

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number:	2017-0886	
Application:	Changes TGAI Product Chemistry-Specifications	
Product:	Fluopyram Technical Fungicide	
Registration Number:	30508	
Active ingredient (a.i.):	Fluopyram	
PMRA Document Number :2807985		

Purpose of Application

The purpose of this application was to provide data from commercial scale production and to update the guarantee of the product.

Chemistry Assessment

Common Name:	Fluopyram
IUPAC* Chemical Name:	N -{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}- α,α,α -
	trifluoro-o-toluamide
CAS [†] Chemical Name:	<i>N</i> -[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-
	(trifluoromethyl)benzamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Fluopyram Technical Fungicide has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	98.3%
Odour	No noticeable odour
Density	1.53 g/cm^3
Vapour pressure	3.1×10^{-6} Pa at 25°C
pH	6.6 (1% solution)
Solubility in water	16 mg/L (20°C, pH 7)
n-Octanol/water partition coefficient	$Log K_{ow} = 3.3 at 20^{\circ}C$

The required chemistry data for Fluopyram Technical Fungicide have been provided, reviewed, and found to be acceptable.

Health Environmental and Value Assessments

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



Conclusion

The Pest Management Regulatory Agency has conducted a review of the information provided in support of this application and has determined that the data are acceptable.

References

PMRA Document Number	Reference
1599748	2008, Fluopyram (AEC 656948) - Technical grade active substance - Discussion of the formation of impurities, DACO: 2.11.4 CBI
1599749	2008, Fluopyram (AEC 656948) - Technical grade active substance - Manufacturing process, DACO: 2.11.1,2.11.2,2.11.3 CBI
1908579	2010, 2nd Amendment to material accountability of fluopyram manufactured at (Privacy information removed) - Five batches of technical fluopyram, DACO: 2.13.3 CBI
2475397	2014, Fluopyram technical grade active substance - Justification of certified limits for USA and Canada, DACO: 2.12.1 CBI
2475398	2012, Fluopyram (AE C656948) - Determination of technical grade active substance HPLC with external standard, DACO: 2.13.1 CBI
2475401	2013, Validation of AM020212MP1 - Fluopyram (AE C656948) - Determination of technical grade active substance, DACO: 2.13.1 CBI
2475403	2006, Identification of substances by NMR (1H, 13C, 19F, 31P), DACO: 2.13.1,2.13.2 CBI
2475405	2014, Validation of AM003906MP5 - Fluopyram (AE C656948) - Impurities in technical grade active substance - HPLC with external standard, DACO: 2.13.1 CBI
2475406	2013, Determination of (CBI removed) in fluapyram - IC - external standard, DACO: 2.13.1 CBI
2475408	2013, Determination of (CBI removed) in fluapyram - IC - external standard, DACO: 2.13.1 CBI
2475409	2014, Fluopyram - Determination of (CBI removed) in technical grade active substance GLC-Headspace - external standard, DACO: 2.13.1 CBI
2475410	2014, Validation of GLC-method AM024514MP1 – Fluopyram Determination of (CBI removed) in technical grade active substance - GLC - external standard (Headspace), DACO: 2.13.1 CBI
2475412	2001, MT 30 Water ; (CBI removed), DACO: 2.13.1
2475413	2012, Analytical method – (CBI removed) - Determination of (CBI removed) on the basis of CIPAC MT 29, DACO: 2.13.1
2729759	2014, Fluopyram (AE C656948) - Impurities in technical grade active substance - HPLC with external standard, DACO: 2.13.1,2.13.2 CBI
2729760	2014, Fluopyram - Determination of (CBI removed) in technical grade active substance - GLC-Headspace - external standard, DACO: 2.13.1 CBI
2729761	2014, Validation of GLC-method AM024614MP1 - Fluopyram - Determination of (CBI removed) in technical grade active substance GLC - External standard (Headspace), DACO: 2.13.1 CBI

- 2729762 2016, Statement on the equivalence of the Ion chromatography methods AM022513MP1 and AM004006MP1, DACO: 2.13.1 CBI
- 2729763 2016, Material accountability of technical fluopyram (AE C656948) Five batches of technical fluopyram, DACO: 2.13.3 CBI

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2017

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.