

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2008-0689

Application: B.4.1 (conversion to full registration without consultation)

Product: DyVel DSp Liquid Herbicide

Registration Number: 27856

Active ingredients (a.i.): Dicamba [DIC]

2,4-D [DXB]

Mecoprop-p (present as dimethylamine salt) [MEQ]

PMRA Document Number: 1913507

Background

During the re-evaluation of the active ingredient mecoprop (racemic: 50/50 R/S isomers), the PMRA had identified significant data gaps for racemic mecoprop that would have to be addressed in order to bring the supporting database up to modern standards (refer to Reevaluation Decision Document RRD2004-09, Mecoprop,). At the time, rather than generating the required data to support continuing registration, the registrants of technical racemic mecoprop decided to discontinue sales of the racemic form of mecoprop and to replace it with a specific isomer of mecoprop known as mecoprop-p.

Purpose of Application

The purpose of this application was to convert the subject end-use product to full registration. This application was assessed at the same time as conversion applications for Marks Mecoprop-p Technical Acid (Registration Number 27441), and Nufarm Mecoprop-p Technical Acid (Registration Number 27631.

Furthermore, there were approximately 60 associated end-use products assessed for conversion from conditional to full registration. The conversion of these applications was dependent on the conversion of the above three applications.

Chemistry Assessment

The chemistry requirements have been fulfilled.

Health Assessments

A toxicology assessment was not required for this application.

Occupational and residential risk resulting from the use of products containing mecoprop-p are not of concern taking into consideration the new toxicology and occupational exposure data.



Residue data for mecoprop-p in cereal grains were submitted to support the conversion to full registration of this active on several end-use product labels. Residue data from field trials conducted in/on barley, corn and wheat were assessed in the framework of this application. In addition, a processing study in treated wheat was also assessed to determine the potential for concentration of residues of mecoprop-p into processed commodities.

Maximum Residue Limit(s)

Based on the maximum residues observed in crops treated according to label directions, maximum residue limits (MRLs) to cover residues of mecoprop-p in/on crops will be established as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under established 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	PHI (days)	Residues		Experimental	Currently	Recommended
			Min	Max	Processing Factor	Established MRL	MRL
Barley grain		53-79	All <0.02 ppm		No concentration observed	Under GMRL of 0.1 ppm	
Corn (K+CWHR)	Postemergence foliar application/	61-79					0.02 ppm (for all crops of
Corn grain	1050 g a.e./ha	114-147					Crop Group 15; Cereal grain)
Wheat grain		58-104					e e e e e e e e e e e e e e e e e e e

Based on the dietary burden and residue data, MRLs of 0.01 ppm in milk, 0.02 ppm in eggs, fat and meat of cattle, goats, hogs, horses, poultry and sheep and 0.05 ppm in meat by-products of cattle, goats, hogs, horses, poultry and sheep to cover residues of mecoprop-p will be established.

Following the review of all available data, MRLs for crops and livestock are recommended to cover residues of mecoprop-p. Residues in these crop/livestock commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

Data were provided from 12 trials conducted in barley (4), wheat (3) and oat (5) to bridge the efficacy and crop tolerance of the racemic formulation of mecoprop to that of the resolved herbicidally active isomer of mecoprop-p. Based on the data provided, efficacy of mecoprop-p was comparable to the racemic mecoprop on a subset of labelled weeds (cleavers and Canada thistle) in wheat, oat and barley. Crop tolerance to mecoprop-p was comparable between racemic and resolved isomer formulations.

Data were also provided from four trials to bridge efficacy and crop tolerance of the conditionally registered resolved isomer formulations of co-formulated turf products containing mecoprop, dicamba and 2,4-D to the racemic formulations. Efficacy between racemic and resolved isomer formulations was comparable for a subset of labelled weeds (stitchwort, clover, dandelion, black medick, ground ivy and chickweed) when applied in turf at labelled rates. In addition, crop tolerance in turf was equivalent between the racemic and resolved isomer formulations. Therefore, based on the data provided, the racemic and resolved isomer formulations of mecoprop can be considered agronomically equivalent.

Conclusion

The PMRA has assessed all available information and is able to support the conversion of the subject end-use product to full registration.

References

PMRA	Reference			
Document				
Number				
1522702	r			
	Professional Lawn Care Operators During the Application of MCPP-p, 2,4-D and			
	Dicamba to Residential Turf, DACO: 5.3			
1522671	2001, The Distribution and Metabolism of [14C]-Mecoprop-p in the Lactating			
	Goat, DACO: 6.2,7.5			
1522673	2007, Mecoprop-p Residues Study in Laying Hens: Request for a Waiver, DACO:			
	6.2			
1522674	1998, 14C Mecoprop-p: Wheat Metabolism Study, DACO: 6.3			
1522675	2000, 14C Mecoprop-p 2-ethylhexyl ester: Wheat Metabolism, DACO: 6.3			
1522676	2000, Amendment to 14C Mecoprop-p 2-ethylhexyl ester: Wheat Metabolism,			
	DACO: 6.3			
1522677	2007, Summary of MCPP-p Cereal Grain Residue Program Conducted in Canada,			
	DACO: 7.1			
1522678	1996, Mecoprop-p and Dichlorprop-p Analytical Method for the Determination of			
	Residues in Animal Products AR 125-96, DACO: 7.2.1,7.2.2,7.2.5			
1522682	2002, Independent Laboratory Validation of the Method of Analysis AR 125-96			
	for the Determination of Mecoprop-p (MCPP-p) and Dichlorprop-p (2,4-DP-p) in			
	Products of Animal Origin, DACO: 7.2.3			
1522684	2007, Position Paper: Data Waiver Request for FDA Multiresidue Methods			
	Testing for MCPA, 2,4-DB, MCPP-p, 2,4-DP-p and MCPB: OPPTS 860.1360			
	Multiresidue Method Test, DACO: 7.2.4			
1522685	2002, Storage Stability of Mecoprop-p Residues in Cereals, DACO: 7.3			
1522686	2006, Magnitude of Mecoprop-p Residues and Decline from Application of			
	Mecoprop-p Dimethylamine Salt to Spring Wheat (in Canada), DACO:			
	7.4.1,7.4.2,7.4.5,7.4.6			

