



Proposed Acceptability for Continuing Registration

PACR2004-11

Re-evaluation of 3-trifluoromethyl-4-nitrophenol

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of 3-trifluoromethyl-4-nitrophenol (TFM). The PMRA has determined that TFM is acceptable for continued registration provided that the proposed mitigation measures are adopted.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for TFM. 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 the Publications Coordinator at the address below.

(publié aussi en français)

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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.

TFM 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 that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient itself and its main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of the USEPA review, 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 TFM and concluded that, based on a health and environmental risk assessment, TFM was eligible for reregistration with implementation of mitigation measures. The PMRA conclusions on the TFM re-evaluation were based on the RED document for TFM¹, with consideration of the Canadian use pattern and Canadian issues (e.g., the Canadian Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

¹ The USEPA RED document for TFM and niclosamide (EPA 738-R-99-007, November 1999) is available from the Chemical Status List on the Office of Pesticide Programs webpage at www.epa.gov/pesticides/reregistration/

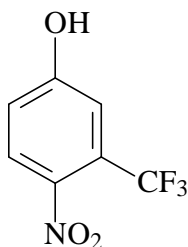
2.0 Re-evaluation of TFM

Chemical names:

IUPAC: 3-trifluoromethyl-4-nitrophenol
CAS: α,α,α -trifluoro-4-nitro-m-cresol, sodium salt

CAS registry number: 88-30-2

Structural formula:



Purity of active: 80% (minimum)

TFM was first registered on a temporary basis in 1970 and is used to control sea lamprey larvae in waters of the Great Lakes basin and the Lake Champlain systems. End-use products containing TFM are classified as restricted and can only be applied by certified applicators of the United States Fish and Wildlife Service (USFWS) and the Department of Fisheries and Oceans in Canada, or persons under their direct supervision, in programs approved by the Great Lakes Fisheries Commission. One technical grade active ingredient and three end-use products are registered in Canada by Clariant Corporation, Kinetic Industries Inc. and the USFWS. These products are listed in Appendix I.

Canadian registered use sites, application rates, application methods and formulation types are also registered in the United States, and the USEPA assessment described in the RED document for TFM and niclosamide are considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and environmental risk assessments conducted by the USEPA are presented in the USEPA RED for TFM and niclosamide.

The federal TSMP² and Regulatory Directive DIR99-03³ were taken into consideration during the review of TFM and TFM is not considered a TSMP Track 1 substance. Given the technical product was reported to contain low levels of PCBs and octachlorodibenzofuran, which have been identified as TSMP Track 1 substances, the registrant of technical TFM is required to submit additional data to allow for review of current levels of these microcontaminants. If levels are found unacceptable, then additional regulatory actions may be recommended.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for TFM, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of TFM that are also registered in Canada. Based on the USEPA RED, and in consideration of the Canadian use pattern, the PMRA has determined that TFM is acceptable for continued registration provided that the mitigation measures specified below are adopted. Additional data requirements are identified in Section 5.0.

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 for these products.

4.0 Proposed regulatory action

The Canadian labels of all TFM end-use products must be amended to include the following statements to protect workers and the environment.

- 1) In the “**Precautions**” section:
 - “Wear a long sleeved shirt, long pants, rubber boots with socks, chemical resistant gloves, a chemical resistant apron or chemical resistant coveralls and a face shield during mixing, loading, application, clean up, repair and other handling activities.”
 - “Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”

² The federal Toxic Substances Management Policy is available through Environment Canada’s website at: www.ec.gc.ca/toxics.

³ *The Pest Management Regulatory Agency’s Strategy for Implementing the Toxic Substances Management Policy*, DIR99-03, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca or through our website at www.hc-sc.gc.ca/pmra-arla

- “Users should 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.”
- “Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”
- “Do not apply this product in a way that will contact workers or other persons, either directly or through drift.”

2) In the “**Environmental Hazards**” section:

- “This chemical is toxic to fish and aquatic invertebrates. Non-target aquatic organisms may be killed at rates recommended on this label.”
- “The directions for use must be strictly followed to minimize hazards to non-target organisms. Do not contaminate water when cleaning equipment or disposing of equipment washwater.”
- “Local and appropriate provincial pesticide regulatory authorities must be consulted about use permits that may be required before product is applied.”
- “Municipalities that use streams requiring treatment as potable water sources must be notified of the impending treatment at least 24 hours prior to application.”
- “Agricultural irrigators that use streams requiring treatment as a source of irrigation water must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators must turn off their irrigation systems during treatment and for a 24 hour period after treatment.”

3) In the “**Directions for Use**” section:

- “Do not apply this product by air.”

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

5.0 Additional data requirements

The registrant of technical TFM is required to submit the following data within 24 months of finalization of the re-evaluation decision:

- All chemistry data required to change the status from temporary to full registration of Lampricide Technical (PCP 25287), Sea Lamprey Larvicide Lampricide (PCP 11763) and Lampricide Sea Lamprey Larvicide (PCP 21124). These will include chemistry data required to review current levels of microcontaminants in the technical source of TFM and chemistry data required to revise the guarantee to a nominal value.
- All data (as they relate to Canadian use pattern) submitted to the USEPA in response to the United States' data call-in prior to the United States reregistration, and the USEPA Data Evaluation Reports (DERs).
- All data (as they relate to Canadian use pattern) that were required by the USEPA as a condition of reregistration of TFM. These include the monitoring study conducted by the USFWS at the time of the USEPA RED publication.
- 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) tables⁴ for Use Site Category (USC) # 2. The relevant sections of the DACO tables that registrants are required to address are as follows:

USC # 2, Aquatic Non-food Sites – TGAI: DACOs 2 through 9, inclusive
USC # 2, Aquatic Non-food Sites – EP: DACOs 5, 8 and 9

Scientific-based rationales to support submitted data waivers may be acceptable. The above data or additional data may be required sooner if expansion of current uses of TFM is requested.

⁴ Use-site category DACO tables can be located at the PMRA website at www.hc-sc.gc.ca/pmra-arla

Appendix I Canadian TFM products currently registered

Product name	Class	Guarantee (% w/w)	Registrant	Registration number
Lamprecid Technical	Restricted	80	Clariant Corporation	25287
Sea Lamprey Larvicide Lamprecid	Restricted	32.5	Clariant Corporation	11763
Lampricide Sea Lamprey Larvicide	Restricted	38	Kinetic Industries Inc.	21124
TFM BAR	Restricted	21.6	USFWS	22610