

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 and C.8.1 Application

Application Number: 2011-5359

Application: Product Chemistry: Guarantee, Identity of Formulants and

Proportion of Formulants

Product: ARY 0454-113 Herbicide

Registration Number: 31242

Active ingredients (a.i.): Flucarbazone (present as flucarbazone-sodium)

PMRA Document Number: 2157143

Purpose of Application

The purpose of this application was to register a new end-use product, ARY 0454-113 Herbicide containing 40% flucarbazone (flucarbazone present as flucarbazone-sodium at 42%) with 8.7% cloquintocet mexyl as a safener, intended for post-emergence application on spring wheat (including durum wheat) for control of wild oats, green foxtail, volunteer tame oats, and certain broadleaf weeds in the Prairie Provinces and Peace River Region of British Columbia. The applicant has cited Everest 70 WDG (Registration Number 26447) as a precedent product. The proposed use pattern for ARY 0454-113 Herbicide, which includes a safener in the formulation, was based on the post-emergence use pattern of Everest 70 WDG.

Chemistry Assessment

ARY 0454-113 Herbicide is formulated as wettable granules containing flucarbazone (present as flucarbazone-sodium) at a nominal concentration of 40%. This end-use product has a density of 0.62-0.66 g/cm³ and pH of 6.0-7.8. With the exception of the storage stability study and complete validation data, the chemistry requirements for ARY 0454-113 Herbicide are complete.

Health Assessments

ARY 0454-113 Herbicide is of low acute toxicity via the oral, dermal and inhalation routes in rats. It is minimally irritating to the eyes and skin of rabbits and was not a skin sensitizer in guinea pigs.

No new residue data were submitted to support the registration of ARY 0454-113 Herbicide containing active ingredient flucarbazone for use on wheat. Since the proposed application rates or use pattern for flucarbazone are the same as those currently registered use on wheat, the proposed use of ARY 0454-113 Herbicide is not expected to increase the magnitude of flucarbazone residues in/on wheat. Therefore, as a result of the proposed use of ARY 0454-113 Herbicide, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.



The use of ARY 0454-113 Herbicide on spring and durum wheat to control broadleaf weeds fits within the registered use pattern for flucarbazone-sodium. The potential exposure for mixers, loaders, applicators and post-application re-entry workers is not expected to exceed the current exposure to registered products provided all label statements and precautions are followed.

Environmental Assessment

The application rate for ARY 0454-113 herbicide results in an active ingredient rate that is the same as the currently registered maximum use rate. Although the environmental exposure from use of ARY 0454-113 Herbicide is not expected to increase, the environmental risk of this product with cloquintocet-mexyl as a safener cannot be determined and more data are required in order to characterize the potential risk to non-target organisms. Additional mitigation measures may be added on the product label, once the environmental assessment is complete.

Value Assessment

Confirmatory data from a total of 15 field trials conducted in Alberta, Manitoba, and Saskatchewan in 2010 were submitted to support registration of ARY 0454-113 Herbicide. Efficacy and crop safety of ARY 0454-113 Herbicide applied alone or in tank mix with Buctril M, Infinity, or Refine SG were directly compared to the cited precedent product Everest 70 WDG applied alone or in tank mix with the same herbicides. The use pattern for ARY 0454-113 Herbicide, which includes a safener in the formulation, was based on the post-emergence use pattern of Everest 70 WDG.

The efficacy of ARY 0454-113 Herbicide for control of wild oats, green foxtail, volunteer canola, wild mustard, and redroot pigweed was visually assessed 2-3 times during the growing season. The level of control of these weeds following the application of the ARY 0454-113 Herbicide treatments was comparable to that of the Everest 70 WDG treatments.

Tolerance of 4 spring wheat varieties in 14 trials to ARY 0454-113 Herbicide applied alone at the labeled maximum rate and the exaggerated 2 x rate or in tank mix with Buctril M, Infinity, or Refine SG was reported 2-3 times during the growing season. Crop injury following the application of the ARY 0454-113 Herbicide treatments was lower than that of the Everest 70 WDG treatments. Grain yield with the ARY 0454-113 Herbicide treatments was slightly greater than that with the Everest 70 WDG treatments.

Based on the weight of evidence, ARY 0454-113 Herbicide is effective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, ARY 0454-113 Herbicide, and has found the information sufficient to support conditional registration of this product.

PMRA Reference Document Number 2125658 2011. ARY 0454-113 Herbicide: Raw data to support the registration of ARY 0454-113 Herbicide applied as a post-emergence treatment. December 31, 2011. pp 167. DACO 10. 2125665 2011, ARY 0454-113 HERBICIDE CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF MANUFACTURING CONCENTRATES AND END-USE PRODUCTS FORMULATED FROM REGISTERED TECHNICAL GRADE OF ACTIVE INGREDIENTS OR INTEGRATED SYSTEM PRODUCTS, DACO: 3.0,3.1,3.1.2,3.1.3,3.1.4,3.2 2142590 2010, Physical Properties of ARY-0454-113, DACO: 3.0,3.5,3.5.1,3.5.2,3.5.3, 3.5.6,3.5.7,3.5.8 2142591 2011, ARY-0454-113: Storage Stability and Corrosion Characteristics, DACO: 3.0,3.5,3.5.10,3.5.14 2010, ARY-0454-113 Product Identity and Composition, Description of Materials 2142592 Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0,3.1,3.2,3.2.1,3.2.2, 3.2.3,3.3.1,3.4,3.4.1 2142595 2010, ARY-0454-113 Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0,3.1,3.2,3.2.1,3.2.2, 3.2.3,3.3.1,3.4,3.4.1 2010, ARY-0454-113 Product Identity and Composition, Description of Materials 2194542 Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0,3.1,3.2,3.2.1,3.2.2. 3.2.3,3.3.1,3.4,3.4.1 2194546 2012, ARY-0454-113 Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0,3.1,3.2,3.2.1,3.2.2, 3.2.3,3.3.1,3.4,3.4.1 2194547 2011, Method Validation for Flucarbazone-Sodium, DACO: 3.0,3.4,3.4.1 2273584 2013, DACO 3: ARY 0454-113 Herbicide Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0,3.1,3.1.1,3.1.2,3.1.3,3 2273585 2013, DACO 3: ARY 0454-113 Herbicide Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0,3.1,3.1.1,3.1.2,3.1.3,3

- 2273586 2013, DACO 3: ARY 0454-113 HERBICIDE CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF MANUFACTURING CONCENTRATES AND END-USE PRODUCTS FORMULATED FROM REGISTERED TECHNICAL GRADE OF ACTIVE INGREDIENTS OR INTEGRATED SYSTEM PRODUCTS, DACO: 3.0,3.1,3.1.1,3.1.2,3
- 2296319 2013, ARY 0454-113 Herbicide Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4,3.4
- 2296320 2013, Confidential: ARY 0454-113 Herbicide Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.2,3.2.1,3.2.2,3.2.3

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2014

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.