1522689	2006, Magnitude of Mecoprop-p Residues and Decline from Application of Mecoprop-p Dimethylamine Salt to Barley (in Canada), DACO:			
	7.4.1,7.4.2,7.4.5,7.4.6			
1522690	2006, Magnitude of Mecoprop-p Residues from Application of Mecoprop-p Dimethylamine Salt to Corn, DACO: 7.4.1,7.4.5,7.4.6			
1522691	2007, Magnitude and Decline of Mecoprop-p Residues from Application of Mecoprop-p Dimethylamine Salt to Barley in Canada, DACO: 7.4.1,7.4.2,7.4.5,7.4.6			
1522692	2007, Magnitude and Decline of Mecoprop-p Residues from Application of Mecoprop-p Dimethylamine Salt to Corn in Canada, DACO: 7.4.1,7.4.2,7.4.5,7.4.6			
1522696	2007, Magnitude of MCPP and Metabolite Residues in Processed Fractions of Spring Wheat Following Treatment with Mecoprop-p Dimethylamine Salt in Canada, DACO: 7.4.1,7.4.2,7.4.5,7.4.6			
1522700	2007, Magnitude and Decline of Mecoprop-p Residues from Application of Mecoprop-p Dimethylamine Salt to Spring Wheat in Canada, DACO: 7.4.1,7.4.2,7.4.6			
1522703	2007, Waiver Request for Field Accumulation in Rotational Crops, DACO: 7.4.4			
1522704	2007, Magnitude of Mecoprop-p Residues from Application of Mecoprop-p Dimethylamine Salt to Spring Wheat in Canada, DACO: 7.4.1,7.4.6			
1522706	2007, Magnitude of Mecoprop-p Residues from Application of Mecoprop-p Dimethylamine Salt to Barley in Manitoba, Canada, DACO: 7.4.1,7.4.6			
1522707	2007, Magnitude of Mecoprop-p Residues from Application of Mecoprop-p Dimethylamine Salt to Corn in Canada, DACO: 7.4.1,7.4.6			
1522708	2007, Interim Draft Report A Confined Rotational Crop Study with 14C Mecoprop-p, DACO: 7.4.3			
1522721	2004, Efficacy Small scale trials: trial reports 10pp., DACO: 10.2.3.3			
1522722	2004, Efficacy Small scale trials: trial reports 15pp., DACO: 10.2.3.3			
1522723	2006, Efficacy Small scale trials: trial reports 9pp., DACO: 10.2.3.3			
1522724	2004, Efficacy Small scale trials: trial reports 17pp., DACO: 10.2.3.3			
1522725	2004, Efficacy Small scale trials: trial reports 14pp., DACO: 10.2.3.3			
1522726	2004, Efficacy Small scale trials: trial reports 20pp., DACO: 10.2.3.3			
1522727	2004, Efficacy Small scale trials: trial reports 9pp., DACO: 10.2.3.3			
1522728	2004, Efficacy Small scale trials: trial reports 16pp., DACO: 10.2.3.3			
1522729	2004, Efficacy Small scale trials: trial reports 18pp., DACO: 10.2.3.3			
1522730	2004, Efficacy Small scale trials: trial reports 9pp., DACO: 10.2.3.3			
1522731	2004, Efficacy Small scale trials: trial reports 28pp., DACO: 10.2.3.3			
1522732	2004, Efficacy Small scale trials: trial reports 23pp., DACO: 10.2.3.3			
1522733	2004, Evaluation of Mecoprop for Weed Control and Crop Tolerance in Oats			
	(Trial L403) 9pp., DACO: 10.2.3.3			
1522734	2004, Evaluation of Mecoprop for Weed Control and Crop Tolerance in Oats			
	(Trial L406) 9, DACO: 10.2.3.3			
1522735	2004, Mecoprop 150 g/l, 600 g/l (2004-MCPP-p-01) Combined Efficacy			
	Tolerance Trial 19pp., DACO: 10.2.3.3			

1522736	2004, Oats and MCPP Trial. Efficacy Small scale trials: trial reports 5pp., DACO:
	10.2.3.3
1522709	2006, Value summary 3-way MCPP-p products –turf 6pp., DACO: 10.1
1522710	2005, Value summary –wheat 5pp., DACO: 10.1
1522711	2005, Value summary – barley 6pp., DACO: 10.1
1522712	2005, Value summary –oats 6pp., DACO: 10.1
1522720	2004, Summary of trials for Mecoprop applications for crop tolerance, weed
	control and yield evaluations in wheat, barley and oat 52pp., DACO: 10.2.3.1

ISSN: 1911-8082

[®] Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2011

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.