

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2008-0697

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

Product: Sword Commercial Herbicide

Registration Number: 27892

Active ingredients (a.i.): Dicamba [DIC], MCPA [MAB], Mecoprop-p (present as

dimethylamine salt) [MEQ]

PMRA Document Number: 1913548

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 Re-evaluation 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

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