

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2019-4871

Application: Submissions Subject to Protection of Proprietary Interests in

Pesticide Data Policy-Equivalency/Data Compensation Assessment

Product: SPUR-M Herbicide

Registration Number: 34458

Active ingredients (a.i.): Clopyralid present as acid, or as salts and MCPA (present as esters)

PMRA Document Number: 3174870

Purpose of Application

The purpose of this application was to register SPUR-M Herbicide, based on a precedent.

Chemistry Assessment

SPUR-M Herbicide is formulated as an emulsifiable concentrate containing clopyralid and MCPA (present as 2-ethylhexyl ester) at a concentration of 50 g/L and 280 g/L, respectively. This end-use product has a density of 1.014 g/mL and pH of 2.92. The required chemistry data for SPUR-M Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

SPUR-M herbicide is considered to be slight acute toxicity in oral, dermal and inhalation route. It is considered to be an eye irritant and has no skin irritation. It is not considered to be a skin sensitizer.

The use pattern of SPUR-M Herbicide fits within the registered use pattern for the precedent product. The potential exposure to clopyralid and MCPA for mixers, loaders, applicators and postapplication workers is not expected to exceed the current exposure to the registered products of these active ingredients. No health risks of concern are expected if workers follow label directions, precautions and restrictions.

No new residue data were submitted in support of the registration of SPUR-M Herbicide based on the precedent. The use pattern of SPUR-M Herbicide was determined to be equivalent to that of the precedent product. Therefore, the previously reviewed residue chemistry data were reassessed in the framework of the current application and it was confirmed that the use of SPUR-M Herbicide is not expected to result in an increase in the magnitude of clopyralid and MCPA (present as esters) residues in/on the treated crops. Therefore, the registration of SPUR-M Herbicide will not pose an unacceptable risk 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 ingredients, clopyralid and MCPA (present as esters), and therefore, no additional risk is expected when SPUR-M Herbicide is used according to label directions. The label includes the required environmental precautions and hazards statements to mitigate risks to the environment.

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 SPUR-M Herbicide to that of the cited precedent product. Based on the weight of evidence, agronomic equivalence between SPUR-M 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 SPUR-M Herbicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support the registration of SPUR-M Herbicide.

References

PMRA Document Number	References
3031013	2017, Addtional product chemistry for Spur-M Herbicide - Parent, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.4,3.5.5 CBI.
3031021	2004, Clopyralid Acid + MCPA Ester: Physical and chemical characteristics, 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
3031022.	2005, Clopyralid Acid + MCPA Ester: Storage stability and corrosion characteristics, DACO: 3.5.10,3.5.14.
3031024	2004, Clopyralid Acid + MCPA Ester: Summary of OPPTS 830.1000 Series product properties test guidelines, DACO: 3.1.3,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1, 3.4.2,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.6,3.5.7,3. 5.8,3.5.9,3.6,3.7.
3031026	2004, Clopyralid Acid + MCPA Ester:OPPTS Product properties test guidelines, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI.
3089102	2020, Spur-M Herbicide Manufacturing process, DACO: 3.1,3.2,3.3.1,3.4 CBI

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2020

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.