

Section 12 Notice **Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration**

Product Name: MECOPROP-P (TECHNICAL ACID)

Registration Number: 27635

Application Number: 2006-7937

PMRA #: 1440704

During the conditional registration period which has been granted to December 31, 2007, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **December 1, 2007** and must indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

The Pest Management Regulatory Agency's decision to grant temporary registration of the subject technical product containing the isomer specific form of mecoprop-p for use in Canada is based on the following conditions:

Please note that if the data requirements presented (specifically Parts 6 and 7) in order to support current food uses are not addressed, the currently registered food uses appearing on end use products containing mecoprop will be discontinued.

PART 4 TOXICOLOGY

DACO: 4.4.4
Title: Rat combined chronic and oncogenicity

Required DATA: **A new rat combined oncogenicity and long-term toxicity study conducted with mecoprop-p at adequate dose levels.**

PARTS 6 and 7 METABOLISM/TOXICOKINETICS STUDIES and FOOD, FEED AND TOBACCO RESIDUE STUDIES

The residue chemistry data requirements for the registration of mecoprop-p are detailed in the PMRA Regulatory Directive 98-02, Residue Chemistry Guidelines (RCG). As the existing data used to initially register mecoprop racemic do not meet contemporary standards, mecoprop-p specific data which meets the requirements set forth in the RCG need to be submitted. This summary is based on the proposed registration of mecoprop-p, (*R*)-2-(4-chloro-*O*-tolylxy) propionic acid, on the same crops which mecoprop racemic, (*RS*)-2-(4-chloro-*O*-tolylxy) propionic acid, is currently registered.

Available Data

No contemporary data is on file for mecoprop or mecoprop-p to cover the data requirements for DACO 6 (Nature of the Residue) or DACO 7 (Food and Feed Residue Studies).

Bioequivalency of Forms

The bioequivalency of mecoprop and mecoprop-p has not been established. Any submitted data based on the mecoprop racemic must provide a rationale for the translation and applicability of racemic data to support registration of the isomerically pure mecoprop-p.

Additional Data Requirements

Drinking Water - As the dietary risk assessment includes exposure from drinking water, suitable quantitative data to estimate the concentration of mecoprop-p in drinking water will be required. The available drinking water surveillance data for mecoprop is either from regional or foreign sources, and is not suitable to support registration of a new active.

Table 2: Mecoprop-p Required Studies (USC 14-15 Terrestrial Food and Feed Crops)

Data Code	Title	Conditions	Relevant Section in DIR98-02 Residue Chemistry Guidelines (RCG)
6	Metabolism/Toxicokinetics Studies (TGAI or EP)		Nature of the Residue RCG § 2
6.1	Summaries		
6.2	Livestock		
6.3	Plants		
6.4	Other Studies/Data/Reports	If available	
7	Food, Feed and Tobacco Residue Studies EP		
7.1	Summaries		
7.2	Analytical Methodology (Food Crops & Tobacco)		Residue Analytical Methods RCG § 3
7.2.1	Supervised Residue Trial Analytical Methodology		
7.2.2	Enforcement Analytical Methodology		
7.2.3	Inter-laboratory Analytical Methodology Validation		
7.2.4	Multi-residue Analytical Methodology Evaluation		Residue Analytical Methods RCG § 4
7.2.5	Storage Stability of Working Solutions in Analytical Methodology		Storage Stability Data RCG § 5

7.3	Freezer Storage Stability Tests	If stored for more than 30 days and/or volatile or labile Studies required	
7.4	Crop Residue Data		Crop Field Trials RCG § 9
7.4.1	Supervised Residue Trial Studies		
7.4.2	Residue Decline Studies		
7.4.3	Confined Crop Rotation Trial Studies		Confined Accumulation in Rotational Crops RCG § 13
7.4.4	Field Crop Rotation Trial Studies		Field Accumulation in Rotational Crops RCG § 14
7.4.5	Processed Food/Feed		Processed Food/Feed RCG § 10
7.4.6	Residue Data for Crops used as Livestock Feed (if needed for forage crops)		
7.5	Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops)		Meat/Milk/Poultry/Eggs RCG § 8
7.7	Tobacco Residue Data	Depends on label instructions	
7.8	Other Studies/Data/Reports	If available	

DACO 6.2: Animal Metabolism

Studies are required for ruminants (goat, cow), poultry and swine. If the metabolism in rat toxicology studies is similar to that in ruminants and poultry, then the requirement for a swine metabolism study may be waived.

DACO 6.3: Plant Metabolism

Studies are required on representative crops for which mecoprop-p registration is proposed. Section 15 of the RCG identifies representative crops and crop groups. For grains, these are wheat, barley and corn. Section 2 of the RCG indicates the scope and purpose of the required metabolism studies.

DACO 7.4: Field Trials

Based on the current label uses for mecoprop and Table 2 in Section 9, Appendix III of the RCG, the required field trials are summarized in Table 3, below. Details on the required sample size for agricultural commodities from supervised field trials for residue analysis can be found in Section 9, Appendix I of the RCG.

Table 3: Required Field Trials for Mecoprop-p

RAC	Field Trials	Samples Required	Crop Zones							
			5	0.2	5B	7	0.3	12	14	
		1								
Barley	16	32		1		1	2			12
Corn (Grain)	12	24		8		4				
Corn (Silage)	5	10		3		2				
Corn (Sweet)	8	16		4		2		1	1	
Oats	16	32	1	1	1	1	2			10
Wheat	20	40		2			7	1		10
Forage and Fodder	To be determined									

Table 4: PMRA Crop Zones (from RCG § 9.6, Field Trial Regions)

Zone	Name	Zone	Name
1	Appalachian	7	Dryland Prairie
5	Southern Ontario	0.2916667	Southern Alberta
0.208333333333	Atlantic	12	Pacific
5B	Northern Shield	14	Northern Prairie

PART 10 VALUE

DACO: 10.2.3
Title: Efficacy

Required DATA: Bridging efficacy data establishing equivalency between the mecoprop racemic and the mecoprop-p.

DACO: 10.3.2
Title: Nonsafety Adverse Effects

Required DATA: Bridging crop tolerance data establishing equivalency between the mecoprop racemic and the mecoprop-p.