Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-4296
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: Stallion II Herbicide
Registration Number: 34459
Active ingredient (a.i.): S-metolachlor and R-enantiomer
PMRA Document Number : 3297077

Purpose of Application

The purpose of this submission is 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.

Chemistry Assessment

Stallion II 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 5.0-9.0. The required chemistry data for Stallion II Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Stallion II Herbicide was considered toxicologically equivalent to the precedent product; therefore no toxicology data were required. Stallion II Herbicide is considered of low acute toxicity by the oral, by dermal and by inhalation routes. It is considered minimally irritating to the eyes and the skin and is not considered to be a dermal sensitizer.

The use pattern of Stallion II 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 product 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 S-metolachlor and R-enantiomer were submitted or are required to support the registration of Stallion II Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Stallion II Herbicide label, including the target crops, method (ground), 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

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the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposure to residues of S-metolachlor and R-enantiomer is not expected to increase with the registration Stallion II Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The environmental risks associated with the use of Stallion II Herbicide are acceptable when the product is used according to the label directions.

Value Assessment

Registration of a generic product may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

Value information consisted of a comparison of the formulation of Stallion II Herbicide to that of the cited precedent product. Based on the weight of evidence, agronomic equivalence between Stallion II Herbicide and the cited precedent product was established. Therefore, all labelled uses and claims found on the precedent product label are supported for inclusion on the Stallion II Herbicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of Stallion II Herbicide.

References

PMRA Document

Number	**Reference**
3155067	2016, Chemical and Physical Characterization of S-metolachlor EC:, DACO: 3.5,3.5.1,3.5.10,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI
3169134	2020, Manufacturing Process of S metolachlor 915 g/L EC, DACO: 3.2.2 CBI
3169137	2020, Chemical and Physical Properties, DACO: 3.3.1,3.5.15,3.5.4,3.5.5 CBI
3173571	2020, Accelerated Storage Stability of S-Metolachlor 915 g/L EC, DACO: 3.5.10 CBI