



Special Review Decision

SRD2018-01

Special Review Decision: Fluopicolide and Its Associated End-use Products

Final Decision Document

(publié aussi en français)

25 September 2018

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

ISSN: 2561-6269 (online)

Catalogue number: H113-17/2018-1E (print version)
H113-17/2018-1E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2018

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.

Special Review Decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) conducted a special review of all registered pest control products containing fluopicolide, based on the decision taken by Norway (Rotterdam Convention, 2016) to prohibit the use of such products due to environmental concerns. The PMRA evaluated the aspects of concern that prompted the special review in accordance with the subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2018-03, *Proposed Special Review Decision for Fluopicolide and Its Associated End-use Products*.

No comments were received during the consultation process. The PMRA, under the authority of the *Pest Control Products Act*, is confirming the current registration of pest control products containing fluopicolide in Canada. No additional risk mitigation measures are required; however, label updates are necessary to meet the current PMRA labelling standard for certain environmental precautions (Appendix I).

To comply with this decision, the required label changes must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this document. Registrants of the products containing fluopicolide will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

Please refer to the Regulatory Directive DIR2014-01, *Approach to Special Reviews*, for details of the PMRA's special review approach.

Other Information

Any person may file a notice of objection¹ regarding this decision on fluopicolide within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

¹ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Fluopicolide

1. For all End-Use Products containing fluopicolide:

Replace the existing leaching statement in the section entitled **ENVIRONMENTAL HAZARDS**

“The use of this chemical may result in the contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.”

With the following statement:

“This product demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of [product name] in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.”

And rename the section title **ENVIRONMENTAL HAZARDS** to read:

“ENVIRONMENTAL PRECAUTIONS.”

References

Published Information

PMRA Document Number	Reference
2142356	Canada, 2011, Pest Management Regulatory Agency. Evaluation Report ERC2011-08, <i>Fluopicolide</i> . 21 November 2011.
2821835	Europe, 2009, Conclusion on pesticide peer review regarding the risk assessment of the active substance fluopicolide. European Food Safety Authority. 4 June 2009. <i>EFSA Scientific Report (2009) 299, 1-158</i> . DACO: 12.5
2675620	Europe, 2010, Conclusion on the peer review of the pesticide risk assessment of the active substance dichlobenil. <i>EFSA Journal</i> 2010; 8(8):1705. [68 pp.]. DACO: 12.5
2821836	Hazardous Substances Data Bank (HSDB), 2001, 2,6-Dichlorobenzamide. U.S. National Library of Medicine. https://toxnet.nlm.nih.gov
2821842	Rotterdam Convention, 2016, Rotterdam Convention PIC Circular XLIII. June 2016. DACO: 12.5
2676577	United States, 2008, United States Environmental Protection Agency. 2,6-Dichlorobenzamide (BAM) as a Metabolite of Fluopicolide and Dichlobenil. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration Actions for Fluopicolide on Root Vegetables (Subgroup 1A), Leaves of Root and Tuber Vegetables (Group 2), Bulb Vegetables (Group 3), and Head and Stem Brassica (Subgroup 5A) and Section 3 Registration Actions for Dichlobenil on Rhubarb, Caneberries (Subgroup 13-07A), Bushberries (Subgroup 13-07B) and Associated Berry Commodities. March 19, 2008. DACO: 12.5
2821838	United States, 2013, United States Environmental Protection Agency. Registration Review: Problem Formulation for the Environmental Fate, Ecological Risk, Endangered species and Drinking Water Exposure Assessments for Fluopicolide. March 14, 2013. DACO: 12.5

Additional Information (Groundwater Monitoring)

Published Information

PMRA Document Number	Reference
2702911	Giroux, I., 2016, Portrait de la présence dans l'eau souterraine près de secteurs maraîchers, vergers, vignes et petits fruits – Échantillonnage 2012 à 2014. Ministère du Développement durable, de l'Environnement et de la Lutte contre les changements climatiques, Direction générale du suivi de l'état de l'environnement. ISBN 978-2-550-75639-2, Available: www.mddelcc.gouv.qc.ca/eau/flrivlac/pesticides.htm , DACO: 8.6

Unpublished Information

PMRA Document Number	Reference
2551838	Ministère du Développement durable, de l'Environnement et de la Lutte contre les Changements climatiques, 2015, Unpublished surface water and groundwater monitoring data for dichlobenil and its transformation product 2,6-dichlorobenzamide (BAM), submitted by the Ministère du Développement durable, de l'Environnement et de la Lutte contre les Changements climatiques in response to the PMRA's June 2, 2015 monitoring data request for active ingredients under special review. Data submitted June 3, 2015, DACO: 8.6
2780518	Ministère du Développement durable, de l'Environnement et de la Lutte contre les Changements climatiques, 2017, Unpublished surface water and groundwater monitoring data for BAM from 2000-2016 submitted by the Ministère du Développement durable, de l'Environnement et de la Lutte contre les Changements climatiques in response to the PMRA's June 6, 2017 monitoring data request for active ingredients undergoing re-evaluation or special review, Data submitted June 21, 2017, DACO: 8.6