



Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2023-1908
Application: Changes to Technical Grade Active Ingredient Product Chemistry-Specifications
Applicant: Nichino America, Inc.
Product: Fenpyroximate Technical
Registration Number: 32244
Active ingredient (a.i.): Fenpyroximate
PMRA Document Number: 3589835

Purpose of Application

The purpose of this application was to update the manufacturing process for Fenpyroximate Technical.

Chemistry Assessment

Common Name: Fenpyroximate

IUPAC* Chemical Name: *tert*-butyl 4-[[[*(E)*-(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylidene]amino]oxy)methyl]benzoate

CAS† Chemical Name: 1,1-dimethylethyl 4-[[[*(E)*-(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene]amino]oxy)methyl]benzoate

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Fenpyroximate Technical has the following properties:

Property	Result
Colour and physical state	Pale yellow solid
Nominal concentration	99.7%
Odour	No distinctive odour
Density	1.237 – 1.257 g/cm ³ at 20°C
Vapour pressure	7.5 x 10 ⁻⁶ Pa at 25°C
pH	5.83 – 6.10

Property	Result	
Solubility in water at 25°C	<u>pH</u>	<u>Solubility (ppb)</u>
	5	21.4
	7	23.1
	9	29.8
n-Octanol/water partition coefficient	log K _{ow} = 5.01	

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

Health Assessment

The toxicological profiles of the new sources of Fenpyroximate Technical are considered to be equivalent to those of the currently registered sources.

Dietary and occupational exposure assessments were not required for this application.

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 has found the information acceptable to support updating the manufacturing process for Fenpyroximate Technical.

References

PMRA Document Number	Reference
3463709	2016, Content analysis of Fenpyroximate Technical [PRIVACY REMOVED], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3463710	2021, Content analysis of Fenpyroximate Technical, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3463711	2020, Batch Analysis of [CBI REMOVED] in Fenpyroximate Technical (Produced at [PRIVACY REMOVED]), DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3463712	2022, Fenpyroximate Technical: Product Chemistry Group A Materials Used, Production Process, Batch Analysis, and Certified Limits, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1 CBI
3463713	2022, Fenpyroximate Technical: Product Chemistry Group A Materials Used, Production Process, Batch Analysis, and Certified Limits, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1 CBI
3479697	2020, Validation of the Analytical Method for [CBI REMOVED] in Fenpyroximate Technical, DACO: 2.13.1 CBI
3479698	2021, Validation of analytical methods for active ingredient and impurities in Fenpyroximate Technical, DACO: 2.13.1 CBI
3584040	2024, Chemistry clarifications for sub. #2023-1908, Reg. #32244, DACO: 2.13.3 CBI

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2024

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.