

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2010-1559

Application: New/Changes to the technical grade active ingredient – new source

(site) same registrant

Product: Pursuit Technical Herbicide AC 263,499

Registration Number: 21536 **Active ingredients (a.i.):** Imazethapyr **PMRA Document Number:** 1932641

Purpose of Application

The purpose of this application is to add a new manufacturing site of the technical grade active ingredient to the currently registered product, Pursuit Technical Herbicide AC 263,499, Registration Number 21536.

Chemistry Assessment

Common name: imazethapyr

Chemical name

(IUPAC): 5-ethyl-2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]nicotinic acid

(CAS): (\pm) -2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yI]-5-ethyl-3-

pyridinecarboxylic acid

Pursuit Technical Herbicide AC 263,499 has the following properties:

Property	Results
Colour and physical state	Off-white to tan solid
Nominal concentration	97.3 %
Odour	Moderate pungent odour
Density	0.495 g/mL
Vapour pressure	4.2×10^{-9} Pa at 20°C
	1.2×10^{-8} Pa at 25°C
pН	2.85 for a 1 % solution
Solubility in water	<u>pH</u> <u>Solubility (g/L)</u>
	distilled water 1.3
	4 2.4
	7 5.0
	9 7.1
	(unspecified) 1.4 at 25°C

n-Octanol/water partition coefficient	pH log Kow
	distilled water (3.9) 0.81
	5 (4.8) -0.03
	7 (6.8) -1.75
	9 (8.7) -2.27
	(neutral form) 1.37 (calculated)
	5 1.04
	7 1.49
	9 1.20

The chemistry requirements for Pursuit Technical Herbicide AC 263,499 have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the addition of a new manufacturing site for the production of Pursuit Technical Herbicide (AC 263,499) is acceptable.

References

1468402	1987, Physical and chemical characteristics for the manufacturing-use product, AC 263,499, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9
1894941	2010, Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient (TGAI), DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
1894942	2010, Product identity and composition of Imazethapyr for the [CBI REMOVED] source change, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1 CBI
1894944	2010, Quali-Quantitative analysis of five batches of Imazethapyr technical (TGAI) manufactured at [CBI REMOVED], DACO: 2.13,2.13.1,2.13.2,2.13.3 CBI
1894948	2010, Validation of the analytical method for the determination of Imazethapyr [CBI REMOVED] in the technical grade active ingredient BAS 685 H by HPLC, DACO: 2.13.1 CBI
1894949	2010, Validation of the analytical method for the determination of impurities in technical grade active ingredient (TGAI) Imazethapyr by HPLC, DACO: 2.13.1 CBI
1894950	2010, Physical properties of Imazethapyr technical grade active ingredient (TC/TGAI) manufactured at [CBI REMOVED], DACO: 2.14,2.14.1,2.14.2,2.14.3,2.14.4,2.14.9 CBI
1894953	2010, Determination of solubility in water and n-Octanol/water partition coefficients for technical Imazethapyr (TGAI) manufactured at [CBI REMOVED] DACO: 2.14.11,2.14.7,2.14.8 CBI



ISSN: 1911-8082
Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2010
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.