

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.1 Application

Application Number: 2016-6798
Application: New end use product; new combination of TGAIs, changes to guarantee, formulant identity and proportion, and application rates
Product: GF-3538 Herbicide
Registration Number: 33028
Active ingredients (a.i.): Fluroxypyr (present as 1-methylheptylester) and pyroxsulam
PMRA Document Number : 2856258

Purpose of Application

The purpose of this application was to register GF-3538 Herbicide, which contains a new combination of actives (fluroxypyr, present as 1-methylheptylester, and pyroxsulam) for use on wheat (spring, durum and winter) in the Prairie Provinces and interior of of British Columbia.

Chemistry Assessment

GF-3538 Herbicide is formulated as suspension emulsion containing fluroxypyr (present as 1-methylheptylester) at 113.5 g/L and pyroxsulam at 12.8 g/L. This end use product has a density of 1.0076 g/mL and pH of 5.02. The required chemistry data for GF-3538 Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

In rats, GF-3538 Herbicide is of low acute toxicity by the oral, dermal, and inhalation routes of exposure. The formulation is mildly irritating to the rabbit eye and skin. It is a skin sensitizer in mice.

The use of GF-3538 Herbicide on spring wheat, durum wheat and winter wheat (not underseeded with legumes) is not expected to result in potential occupational or bystander exposure over the registered use of pyroxsulam, fluroxypyr present as 1-methylheptyl ester and the safener cloquintocet acid. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

New food residue data were not submitted for pyroxsulam, fluroxypyr-meptyl and the safener cloquintocet acid to support the registration of GF-3538 Herbicide. Previously reviewed residue data were considered in the context of the current submission. The established maximum residue limits (MRLs) for these two active ingredients and the safener are adequate to cover the expected residue levels resulting from the use of GF-3538 Herbicide. The dietary exposure assessments on file are also considered acceptable to estimate the dietary exposure and no health risks of concern have been identified for any segment of the population including infants, children, adults and

seniors.

Environmental Assessment

The use pattern for GF-3538 Herbicide, including the application rates, sites and methods, is within the registered use pattern for other registered products containing fluroxypyr and pyroxsulam. Therefore no additional environmental risk is expected from the use of the GF-3538 Herbicide. The label contains all the applicable and required environmental hazards and precaution statements, including buffer zone information.

Value Assessment

The availability of GF-3538 Herbicide will provide wheat farmers in western Canada with an option to use a co-formulated product to manage both grasses and broadleaf weeds in spring, durum and winter wheat. The benefits of a co-formulated product include a reduction in packaging requirements, ease of shipping and storing product and a reduction in handling requirements, from production through to the farm end user (e.g. loading into the sprayer).

Efficacy and host crop tolerance data from field trials conducted in western Canada were provided for review. The provided trial data demonstrated that GF-3538 Herbicide applied at the high rate of 1.17 L/ha (148 g ai/ha) would be expected to perform in a similar manner (efficacy and crop tolerance) to that of the precedent products. At the low rate of 0.88 L/ha (111 g ai/ha), the majority of weed claims were supported. When tank mixed with 2,4-D Ester for broader spectrum weed control, all weed claims were supported and acceptable crop tolerance would be expected.

No rotational crop tolerance data were provided for review. However, given that 1) the rotational crops for GF-3538 Herbicide are the most restrictive of those that appear on the precedent product labels and 2) residual soil carryover of the active ingredients in GF-3538 Herbicide are not typically influenced by formulation differences, all rotational cropping claims can be supported for the GF-3538 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 GF-3538 Herbicide for postemergent use on wheat (spring, durum and winter) in the Prairie Provinces and interior of British Columbia.

References

PMRA

Document

Number	Reference
2693600	2016, Product Identification of GF-3538, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI

- 2693601 2016, Group A Report: Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for GF-3538, an End Use Product Containing Fluroxypyr-meptyl and Pyroxsulam, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4, 3.4.1, 3.4.2 CBI
- 2693602 2016, Chemical and Physical Properties of GF-3538 Herbicide, DACO: 3.5.10, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.4, 3.5.5 CBI
- 2693604 2016, Group B: Determination of Color, Physical State, Odor, Oxidizing and Reducing Action, Flammability, pH, Viscosity, and Density of GF-3538, an End Use Product Containing [CBI Removed], Pyroxsulam, and Fluroxypyr-methyl, DACO: 3.5.1, 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 CBI
- 2752996 2017, GF-3538 Accelerated Storage Stability & Corrosion Characteristics in F-HDPE, DACO: 3.5.10 CBI
- 2804516 2017, Description of Formulation Process, Particle Size, DACO: 3.2.2 CBI
- 2804517 2017, GF-3538 Two-Week Accelerated Storage Stability and Packaging Corrosion Characteristics in F-HDPE and EVOH, DACO: 3.5.10 CBI
- 2693605 2016. Acute oral toxicity study of GF-3538 in rats. JRF Study No. 401-1-01-13792; DACO 4.6.1.
- 2693606 2016. Acute dermal toxicity study of GF-3538 in rats. JRF Study No. 403-1-01-13793; DACO 4.6.2.
- 2693607 2016. Acute inhalation toxicity study of GF-3538 in rats. JRF Study Number 405-1-01-13794; DACO 4.6.3.
- 2693608 2016. Acute eye irritation study of GF-3538 in rabbits. JRF Study No. 407-1-01-13796; DACO 4.6.4.
- 2693609 2016. Acute dermal irritation study of GF-3538 in rabbits. JRF Study No. 406-1-01-13795; DACO 4.6.5
- 2693610 2016. Skin Sensitisation Study of GF-3538 by Local Lymph Node Assay in Mice. JRF Study No. 409-1-01-13797; DACO 4.6.6
- 2726110 2016, GF-3538 Herbicide, 2015-2016 Trial Reports (19), Submission 2016-7898, DACO: 10.2.3.3, 10.3.2.
- 2739047 2017, 10.1 Efficacy of GF-3538 rationale, DACO: 10.1.

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2018

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.