



Proposed Acceptability for Continuing Registration

PACR2003-12

Re-evaluation of (Z)-9-tricosene

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 (Z)-9-tricosene. The PMRA has determined that (Z)-9-tricosene is acceptable for continued registration provided that the proposed mitigation measures are adopted and the data requirements are addressed.

This Proposed Acceptability for Continuing Registration (PACR) provides a rationale for the proposed regulatory decision for (Z)-9-tricosene. 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 General background on re-evaluation

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products that were registered prior to December 31, 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.

(Z)-9-tricosene has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. In Program 1, the PMRA relies as much as possible on foreign reviews to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review which covers the main science areas that are necessary for Canadian regulatory decisions, which addresses the active ingredient itself and its main formulation types registered in Canada, and which is relevant to registered Canadian uses. Based on the outcome of the foreign review, the PMRA will propose, under Program 1, appropriate mitigation measures for Canadian uses of an active ingredient. Program 1 assessments will be used as a starting point for planning and prioritizing future re-evaluation activities for these active ingredients.

The United States Environmental Protection Agency (USEPA) conducted a re-evaluation of the safety of (Z)-9-tricosene by examining related health and environmental effects, and recommending measures to mitigate identified risks. PMRA conclusions on the (Z)-9-tricosene re-evaluation were based on the Re-registration Eligibility Decision (RED) document (USEPA 1994) for (Z)-9-tricosene, with consideration of the Canadian use pattern and Canadian-specific issues (e.g., the Canadian Toxic Substance Management Policy). A review of the chemistry of Canadian products was conducted.

2.0 Re-evaluation of (Z)-9-tricosene

Common name: Muscalure

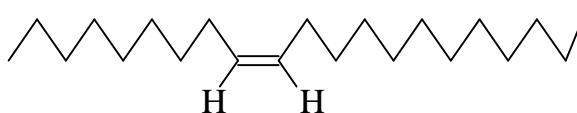
Chemical name:

(IUPAC): (Z)-tricos-9-ene

(CAS): (Z)-9-tricosene

CAS Registry Number: 27519-02-4

Structural Formula:



Purity of active: 86.55% (minimum); 93.48% (nominal)

(Z)-9-tricosene was first registered in 1975. It is a female fly sex pheromone used to attract both female and male house flies and several other fly species to bait, containing either methomyl or azamethiphos insecticide. The granular bait is placed in and around agricultural buildings, feed lots and kennels. One technical and five end-use products are registered in Canada. These products are listed in Appendix I.

Canadian registered use sites, application rates, application methods and formulation types are also registered in the U.S. and the USEPA assessment described in the Re-registration Eligibility Decision (RED)¹ document for (Z)-9-tricosene 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 RED¹ for (Z)-9-tricosene.

The federal Toxic Substances Management Policy (TSMP)² and Regulatory Directive DIR99-03³ were taken into consideration during the review of (Z)-9-tricosene and (Z)-9-tricosene is not a TSMP Track-1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, or TSMP Track-1 substances as identified in DIR99-03 Appendix II.

3.0 Proposed re-evaluation decision

A Re-registration Eligibility Decision (RED) document, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment, was published for (Z)-9-tricosene by the USEPA. This document addressed uses of (Z)-9-tricosene that are also registered in Canada. Based on the review of the USEPA RED, and in consideration of the Canadian use pattern, the PMRA has determined that (Z)-9-tricosene is acceptable for continued registration provided that the mitigation measures specified below are adopted for Canada and the data requirements outlined in this document are addressed. Acceptable uses of (Z)-9-tricosene in Canada are listed in Appendix II. End-use products containing other active ingredients under

¹ The USEPA Re-registration Eligibility Decision (RED) document for (Z)-9-tricosene is available from the Chemical Status List on the Office Of Pesticide Programs Web page at www.epa.gov/pesticides/reregistration.

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

³ The PMRA'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 1-613-736-3799 outside Canada (long distance charges apply); Fax (613) 736-3798; E-Mail pmra_infoserv@hc-sc.gc.ca or through our Web site at www.hc-sc.gc.ca/pmra-arla.

re-evaluation will be accepted for continued registration only when all the affected active ingredients have been determined acceptable for continued registration.

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

Current Canadian labels for products containing (Z)-9-tricosene should be modified as follows:

- For (Z)-9-tricosene technical grade active ingredient (TGAI) product, based on findings by the USEPA:

The statement “z-9-tricosene is not considered to be a skin sensitizer” should be replaced by the signal words “POTENTIAL SKIN SENSITIZER” on the primary panel of the label.

