

Evaluation Report for Category L, Subcategory 1.1 Application

Application Number: 2022-0218
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
Product: Saflufenacil Technical Herbicide 2
Registration Number: 34872
Active ingredient (a.i.): Saflufenacil
PMRA Document Number: 3449460

Purpose of Application

The purpose of this application was to register Saflufenacil Technical Herbicide2, a new source of the active ingredient saflufenacil, based on a registered precedent product.

Chemistry Assessment

Common Name: Saflufenacil
IUPAC* Chemical Name: 2-chloro-4-fluoro-*N*-[isopropyl(methyl)sulfamoyl]-5-[3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydropyrimidin-1(2*H*)-yl]benzamide
CAS† Chemical Name: 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Saflufenacil Technical Herbicide2 has the following properties:

Property	Result
Colour and physical state	White cream powder
Nominal concentration	97.1%
Odour	No chemical characteristic odour
Density	1.595 g/cm ³ at 20°C
Vapour pressure	< 1 mPa at 20°C
pH	4 – 5

Property	Result	
Solubility in water	<u>pH</u>	<u>Solubility (g/L)</u>
	4	0.014
	5	0.025
	7	2.1
	9	N/A – product degrades
n-Octanol/water partition coefficient	log K _{ow} = 2.6	

The required chemistry data for Saflufenacil Technical Herbicide2 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 support the registration of Saflufenacil Technical Herbicide2.

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
3195235	2020, Chemistry-2.1-2.2, 2.3,2.3.1, 2.12.1, 2.14.5-Saflufenacil TGAI-21dec2020-[Privacy Info Removed], DACO: 2.1,2.14.5,2.2,2.3,2.3.1
3195238	2020, Physical and Chemical Properties of One Batch Saflufenacil TC, DACO: 2.14.1,2.14.13,2.14.2,2.14.3,2.14.4,2.14.9 CBI
3195239	Tompkins, J., 2009, EPA Pesticide Fact Sheet-Saflufenacil, https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-118203_01-Aug-09.pdf , DACO: 2.14.10,2.14.11,2.14.12,2.14.6,2.14.7,2.14.8
3310914	2021, Manufacturing Process and Discussion of Formation of Impurities for Saflufenacil Technical, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.4,2.5,2.6,2.7,2.8,2.9 CBI
3310915	2021, Saflufenacil Technical - Partial Methods Validation and Five Batch Analysis, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3310916	2022, 5 Batches Analysis of Saflufenacil Technical - [CBI Removed], DACO: 2.13.2,2.13.3,2.13.4 CBI
3378005	2020, Saflufenacil Study Report No. K456/LL 000105604, DACO: 2.13.1
3381167	2022, Saflufenacil Study Report No. K631/LL 000109670-2.0, DACO: 2.13.1
3394440	2021, Saflufenacil Technical - Manufacturing Process, DACO: 2.11 CBI
3394441	2022, Determination of [CBI Removed] in Saflufenacil, DACO: 2.13.4 CBI

© 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.