



Proposed Acceptability for Continuing Registration

PACR2005-03

Re-evaluation of Oxyfluorfen

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated oxyfluorfen. The PMRA has determined that oxyfluorfen is acceptable for continued registration provided that the proposed mitigation measures are adopted. Additional data requirements are identified. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing oxyfluorfen with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for oxyfluorfen. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications at the address below.

(publié aussi en français)

30 June 2005

**This document is published by the Alternative Strategies and Regulatory Affairs Division,
Pest Management Regulatory Agency. For further information, please contact:**

**Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9**

**Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca**

**Information Service:
1 800 267-6315 or (613) 736-3799
Facsimile: (613) 736-3758**

ISBN: 0-662-40909-4 (0-662-40910-8)

Catalogue number: H113-18/2005-3E (H113-18/2005-3E-PDF)

**© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2005**

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.

1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products, that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive [DIR2001-03](#), *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Oxyfluorfen has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of oxyfluorfen and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 2002 RED document for oxyfluorfen. In its re-evaluation of oxyfluorfen, the PMRA based its conclusions on this 2002 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of Oxyfluorfen

Active substance: Oxyfluorfen

Function: Herbicide

Chemical names:

IUPAC: 2-chloro- α,α,α -trifluoro-p-tolyl-3-ethoxy-4-nitrophenyl ether

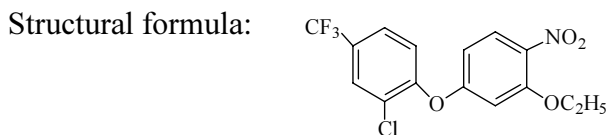
CAS: 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene

Chemical class: Diphenyl ether

CAS number: 42874-03-3

Molecular formula: C₁₅H₁₁ClF₃NO₄

Molecular weight: 361.7



In Canada, oxyfluorfen was first registered in 1985. According to the current end-use product label, it is registered in Canada for the post-emergent control of certain broad-leaved weeds in dry bulb onions and strawberries, as well as for primocane control in raspberries grown in British Columbia. Currently registered Canadian products containing oxyfluorfen are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessments described in the RED document for oxyfluorfen are considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the USEPA RED for oxyfluorfen.

The federal TSMP and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of oxyfluorfen, and it was concluded that oxyfluorfen is not a candidate for Track 1 classification. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive [DIR98-04](#) or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed Re-evaluation Decision

The USEPA published a RED document for oxyfluorfen addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of oxyfluorfen that are also registered in Canada. The PMRA has determined that oxyfluorfen is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are identified in Section 6.0.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision. Registrants of products containing oxyfluorfen should not apply for label amendments or submit the additional data described in Section 6.0 during this comment period; they will be informed by letter of the specific instructions for addressing label changes and data requirements once the re-evaluation decision has been finalized.

4.0 Proposed Regulatory Actions

Canadian end-use product labels should be amended to include the following statements to further protect workers and the environment.

In the PRECAUTIONS section:

- “Wear goggles or a face shield, chemical-resistant gloves, coveralls over a long-sleeved shirt and long pants, chemical-resistant footwear such as rubber boots, and a chemical-resistant apron during mixing, loading, cleanup and repair activities. Applicators must wear chemical-resistant gloves, coveralls over a long-sleeved shirt and long pants, and chemical-resistant footwear such as rubber boots.”
- “Do not re-enter treated areas until 24 hours after application to raspberries or strawberries, and 48 hours after application to onions.”
- “Remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands (or any other skin that came into contact with the product) with soap and water and change into clean clothing.”
- “Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”
- “Remove clothing/personal protective equipment immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing before reuse.”

In the ENVIRONMENTAL HAZARDS section:

- “Observe buffer zones specified under DIRECTIONS FOR USE.”

In the DIRECTIONS FOR USE section:

- “Field sprayer application: **DO NOT** apply during periods of dead calm or when winds are gusty. **DO NOT** apply with spray droplets smaller than the ASAE coarse classification. **DO NOT** apply with a boom height greater than 60 cm above crop canopy.”
- “**DO NOT** apply by air.”

- **“Buffer zones:**
The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, pastures, rangelands and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats.

Method of application	Crop	Buffer zone (metres) required for the protection of:		
		Freshwater habitat	Estuarine/marine habitat	Terrestrial habitat
Field sprayer	Dry bulb onion, raspberry (B.C.)	45	45	30
	Strawberry	25	25	15
Field sprayer with shrouds	Dry bulb onion, raspberry (B.C.)	15	15	10
	Strawberry	8	8	5
Field sprayer with cones	Dry bulb onion, raspberry (B.C.)	30	30	20
	Strawberry	20	20	1

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

5.0 Maximum Residue Limits

Oxyfluorfen is currently registered for use on dry bulb onions, raspberries and strawberries in Canada. The maximum residue limits (MRLs) specified for oxyfluorfen in Table II, Division 15 of the Canadian Food and Drug Regulations (FDR) is 0.05 ppm in strawberries. Residues in other commodities approved for treatment in Canada, i.e., dry

bulb onions and raspberries, must not exceed 0.1 ppm, a general MRL specified in subsection B.15.002(1) of the FDR. Oxyfluorfen may be used on agricultural crops in other countries, and it is noted that the United States has established tolerances for residues of oxyfluorfen on various commodities. Currently, any residues of oxyfluorfen on food imported into Canada must not exceed 0.1 ppm, a general MRL specified in subsection B.15.002(1) of the FDR. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document [DIS2003-01](#), *Revocation of the 0.1 ppm General maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002 (1)]*.

6.0 Additional Data Requirements

The USEPA required additional surface water monitoring data to confirm that acceptable levels were not exceeded. This is also required by the PMRA. The surface water monitoring study required as a condition of reregistration by the USEPA, with the inclusion of a science-based rationale to support the relevance to Canada, may be acceptable. Any existing Canadian drinking water monitoring data are required. The technical registrant of oxyfluorfen will be required to submit these data within 24 months of finalization of the decision document.

The technical registrant of oxyfluorfen will also be required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in prior to the reregistration in the United States and USEPA Data Evaluation Reports (DERs);
- all data (as they relate to the Canadian use pattern) that were required by the USEPA as a condition of reregistration of oxyfluorfen;
- a commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. These are outlined in the PMRA's data code (DACO) tables for Use-site Category # 14 (Terrestrial Food Crops). The registrant is required to address the following sections of DACO tables:
 - for the technical grade active ingredient: DACOs 2 through 9, inclusive
 - for the end-use product: DACOs 5 through 9, inclusive

The above data and additional data may be required sooner if expansion of current uses of oxyfluorfen is requested.

7.0 Supporting Documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or 1 (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3758; E-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document, *Oxyfluorfen*, was published in October 2002 and is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

**Appendix I Products Containing Oxyfluorfen Registered in Canada as
of 31 August 2004**

Product Name	Registrant	Registration Number	Guarantee	Class
Goal* Technical Herbicide 99%	Dow AgroSciences Canada Inc.	27000	99%	Technical
Goal* Technical Manufacturing Herbicide ¹	Dow AgroSciences Canada Inc.	25653	72%	Technical
Goal* 2XL Emulsifiable Concentrate Herbicide	Dow AgroSciences Canada Inc.	24913	248 g/L	Restricted

¹ This product was discontinued on 31 December 2002 and will expire on 31 December 2005.

* Trademark of Dow AgroSciences LLC.