



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2023-0630
Application: Application Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Epitome Herbicide
Registration Number: 35182
Active ingredient (a.i.): EPTC (S-ethyl dipropylcarbamate)
PMRA Document Number: 3571139

Purpose of Application

The purpose of this application was to register the end-use product, Epitome Herbicide, based on a registered precedent product.

Chemistry Assessment

Epitome Herbicide is formulated as an emulsifiable concentrate containing Aceto EPTC Technical (Reg. No. 35110) at a concentration of 838 g/L. This end-use product has a density of 0.962 g/mL and a pH of 4.26. The required chemistry data for Epitome Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Epitome Herbicide was considered toxicologically equivalent to the precedent product; therefore no toxicology data were received or required. Epitome Herbicide is considered to be of slight acute toxicity by the oral, dermal and inhalation routes. It is not considered to be a skin or eye irritant. It is not considered to be a skin sensitizer.

The use pattern of Epitome Herbicide containing EPTC 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 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 EPTC were submitted or required to support the registration of Epitome Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Epitome Herbicide label, including the target crops, method(ground and sprinkler irrigation), maximum rate/application, timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent end-use 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 EPTC is not expected to increase with the registration of Epitome 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 on labeled crops is within the currently registered use pattern for EPTC. Therefore, the risk is acceptable when Epitome Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The availability of Epitome Herbicide will provide growers with an alternative option to control/suppress annual grass and broad leaf weeds, and perennial grass weeds in alfalfa, birdsfoot trefoil, beans (snap, common or dry common), dry common kidney beans (white and red only), cicer milkvetch, sweet clover, flax (excluding low linolenic acid varieties), sunflowers, sugar beets, turnips and potatoes (Irish). Registration of Epitome Herbicide may increase competition in the market, which may result in a reduction in purchasing cost of similar products, thus lowering growers' overall input costs.

The formulations of Epitome Herbicide were compared to the formulation of the registered precedent product. It was concluded that the performance of Aceto EPTC 7E Herbicide was agronomically equivalent to the precedent product. Therefore, all labelled uses and claims for Aceto EPTC 7E Herbicide are supported for inclusion since they are registered on the precedent product 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 Epitome Herbicide.

References

PMRA

Document

Number

Reference

3436175	2022, EPTC 7E Herbicide, Physical and Chemical Properties - Product Chemistry, Group A: Product Identity and Composition, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.2 CBI
3436177	2022, Method Validation of AG36977 7E Herbicide, DACO: 3.4.1
3436178	2022, Method Validation of AG36977 7E Herbicide, DACO: 3.5.12,3.5.13,3.5.15
3436179	2022, Storage Stability and Corrosion Characteristics of AG36977 7E Herbicide, DACO: 3.5.10,3.5.14
3436180	2022, Physical and Chemical Characteristics of AG36977 7E Herbicide, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3559068	2024, Enforcement Method for the EPTC Content in AG36977 7E Herbicide - Revised, DACO: 3.4.1
3559069	2024, EPTC 7E Herbicide - Clarification Response, DACO: 3.2.2 CBI

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2024

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.