



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-1772
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: Fluent 125 EC Herbicide
Registration Number: 35385
Active ingredient (a.i.): Fluazifop-p-butyl
PMRA Document Number : 3360729

Purpose of Application

The purpose of this application was to register a new commercial herbicide, Fluent 125 EC Herbicide, for post-emergence grassy weed control in broadleaf field crops, legume forages, vegetables, fruit and outdoor ornamentals, based on a precedent product.

Chemistry Assessment

Fluent 125 EC Herbicide is formulated as an emulsifiable concentrate containing fluazifop-p-butyl at a concentration of 125 g/L. This end-use product has a density of 0.9665 – 0.9676 g/mL and pH of 4.73 (1% solution). The required chemistry data for Fluent 125 EC Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Fluent 125 EC Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Fluent 125 EC Herbicide is considered to be of low acute toxicity by the oral and dermal routes of exposure. It is considered to be extremely irritating to the eyes and skin, and is considered to be a dermal sensitizer.

The use pattern of Fluent 125 EC 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 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 fluazifop-p-butyl were submitted or are required to support the registration of Fluent 125 EC Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Fluent 125 EC Herbicide label, including the target crops, method (ground), rates, number and timing of application, 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 fluazifop-p-butyl is not expected to increase with the registration of Fluent 125 EC Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses on the Fluent 125 EC Herbicide label are within the currently registered use pattern of the active ingredient fluazifop-p-butyl. Therefore, no additional risk is expected when Fluent 125 EC Herbicide is used in accordance with the label, which includes 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 Fluent 125 EC Herbicide to that of the cited precedent product. Based on the weight of evidence, agronomic equivalence between Fluent 125 EC 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 Fluent 125 EC 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 Fluent 125 EC Herbicide.

References

PMRA Document Number	References
3224252	2021, Manufacturing Process for Fluazifop-p-butyl 125 EC, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3224256	2021, Additional Product Chemistry for Fluent 125 EC Herbicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.15,3.5.4,3.5.5
3224262	2020, Determination of Storage Stability and Corrosion Characteristics of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7
3224263	2019, Determination of Flash Point of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.11
3224264	2019, Determination of Explosiveness of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.12
3224265	2019, Determination of Miscibility of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.13

3224266	2019, Determination of Appearance (Color, Odor, Physical State) of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.1,3.5.2,3.5.3
3224267	2019, Determination of Density of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.6
3224268	2019, Determination of pH Value of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.7
3224269	2019, Determination of Oxidation/Reduction: Chemical Incompatibility of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.8
3224270	2019, Determination of Viscosity of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.5.9
3237249	2020, Active Ingredient Analysis with Method Validation of Fluazifop-P-Butyl 125 g/L EC, DACO: 3.4.1

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

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.