- For all (Z)-9-tricosene end-use products, based on findings by the USEPA, the label should include the following information:

In the **DIRECTIONS FOR USE** section the following must be included:

“When used in areas accessible to birds, bait must be placed in a bait station which prevents birds from consuming the bait.”

- All (Z)-9-tricosene end-use products should include the following statement:

“Wear chemical-resistant gloves during application.”

5.0 Additional data requirements

Registrants of technical (Z)-9-tricosene are required to submit the following within 90 days of finalization of the re-evaluation decision:

- all data (as it relates to Canadian use pattern) submitted to the USEPA in response to the U.S. data call-in prior to the U.S. re-registration, USEPA Data Evaluation Reports (DERs) and all data (as it relates to Canadian use pattern) which was required by the USEPA as a condition for the re-registration of (Z)-9-tricosene.

The registrant of technical (Z)-9-tricosene is required within 90 days of finalization of the re-evaluation decision to submit the following:

- Statement of Product Specification Form (SPSF) in accordance with Table 1 in Section 2.12 of DIR98-04 with the guarantee expressed as the nominal value for the registered TGAI.

The registrant of technical (Z)-9-tricosene is also required to address any additional Canadian-specific data requirements. These consist of all data outlined in Regulatory Proposal PRO2002-02, *Guidelines for Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*⁴, which are not addressed through submission of the data outlined above. Moreover, the registrant of technical (Z)-9-tricosene is required to inform the PMRA of their commitment to address these Canadian-specific requirements by the next round of re-evaluation.

Additional data may be required if expansion of current uses of (Z)-9-tricosene is requested.

⁴ The PMRA's Regulatory Proposal PRO2002-02 is 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) 736-3798; E-mail pmra_infoserv@hc-sc.gc.ca or through our Web site at www.hc-sc.gc.ca/pmra-arla.

Appendix I Canadian (Z)-9-tricosene products currently registered

Product Name	Class	Guarantee	Registrant	Registration Number
Bedoukian (Z)-9-tricosene Technical Pheromone	Technical	86.55%	Bedoukian Research, Inc.	24957
STIMUKIL Fly Bait	Commercial	0.025%	Troy Biosciences Inc.	24969
STARBAR Premium Fly Bait	Commercial	0.025%	Wellmark International	15176
SNIP Fly Bait	Commercial	0.02%	NOVARTIS Animal Health Canada Inc.	25808
BLUE STREAK Fly Bait	Commercial	0.025%	Farnam Companies, Inc.	25358
Apache Fly Bait	Commercial	0.025%	Farnam Companies, Inc.	22303

Appendix II Use standard for commercial class products containing (Z)-9-tricosene

(NOTE: The information in this Appendix summarizes the acceptable uses and precautions for commercial class products containing (Z)-9-tricosene, but does not identify all label requirements for such products. Registrants are referred to the PMRA Registration Handbook for further guidance on label requirements for pest control products.)

COMMON NAME: muscalure

CHEMICAL NAME: (IUPAC): (Z)-tricos-9-ene
 (CAS): (Z)-9-tricosene

FORMULATION TYPE: Granular

USE SITE CATEGORIES: Structural (20)

DIRECTIONS FOR USE:

“When used in areas accessible to birds, bait must be placed in a bait station that prevents birds from consuming the bait.”

PRECAUTIONARY STATEMENTS:

Keep out of reach of children. (Z-9-tricosene/methomyl)

or

Keep out of reach of children, pets, domestic animals and wildlife. (Z-9-tricosene/azamethiphos)

Do not contaminate feed, water, food or litter.

Do not apply where poultry or animals can pick it up or lick the product.

Do not use in homes or where food is processed or stored. (Z-9-tricosene/methomyl)

Use only in areas inaccessible to food-producing animals. (Z-9-tricosene/methomyl)

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Wear chemical-resistant gloves during application.

ENVIRONMENTAL PRECAUTIONS:

Keep out of lakes, streams or ponds.

Do not contaminate water by cleaning of equipment or disposal of wastes.

ACCEPTABLE USES FOR (Z)-9-TRICOSENE:

SITE	PESTS	RATE	APPLICATION
Use Site Category 20, Structural			
Use in and around agricultural buildings such as poultry houses, dairies, stables, hog houses or livestock barns and also feed lots and dog kennels.	House flies and some other fly species.	6.25×10^{-4} g a.i./m ² (products with methomyl) 5.0×10^{-4} g a.i./m ² (product with azimethiphos)	Scatter granular bait or place it in a bait station. When used in areas accessible to birds, bait must be placed in a bait station which prevents birds from consuming the bait. Apply out of reach of domestic animals. Wear chemical-resistant gloves during application