in cropland, pasture and rangeland, golf course, and industrial non-crop areas as a broadcast treatment and for control of woody brush and young trees as a basal bark and stump treatment. Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of Sharmina 660 EC Herbicide was compared to the formulation of the cited precedent product. It was concluded that differences were unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance. Value information from field research trials was also submitted for review. The trial information corroborated the conclusion from the formulation comparison.

Based on the weight of evidence, the agronomic equivalence between Sharmina 660 EC Herbicide and the precedent product can be established. All labelled uses and claims found on the precedent product label are supported for inclusion on the Sharmina 660 EC Herbicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register Sharmina 660 EC Herbicide.

References

PMRA Document Number	Reference
2871362	2018, Description of Process Formulation to 2,4-D 2-Ethylhexyl ester 660 g a.e./l EC Sharda, DACO: 3.2,3.2.1,3.2.2,3.2.3,3.3.1 CBI
2871363	2017, Validation of the Analytical Method for the Determination of the Active Ingredient of 2,4-D Ethyl Hexyl Ester660 g/L EC, DACO: 3.4,3.4.1 CBI
2871364	2017, Appearance (Colour, Physical State, Odor) of 2,4-D Ethyl Hexyl Ester 660 g/L EC, DACO: 3.5.1,3.5.2,3.5.3
2871365	2017, Relative Density of 2,4-D Ethyl Hexyl Ester 660 g/L EC, DACO: 3.5.6
2871366	2017, pH of 2,4-D Ethyl Hexyl Ester 660 g/L EC, DACO: 3.5.7
2871367	2017, Oxidizing Properties of 2,4-D Ethyl Hexyl Ester 660 g/L EC;, DACO: 3.5.8
2871368	2017, Viscosity of 2,4-D Ethyl Hexyl Ester 660 g/L EC, DACO: 3.5.9
2871369	2017, Flash Point of 2,4-D Ethyl Hexyl Ester 660 g/L EC, DACO: 3.5.11
2871370	2017, Determination of the Accelerated Storage Stability and Corrosion Characteristics of 2,4-D Ethyl Hexyl Ester 660 g/L EC, DACO: 3.5.10,3.5.14
2871361	2018, Product Identity, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.5.13,3.5.15,3.5.5 CBI
2871371	2016, Efficacy trials, DACO: 10.2.3, 10.2.3.2(B), and 10.3.
2871372	2016, Efficacy, phytotoxicity, and yield protocol for Sharda Cropchem Ltd. generic herbicides on wheat, DACO: 10.2.3, 10.2.3.3(B), and 10.3.