Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2018-3729
Application: Submission subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) policy - Equivalency/Data Compensation Assessment
Product: Stallion Herbicide
Registration Number: 34334
Active ingredient (a.i.): S-metolachlor and R-enantiomer
PMRA Document Number: 3234868

Purpose of Application

The purpose of this application was to register a new herbicide product for use on terrestrial food and feed crops, forests and woodlots and outdoor ornamentals, based on a registered precedent product.

Chemistry Assessment

MPower S-metolachlor Herbicide is formulated as an emulsifiable concentrate containing S-metolachlor and R-enantiomer at a concentration of 915 g/L. This end-use product has a density of 1.11 g/mL at 20°C and pH of 6-8. The required chemistry data for MPower S-metolachlor Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

MPower S-metolachlor Herbicide was considered toxicologically equivalent to the precedent product; therefore no toxicology data were required. MPower S-metolachlor Herbicide is considered to be of low acute toxicity in rats via the oral, dermal and inhalation routes. It is considered moderately irritating to the eyes and slightly irritating to the skin. It is considered to be a potential skin sensitizer.

The use pattern of MPower S-metolachlor Herbicide is identical to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators and postapplication workers is not expected to exceed the current exposure to the registered products containing S-metolachlor and R-enantiomer. No health concerns are expected for workers and bystanders when label directions, precautions and restrictions are followed.
No new residue data for the active ingredient S-metolachlor and R-enantiomer were submitted or are required to support the registration of MPower S-metolachlor Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

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The use directions on the MPower S-metolachlor Herbicide label, including the target crops, method (ground), rates and timings of application (for the product alone and in tank-mix), geographical restrictions, preharvest intervals and grazing restrictions, and crop rotation restrictions are identical 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 S-metolachlor and R-enantiomer is not expected to increase with the use of MPower S-metolachlor Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The new uses are within the currently registered use pattern of the active ingredient, S-metolachlor and R-enantiomer, and therefore, no increase in exposure to the environment is expected when M-Power S-metolachlor is used according to label directions. The label includes the required environmental precautions and hazards statements.

Value Assessment

The availability of MPower S-metolachlor Herbicide would provide farmers with an alternative option to manage broadleaf and grassy weeds in a wide variety of crops grown throughout Canada. 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 MPower S-metolachlor 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 MPower S-metolachlor Herbicide.

References

PMRA Document Number	Title
2909662	2018, Manufacturing process and quality control of S-metolachlor 915 G/L EC, DACO: 3.2.1, 3.2.2, 3.3.1, 3.4.1, 3.5.1, 3.5.2, 3.5.3, 3.5.7 CBI
3091252	2016, Determination of Oxidation/Reduction: Chemical Incompatibility of S-Metolachlor 915 g/L EC, DACO: 3.5.8 CBI
3091253	2016, Determination of Density of S-Metolachlor 915 g/L EC, DACO: 3.5.6 CBI
3091254	2016, Determination of pH of S-Metolachlor 915 g/L EC, DACO: 3.5.7 CBI
3091255	2016, Determination of Viscosity of S-Metolachlor 915 g/L EC, DACO: 3.5.9 CBI
3091256	2016, Determination of Flash Point of S-Metolachlor 915 g/L EC, DACO: 3.5.11 CBI
3091258	2016, Determination of Miscibility of S-Metolachlor 915 g/L EC with Hydrocarbon Oil, DACO: 3.5.13 CBI
3091259	2016, Determination of Explosive Property of S-Metolachlor 915 g/L EC, DACO: 3.5.12 CBI
3173571	2020, Accelerated Storage Stability of S-Metolachlor 915 g/L EC, DACO: 3.5.10 CBI
3091261	2020, Study for [CBI removed] Analysis of [CBI removed] Technical Batches, DACO: 2.13.4 CBI
2909651	2018, Manufacturing Process and Quality Control of [CBI removed] Technical, DACO: 2.11.1,2.11.2,2.11.3 CBI
2909653	2018, Discussion of the presence of impurities in [CBI removed] Technical, DACO: 2.11.4 CBI
2909654	2017, Five-batch analysis of [CBI removed] Technical Grade Active Ingredient, DACO: 2.12.1,2.13.1,2.13.2,2.13.3 CBI
2909655	2018, Determination of Appearance (Color, Odor and Physical State) of [CBI removed] TC, DACO: 2.14.1,2.14.2,2.14.3 CBI
2909656	2018, UV-VIS Absorption Spectra of [CBI removed] TC, DACO: 2.14.12 CBI
2909657	2018, Stability to Normal and Elevated Temperatures, Metals and Metal Ions of [CBI removed] TC, DACO: 2.14.13 CBI
2909658	2018, Determination of melting Temperature of [CBI removed] TC, DACO: 2.14.4 CBI
2909659	2018, Accelerated Storage Stability and Corrosion Characteristics of [CBI removed] TC by Heating at Elevated Temperature of 54 +/- 2oC, DACO: 2.14.14 CBI
3215147	2018, Determination of Density of [CBI removed] TC, DACO: 3.5.6 CBI