

Evaluation Report for Category B, Subcategory B.3.12, B.3.5 Application

Application Number: 2013-1598
Application: Label amendments; new crops and changes to the plant back interval.
Product: Accord Dry Flowable Herbicide
Registration Number: 25118
Active ingredients (a.i.): Quinclorac (QUC)
PMRA Document Number: 2315232

Purpose of Application

The purpose of this application was to add canola, Clearfield canola quality *Brassica juncea*, and tame mustard (brown and oriental) to the Accord Dry Flowable Herbicide (Registration Number 25118) label.

At the time of the review of this application, Accord Dry Flowable Herbicide was already registered for selective post-emergent control of green foxtail, cleavers, volunteer flax, barnyard grass and suppression of sow-thistle in spring and durum wheat, spring barley and canary seed in the Prairie Provinces and the Peace River region of British Columbia.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Quinclorac-methyl ester is a novel metabolite of quinclorac in canola. In order to characterize the toxicity of the metabolite, the registrant submitted a metabolism study, an acute oral toxicity study and a 90-day oral toxicity study in rats. Quinclorac-methyl ester is quickly and extensively absorbed and excreted, predominantly in the bile and urine, and more extensively metabolized than the parent. It is of low acute oral toxicity in rats. In the 90-day rat oral toxicity study, the NOAEL of 128 mg/kg bw per day was based on decreased body weight and body weight gains, increased relative thyroid weights and increased histopathological changes in the thyroid in males and females, decreased food consumption and increase adrenal weights in males and decreased rearing in females. It was determined that the metabolite should be included in the risk assessment for quinclorac.

Exposure for mixing, loading and applying quinclorac to canola, Clearfield canola quality *Brassica juncea*, brown and oriental tame mustard was estimated using PHED Version 1.1. No risks of concern were identified for handlers wearing long sleeves, long pants and gloves.

The potential for post-application exposure to workers entering treated fields is negligible since the product is applied to bare ground before the crop has emerged. No appreciable residues are expected on the surface of the crops.

Analytical methods for the determination of quinclorac and quinclorac-methyl ester in plants and storage stability data for the metabolite quinclorac-methyl ester were submitted to support the addition of canola, Clearfield canola quality *Brassica juncea*, and tame mustard (brown and oriental). Previously reviewed residue data from field trials conducted in/on canola were reassessed in the framework of this application. In addition, a metabolism study in canola was reassessed to determine the residue definitions in oilseeds and a processing study in treated canola was also reassessed to determine the potential for concentration of residues of quinclorac into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for quinclorac was based upon the residues observed in crop commodities treated according to label directions from submitted field trials, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of quinclorac and the metabolite quinclorac-methyl ester in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the recommended MRLs for the raw agricultural commodities (RACs).

TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limit(s) (MRLs)							
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Canola	Ground foliar / 100	60	Quinclorac			None	1.5 ppm
			<0.05	0.85	Meal: 1.3x Refined oil: No concentration observed		
			Quinclorac-methyl ester *				
			<0.05	0.23	No concentration observed in meal or refined oil.		
			Combined residues *				
			<0.10	1.00	--		

* Residues expressed as quinclorac equivalents.

A MRL of 1.5 ppm for all crops of Crop Subgroup 20A is recommended to cover residues of quinclorac and the metabolite quinclorac-methyl ester. Residues of quinclorac and the metabolite quinclorac-methyl ester in these crop commodities at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No additional environmental data were required to expand the use of Accord Dry Flowable Herbicide canola, Clearfield canola quality *Brassica juncea*, and tame mustard (brown and oriental). The rate, number of applications, interval between applications and application equipment are similar to those registered for use on other crops. No increase in environmental exposure to quinclorac is expected from the label expansion of Accord Dry Flowable Herbicide.

Value Assessment

Value information submitted included data from 14 dedicated crop tolerance trials. Injury to each of six varieties of canola, five Clearfield canola quality *B. juncea* varieties, three brown mustard varieties, and three oriental mustard varieties were reported for treatments at the labeled rate of 100 g a.i./ha and the 2 x rate of 200 g a.i./ha. Crop injury was either minor or not observed for the treatment at the labelled 1 x rate. Yield data further confirmed that these crops are expected to exhibit an adequate margin of crop safety when applied in accordance with the label instructions.

