



Evaluation Report for Category B, Subcategory B.4.1 Application

Application Number: 2008-5911 / 2008-5918
Application: Conversion from conditional registration to full registration
Product: Aminopyralid Herbicide / Aminopyralid Technical Herbicide
Registration Number: 28137 / 28136
Active ingredients (a.i.): Aminopyralid
PMRA Document Number: 1981342
PMRA Document Number (English PDF): 2416212
PMRA Document Number (French PDF): 2416213

Purpose of Application

The purpose of this application was to convert Aminopyralid Technical and Aminopyralid Herbicide from conditional registration to full registration. Aminopyralid Technical and Aminopyralid Herbicide were granted conditional registration in 2006. The detailed review can be found in Regulatory Note REG2007-01, *Aminopyralid*. The conditions of registration included batch data from commercial scale production facilities, storage stability data and corrosion characteristics for the end-use product, and enforcement analytical methodology in plant matrices.

Chemistry Assessment

Aminopyralid Herbicide is formulated as a solution containing aminopyralid at a nominal concentration of 240 g/L. This end-use product has a density of 1.14 g/mL at -20°C and a pH of 7.33. The chemistry requirements for Aminopyralid Herbicide are complete.

Common Name: Aminopyralid
Chemical Name: 4-amino-3,6-dichloropyridine-2-carboxylic acid
Aminopyralid Technical Herbicide has the following properties:

Property	Result
Colour and physical state	Off-white solid (powder)
Nominal concentration	94.9%
Odour	Odourless
Specific gravity	1.72
Vapour pressure	2.59×10^{-8} Pa at 25°C and 9.52×10^{-9} Pa at 20°C
pH	2 - 2.5 in 1% slurry

Property	Result		
Solubility in water	<u>pH</u>	<u>Solubility (g/L)</u>	<u>Temp (°C)</u>
	Unbuffered in water	2.48	18
	5	212	20
	7	205	20
	9	203	20
n-Octanol/water partition coefficient	<u>pH</u>	<u>Log K_{ow}</u>	
	Unbuffered water	0.201	
	5	-1.76	
	7	-2.87	
	9	-2.96	

The chemistry requirements for Aminopyralid Technical and Aminopyralid Herbicide have been completed.

Health Assessments

Regulatory Note REG2007-01 *Aminopyralid* indicated an enforcement analytical methodology in plant matrices was required. Additional experiments were performed to confirm the selectivity of the Method GRM 02.31. It was demonstrated that the MS/MS (tandem mass spectrometry) transition ions monitored in Method GRM 02.31 are suitable for confirmation of aminopyralid. Also, it has been proven that the presence of clopyralid or picloram does not interfere in the quantitation of aminopyralid.

Additional freezer storage stability data demonstrated that residues of aminopyralid, when stored at approximately -20°C, are stable for up to 16 months in/on grass hay and forage, and wheat grain and straw.

Please refer to Regulatory Note REG2007-0, *Aminopyralid*, for more details on health assessments for these products.

Impact on the Environment

Please refer to Regulatory Note REG2007-01, *Aminopyralid*, for the detailed assessment of the environmental impact of aminopyralid.

Value Assessment

Please refer to Regulatory Note REG2007-0, *Aminopyralid*, for the full assessment details of the value of the end-use product of Aminopyralid Herbicide.

Conclusion

The PMRA has completed an evaluation of the information provided to address the conditional registration of Aminopyralid Technical and Aminopyralid Herbicide. The PMRA has concluded that these two products are acceptable for full registration.

List of Abbreviations

g	gram
L	litre
log K _{ow}	n - octanol - water partition coefficient
ml	millilitre
MS/MS	tandem mass spectrometry
Pa	Pascal
REG	Regulatory Note

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
1688582	2007, Group A: Description of Materials used to Produce the Product, Description of the Production Process, Discussion of the Formation of Impurities, Preliminary Analysis and Certified Limits for Aminopyralid (XDE-750) Technical - Supplemental Information
1688583	2007, Group A: Product Identity and Composition, Description of Materials used to Produce the Product and Description of the Production Process for Aminopyralid (XDE-750) Technical - Supplemental Information for MRID 46235701, DACO: 2.11.1,2.11.2,2.11.3,2
1688584	2006, Batch Characterization of Aminopyralid Technical, DACO: 2.13.3 CBI
1688585	2003, Amended Report for Method Validation for the Determination of Impurities in XDE-750, DACO: 2.13.1 CBI
1688588	2003, Amended Report for Method Validation for Assay of XDE-750 Technical, DACO: 2.13.1 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
1688444	2006, A Confirmatory Technique for the Determination of Residues of Aminopyralid in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometry Detection, DACO: 7.2.2
1688445	2008, Determination of Residues of Aminopyralid in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometric Detection, DACO: 7.2.2

1688446

2004, Frozen Storage Stability of XDE-750 in Range Land and
Pasture Grass and Hay and Wheat Straw and Wheat Grain,
DACO: 7.3

3.0 Environment

None

4.0 Values

None

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2012

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.