

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2021-0642
Application: New TGAI Product Chemistry, New Source Same Registrant
Product: Nicosulfuron Technical Herbicide
Registration Number: 23516
Active ingredient (a.i.): Nicosulfuron
PMRA Document Number: 3351844

Purpose of Application

The purpose of this application was to add a new manufacturing site for the technical product, Nicosulfuron Technical Herbicide.

Chemistry Assessment

Common Name: Nicosulfuron
IUPAC* Chemical Name: 2-[[[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl]-*N,N*-dimethylpyridine-3-carboxamide
CAS† Chemical Name: 2-[[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-*N,N*-dimethyl-3-pyridinecarboxamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Nicosulfuron Technical Herbicide has the following properties:

Property	Result
Colour and physical state	white solid
Nominal concentration	93.0 %
Odour	paste-like
Density	0.31 mg/mL
Vapour pressure	1.6×10^{-11} mPa (at 25°C)
pH	4.5
Solubility in water	7.4 g/L

Property	Result
n-Octanol/water partition coefficient	-1.8 (pH 7)

The required chemistry data for Nicosulfuron Technical Herbicide 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 it sufficient to support the addition of the new manufacturing site for Nicosulfuron Technical Herbicide.

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
3326678	2007, DuPont-22798 Confidential, DACO: 2.11 CBI
3200230	2021, Group A - Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method for Nicosulfuron, DACO: 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13, 2.13.1, 2.13.2 CBI
3200233	2021, Group A - Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method for Nicosulfuron, DACO: 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13, 2.13.1, 2.13.2 CBI
3338328	2022, Specification Lier Position Paper - 01Apr22 - sig, DACO: 2.11 CBI

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

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.