

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2022-4454
Application: Changes to Technical Grade Active Ingredient (Product Chemistry) – New Source (Site) Same Registrant
Product: Technical Fluazinam Fungicide
Registration Number: 27516
Active ingredient (a.i.): Fluazinam
PMRA Document Number: 3504870

Purpose of Application

The purpose of this application was to add an alternate manufacturing site to Technical Fluazinam Fungicide.

Chemistry Assessment

Common Name: fluazinam
 IUPAC* Chemical Name: 3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)pyridin-2-amine
 CAS† Chemical Name: 3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Technical Fluazinam Fungicide has the following properties:

Property	Result								
Colour and physical state	Yellow solid (granular powder)								
Nominal concentration	97.47%								
Odour	Strong musty odour								
Density	1.74 g/mL (20 °C)								
Vapour pressure	2.3×10^{-5} Pa (25 °C)								
pH	6.1–6.2								
Solubility in water	<table style="border: none;"> <tr> <td style="text-align: right;"><u>pH</u></td> <td style="text-align: left;"><u>Solubility (mg/L)</u></td> </tr> <tr> <td style="text-align: right;">5</td> <td style="text-align: left;">0.131</td> </tr> <tr> <td style="text-align: right;">7</td> <td style="text-align: left;">0.157</td> </tr> <tr> <td style="text-align: right;">9</td> <td style="text-align: left;">3.384</td> </tr> </table>	<u>pH</u>	<u>Solubility (mg/L)</u>	5	0.131	7	0.157	9	3.384
	<u>pH</u>	<u>Solubility (mg/L)</u>							
	5	0.131							
	7	0.157							
9	3.384								

Property	Result
n-Octanol/water partition coefficient	log K_{ow} = 4.03 (25 °C)

The required chemistry data for Technical Fluazinam 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 completed an assessment of the information provided, and has found the information acceptable to amend the registration of Technical Fluazinam Fungicide.

Additional Information Being Requested

Since this technical product is manufactured only at pilot scale before registration, five-batch data representing commercial-scale production at the approved manufacturing site will be required as post-market information after registration.

References

PMRA

Document

Number

Reference

3385913	2022, IKF-1216 technical: Five-batch analysis (Source: [PRIVACY INFO REMOVED]), DACO: 2.13.3 CBI
3385914	2016, Spectra: IKF-1216 and the impurities, DACO: 2.13.2,2.13.3 CBI
3389779	2022, Amendment to Final Report 22GT006 IKF-1216 technical: Five-batch analysis (Source: [PRIVACY INFO REMOVED]), DACO: 2.13.3 CBI
3418736	2021, IKF-1216 technical: Method validation, DACO: 2.13.3 CBI
3496839	2023, Batch Data commitment, DACO: 2.13.1

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

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 Health Canada, Ottawa, Ontario K1A 0K9.