Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-0115
Application: Submission subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) policy - Equivalency/Data Compensation Assessment
Product: 2,4-D Ester 700 II Herbicide
Registration Number: 34808
Active ingredient (a.i.): 2,4-D (present as 2-ethylhexyl ester)
PMRA Document Number: 3429555

Purpose of Application

The purpose of this application was to register a commercial end-use product, MPOWER 2,4-D Ester Herbicide, for the control of broadleaf weeds in wheat, based on precedent products.

Chemistry Assessment

2,4-D Ester 700 II Herbicide is formulated as an emulsifiable concentrate containing 2,4-D, present as 2-ethylhexyl ester, at a concentration of 660 g/L. This end-use product has a density of 1.1 – 1.2 g/mL and pH of 3 – 5. The required chemistry data for 2,4-D 700 II Ester Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

2,4-D Ester 700 II Herbicide was considered toxicologically equivalent to the precedent products ; therefore no toxicology data were required. 2,4-D Ester 700 II Herbicide is considered of high acute toxicity by the oral route and of low acute toxicity by the dermal and inhalation routes. It is considered minimally irritating to the eyes and moderately irritating to the skin, and is considered to be a potential skin sensitizer.

The use pattern of 2,4-D Ester 700 II Herbicide is comparable to the registered use patterns of the precedent products. 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 2,4-D were submitted or are required to support the registration of 2,4-D Ester 700 II Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

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The use directions on the 2,4-D Ester 700 II Herbicide label, including the target crop,method (ground or aerial), rates and timing of application, preharvest intervals, and feeding restrictions are comparable to those on the label of the precedent product.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of 2,4-D is not expected to increase with the registration of 2,4-D Ester 700 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 use pattern for 2,4-D Ester 700 II Herbicide is within the registered use pattern of the active ingredient 2,4-D, present as 2-ethylhexyl ester, therefore, no additional risk is expected from the use of 2,4-D Ester 700 II Herbicide.

The label includes all the required environmental precautions, directions for use and spray buffer zone information which adequately mitigate risks to the environment.

Risk from use of 2,4-D Ester 700 II Herbicide is acceptable from the environmental perspective when used according to label directions.

Value Assessment

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

The formulation of 2,4-D Ester 700 II Herbicide was compared to the formulations of the precedent products. The differences among the formulations were considered minor, which are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the precedent product labels are supported for inclusion on the 2,4-D Ester 700 II Herbicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of 2,4-D Ester 700 II Herbicide.

References

PMRA Document Number	Reference
3308797	2021, Request for Consideration of Surrogate Studies in Support of Registration of MPower 2,4-D Ester Herbicide, DACO: 3.4.1,3.5.1,3.5.10,3.5.11,3.5.14,3.5.2,3.5.3, 3.5.6,3.5.7,3.5.9 CBI
3308799	2020, Determination of Density of 2,4-D EHE 970 g/L EC, DACO: 3.5.6
3308800	2021, Validation of the Analytical Method for the Determination of Active Ingredient Content of 2,4-D EHE 970 g/L EC (5-batch) by HPLC, DACO: 3.4.1
3308801	2020, Determination of pH of 2,4-D EHE 970 g/L EC (5-batch) by HPLC, DACO: 3.5.7
3308802	2020, Accelerated Storage Stability of 2,4-D EHE 970 g/L EC (5-batch) by HPLC, DACO: 3.5.10
3308803	2020, Determination of Viscosity of 2,4-D EHE 970 g/L EC (5-batch) by HPLC, DACO: 3.5.9
3308804	2020, Determination of Flash Point of 2,4-D EHE 970 g/L EC (5-batch) by HPLC, DACO: 3.5.11
3308805	2020, Determination of Physical State, Color and Odor of 2,4-D EHE 970 g/L EC (5-batch) by HPLC, DACO: 3.5.1,3.5.2,3.5.3
3308806	2021, Formulation Process of 2,4-D EHE 660g/L a.e. EC, DACO: 3.1.2,3.2,3.2.1, 3.2.2 CBI
3308811	2021, Recipe of 2,4-D 2-EHE (660g/L a.e.) EC, DACO: 3.2.1
3308812	2021, Applicants Name and Office Address, Formulating Plant and address, Identity for MPower 2,4-D Ester Herbicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.13, 3.5.15,3.5.5,3.5.8
3424053	2023, Formulation Process of 2,4-D EHE 660g/L a.e. EC, DACO: 3.2.2 CBI
3424054	2023, Waiver Request for Corrosion Characteristics Study, DACO: 3.5.14 CBI