



Proposed Acceptability for Continuing Registration

PACR2004-19

Re-evaluation of Mitin FF

The purpose of this document is to inform the registrant, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of Mitin FF. PMRA has determined that Mitin FF 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 Mitin FF. 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*, outlines the details of the re-evaluation activities and program structure.

Mitin FF 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 Mitin FF and concluded that, based on the health and environmental risk assessment, it was eligible for reregistration with implementation of mitigation measures. The PMRA conclusions on the Mitin FF re-evaluation were based on the USEPA RED document for Mitin FF¹, with consideration of 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.

¹ The USEPA RED document for Mitin FF 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 Mitin FF

Common name:	Sulcofuron-sodium
Chemical name:	Sodium 5-chloro-2-[4-chloro-2-[[[(3,4-dichlorophenyl)amino]carbonyl]amino]phenoxy]benzenesulfonate
IUPAC name:	Sodium 5-chloro-2-[4-chloro-2-[3-(3,4-dichlorophenyl)ureido]phenoxy]benzenesulfonate
Trade name:	Mitin FF
CAS registry number:	3567-25-7

Mitin FF was first registered in 1954. It is a moth proofing compound used for the treatment of wool. One end-use product is currently registered in Canada and described in Appendix I.

Canadian registered use sites, application rates, application method and formulation type are also registered in the United States; and the USEPA assessment described in the RED document for Mitin FF is 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 outlined in the USEPA RED for Mitin FF.

The federal TSMP² and Regulatory Directive DIR99-03³ were taken into consideration during the re-evaluation of Mitin FF and this active ingredient is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in DIR 98-04 or TSMP Track 1 substances as identified in DIR99-03 Appendix II.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for Mitin FF, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of Mitin FF that are also registered in Canada.. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that Mitin FF is acceptable for continued registration provided that the mitigation

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_info@hc-sc.gc.ca; or through our website at www.hc-sc.gc.ca/pmra-arla

measures specified below are adopted. Additional data requirements are outlined 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 this product.

4.0 Proposed regulatory action

To protect workers and the environment, the label of the Canadian end-use product containing Mitin FF must be modified to include the following statements.

- 1) In the section entitled “Precautions”:
 - “Wear a long-sleeved shirt, long pants and shoes when handling the product.”
 - “Do not apply this product in a way that will contact workers or other persons.”
 - “Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.”
 - “Users should remove clothing 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 separate from other laundry before re-use.”

- 2) In a new section entitled “Environmental Hazards”:
 - “This product is toxic to fish and other aquatic organisms. It is not to be used in circumstances that would cause or allow it to enter lakes, streams, ponds, estuaries, oceans or other waters in contravention of federal or provincial regulatory requirements. The requirements of applicable laws should be determined before using the product.”

The registrant is also required to package the end-use product in water soluble bags.

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

5.0 Data requirements

The registrant of Mitin FF is required to submit the following within 24 months of finalization of the re-evaluation decision:

- an application to register the technical source of the active ingredient for Mitin FF;
- all data (as it relates to Canadian use pattern) submitted to the USEPA in response to the United States data call-in prior to the United States reregistration and USEPA Data Evaluation Reports (DERs); and
- a commitment and schedule to address Canadian-specific data 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) #18. The relevant sections of the DACO tables that the registrant is required to address are as follows:

USC#18, Material – TGAI: DACOs 2 through 9 inclusive

USC#18, Material – EP: DACOs 5, 8, and 9

The above data as well as additional data may be required sooner if expansion of current uses of Mitin FF 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 Registered Canadian product containing Mitin FF
(as of 31 December 2003)**

Product name	Class	Guarantee	Registrant	Registration number
Mitin FF High Concentrate	Commercial	80%	CIBA Specialty Chemicals Corp.	5059