Following review of the value information, the inclusion of canola, Clearfield canola quality *B. juncea*, and tame mustard (brown and oriental) as host crops on the Accord Dry Flowable Herbicide label is supported. The registration of the requested amendment to Accord Dry Flowable Herbicide will offer an additional weed management tool on canola, Clearfield canola quality *B. juncea*, and tame mustard.

Conclusion

Following the review, the label of Accord Dry Flowable Herbicide was amended to add use on canola, Clearfield canola quality *Brassica juncea*, and tame mustard (brown and oriental).

A MRL of 1.5 ppm for all crops of Crop Subgroup 20A is recommended to cover residues of quinclorac and the metabolite quinclorac-methyl ester.

References

PMRA

Document

References

- 2185526 2010, Analytical Report, Registration Number 161555 (Metabolite of BAS 514 H), Homogeneity and Concentration Control Analysis in deionized water with 0.5% carboxymethylcellulose, DACO: 4.2.1
- 2185528 2010, Registration Number 161 555 (metabolite of BAS 514 H) - Acute oral toxicity study in rats, DACO: 4.2.1
- 2185529 2011, Registration Number 161555 (Metabolite of BAS 514 H) - Repeated Dose 90-day Oral Toxicity Study in Wistar Rats - Administration via the Diet, DACO: 4.3.1
- 2185530 2011, 14C-Registration Number 161555 (Metabolite of BAS 514 H) - Study on Bile Excretion in Rats, DACO: 4.5.9
- 2185535 2011, Metabolism investigation of 14C Registration Number 161555 (Metabolite of BAS 514 H) of Samples from a Bile Excretion Study of Male Wistar Rats After Oral Administration, DACO: 4.5.9
- 2185536 2012, Structure Elucidation of Bile Metabolites of Male Rats after oral Administration of 14C Registration Number 161555 (Metabolite of BAS 514 H), DACO: 4.5.9
- 2185547 2012, BASF Request For Waiver of Animal Feeding Studies and Metabolism Studies in Animals for the Methyl Ester Metabolite of Quinclorac, DACO: 6.2,7.5
- 1189904 1998, Nature of the residue in BAS 514 H in canola, DACO: 6.3
- 2185549 2012, Exemption from Metabolism Requirement for the Use of Quinclorac on LibertyLink, Roundup Ready, and Clearfield Canola, DACO: 6.3
- 1189907 1998, Validation of BASF method number D9806: analytical method for the determination of quinclorac-methyl ester residues in canola seed and oil, DACO: 7.2.1
- 2185552 1998, Validation of BASF Method Number D9708/1: Analytical Method for the Determination of Quinclorac Residues in Cereal Grain and Oil Seed Crops Using LC/MS/MS, DACO: 7.2.1
- 2295258 2013, Independent laboratory validation of: BASF Analytical Method D9708/02 titled: Analytical Method for the Determination of the Residues of Quinclorac (Registration Number 150732) in Plant Matrices Using LC-MS/MS and BASF Analytical Method D9806/02 Titled: Analytical Method for the Determination of the Quinclorac-Methyl Ester (Registration Number 161555) in Canola Seed Using LC-MS/MS, DACO: 7.2.3
- 2185554 2012, Freezer storage stability of quinclorac (BAS 514 H) and its Metabolite Quinclorac-Methyl Ester (BH 514-ME) in Canola, DACO: 7.3
- 1189910 1998 The magnitude of quinclorac residues in canola, amended report, DACO: 7.4.1
- 1189914 1998 The magnitude of quinclorac residues in canola seed processed fractions, DACO: 7.4.5

**PMRA
Document**
2185495

References

2012, Application to register Accord Soluble Liquid Herbicide, a formulation replacement for Accord Dry Flowable Herbicide. DACO: 10.1,10.2,10.2.1, 10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.3,10.3.1,10.3.2,10.3.3,10.4,10.5, 10.5.1,10.5.2,10.5.3,10.5.4,10.6

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2013

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.