



Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2014-5390
Application: New / Changes TGAI or ISP Prod Chemistry-Specifications
Product: Fluopyram Technical Fungicide
Registration Number: 30508
Active ingredients (a.i.): Fluopyram
PMRA Document Number : 2579517

Purpose of Application

The purpose of this application was to amend the manufacturing process of the active ingredient fluopyram, and to update the product specifications.

Chemistry Assessment

Common Name: Fluopyram
IUPAC* Chemical Name: N-{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethyl}-2-(trifluoromethyl)benzamide
CAS† Chemical Name: N-[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	97.4%
Odour	No noticeable odour
Density	1.53 g/cm ³
Vapour pressure	3.1 × 10 ⁻⁶ Pa (at 25°C)
pH	6.6
Solubility in water	16 mg/L (20°C, pH 7)

Property	Result
n-Octanol/water partition coefficient	Log K _{ow} = 3.3 at 20°C

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

Health Assessments

No new toxicological data were required since the manufacturing process amendments had no impact on the toxicology profile.

No new residue data for fluopyram were required in support of the amendments to the manufacturing process and product specifications for Fluopyram Technical Fungicide. Fluopyram is currently registered in Canada for use on various crops. As Fluopyram Technical Fungicide will be used to formulate registered end-use products within the existing use pattern, no changes in the magnitude of the residues in food and feed crops are expected and therefore, no increase in dietary exposure is anticipated.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and is able to support the registration of Fluopyram Technical Fungicide.

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
2475390	2014, Part 2 report - Fluopyram Technical Fungicide - PART 2 Chemistry requirements for the registration of a technical grade of active ingredient (TGAI)- new manufacturing process, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2475391	2014, Fluopyram (AE C656948) - Description of the manufacturing process of the technical grade active substance, DACO: 2.11.1,2.11.2,2.11.3 CBI

2475392	2014, Fluopyram (AE C656948) - Technical grade active substance - Discussion on the formation of impurities, DACO: 2.11.4 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
2475404	2014, Fluopyram (AE C656948) - Impurities in technical grade active substance - HPLC with external standard, 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 fluopyram - (CBI removed) - external standard, DACO: 2.13.1 CBI
2475408	2013, Determination of (CBI removed) in fluopyram - (CBI removed) - external standard, DACO: 2.13.1 CBI
2475409	2014, Fluopyram - Determination of (CBI removed) in technical grade active substance (CBI removed) - external standard, DACO: 2.13.1 CBI
2475410	2014, Validation of (CBI removed)-method AM024514MP1 - Fluopyram Determination of (CBI removed) in technical grade active substance - (CBI removed), DACO: 2.13.1 CBI
2475412	2001(CBI removed), DACO: 2.13.1
2475413	2012, Analytical method - (CBI removed)- Determination of (CBI removed) on the basis of (CBI removed), DACO: 2.13.1
2475414	2014, Material accountability of technical fluopyram (AE C656948), DACO: 2.13.3 CBI
2475474	2014, Fluopyram Technical Fungicide, containing fluopyram, TGAI -WAIVER REQUEST for DACO 2.13.3 BATCH DATA , DACO: 2.13.3 CBI
2486495	2014, Material accountability of technical fluopyram (AE C656948), 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 2016**

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.