

Evaluation Report for Category B, Subcategory 2.1, 2.2, 2.3, 2.4 Application

Application Number: 2016-3378
Application: B.2.1: Guarantee
B.2.2: Form of TGAI
B.2.3: Identity of Formulants
B.2.4: Proportion of Formulants
Product: Lontrel XC Herbicide
Registration Number: 32795
Active ingredients (a.i.): Clopyralid
PMRA Document Number: 2781967

Purpose of Application

The purpose of this application was to register the end use product Lontrel XC Herbicide containing 600 g/L clopyralid present as the dimethylamine (DMA) salt.

Chemistry Assessment

Lontrel XC Herbicide is formulated as a solution containing clopyralid (present as dimethylamine salt) at a nominal concentration of 600 g/L. This end-use product has a density of 1.215-1.235 g/mL and pH of 5.1-6.1. The required chemistry data for Lontrel XC Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Lontrel XC Herbicide is of low acute toxicity in the rat via the oral, dermal and inhalation routes of exposure. It is minimally irritating to the eye and non-irritating to the skin of the rabbit. It is not a skin sensitizer in the mouse via the local lymph node assay.

Lontrel XC Herbicide for use in field crops, Christmas tree plantations, pasture, rangeland, vegetable and fruit crops, and non-crop land to control perennial and annual broadleaved weeds fits within the registered use pattern for clopyralid. The exposure for mixers, loaders, applicators and postapplication re-entry workers is considered acceptable when label directions and precautionary statements are adhered to.

The use pattern of the end-use product was determined to be similar to that of the registered product. Therefore, the previously reviewed data were reassessed in the framework of the current submission and it was confirmed that the use of Lontrel XC Herbicide is not expected to result in an increase in the magnitude of clopyralid residues in the treated crops.

Therefore, the use of Lontrel XC Herbicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of Lontrel XC Herbicide, containing clopyralid present as the dimethylamine salt is acceptable from an environmental perspective. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

The registration of Lontrel XC Herbicide, which contains 67% or more active ingredient compared to the registered clopyralid containing products in liquid formulation, will provide value to growers by significantly reducing transportation costs, handling requirements, the number of non-returnable small jugs, etc.

Based on the weight of evidence, the performance, in terms of both efficacy and crop tolerance, of Lontrel XC Herbicide can be expected to be similar to the cited precedent product. Therefore, all claims and uses registered on the cited precedent product label are supported for inclusion on the Lontrel XC Herbicide label. The evidence includes product formulation comparison, scientifically sound rationales, and data from field trials. The field trials were conducted in various OECD countries which are considered generally similar to the climate and environmental conditions in Canada.

Conclusion

The PMRA has reviewed the information provided in support of this application. Based on the results of this application, Lontrel XC Herbicide is acceptable for registration.

References

- 2656849 2011, Lontrel 600 - Efficacy trial reports (7), DACO: 10.2.3.3.
- 2656850 2011, Lontrel 600 - Non safety adverse effects trial reports (5), DACO: 10.3.2.
- 2656851 2013, Biology dossier for GF-2895 submitted to UK, DACO: 10.6.
- 2656852 2011, GF-2551 - Product Chemistry and Manufacture, DACO:
3.1,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.2,3.5.3,
3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
- 2656854 2010, [CBI Removed] - Certificate of Analysis, DACO: 3.4 CBI
- 2656855 1995, Analytical Method for the Determination of Clopyralid in Technical Grade Clopyralid Produced by the [CBI Removed], DACO: 3.4,3.4.1 CBI
- 2656856 2010, Validation of an Analytical Method for the Determination of Active Ingredients in GF-2551, GF-2554, GF-2576, and GF-2646, DACO: 3.4,3.4.1 CBI
- 2656857 2000, Analytical Method: Determination Of Density of Liquid and Liquid Suspensions by use of the Oscillating Density Meter Author, DACO: 3.5.6 CBI
- 2656858 2000, Analytical Method: Determination Of pH Values, DACO: 3.5.6 CBI
- 2656859 2010, Physical properties and Two Week 54°C Stability of GF-2551 (49.2 % w/w clopyralid) in HDPE Packaging, DACO: 3.5.10,3.5.14 CBI
- 2656860 2011, Acute Oral Toxicity of GF-2551 in Rats, DACO: 4.6.1 CBI
- 2656861 2011, Acute Dermal Toxicity of GF-2551 in Rats, DACO: 4.6.2
- 2656862 2011, Acute Inhalation Toxicity Study in Rats (GF-2551), DACO: 4.6.3
- 2656863 2011, Acute Eye Irritation Study of GF-2551 in Rabbits, DACO: 4.6.4
- 2656864 2011, Acute Dermal Irritation Study of GF-2551 in Rabbits, DACO: 4.6.5
- 2656865 2011, Skin Sensitization Study of GF-2551 by Local Lymph Node Assay in Mice, DACO: 4.6.6
- 2115788 2008, Data Submitted by the Agricultural Rentry Task Force (ARTF) to Support Revision of Agricultural Transfer Coefficients, DACO 5.6
- 1913109 2009, Agricultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays, DACO: 5.3,5.4
- 2572745 2015, Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid Formulations, DACO: 5.3,5.4

ISSN: 1911-8082

**8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2017**

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.