Proposed Acceptability for Continuing Registration

PACR2006-04

Re-evaluation of Di-n-propyl isocinchomeronate

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 di-n-propyl isocinchomeronate (MGD). The PMRA is proposing that MGD is acceptable for continued registration. Additional mitigation measures to further protect human health and the environment are identified in this document. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing MGD with specific direction on how to address these measures.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for MGD. 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)

13 April 2006

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

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ISBN: 0-662-43213-4 (0-662-43214-2)

Catalogue number: H113-18/2006-4E (H113-18/2006-4E-PDF)

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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.

MGD 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 MGD 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 2003 RED document for MGD. In its re-evaluation of MGD, the PMRA based its conclusions on this 2003 RED document taking into account the Canadian use pattern and issues (e.g., the federal Toxic Substances Management Policy). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of Di-n-propyl isocinchomeronate

Active substance: Di-n-propyl isocinchomeronate

Chemical name:

IUPAC: Di-n-propyl isocinchomeronate CAS: Dipropyl 2,5-pyridinedicarboxylate

CAS number: 136-45-8

In Canada, MGD was first registered in 1952. According to current end-use product labels, this active ingredient is registered in Canada for use as insecticide on cattle, horses, ponies and dogs. It is also registered as surface/space spray or fog for use in farm buildings. Canadian products containing MGD are listed in Appendix I.

The Canadian registrant of the technical grade active ingredient has indicated that the use of MGD on cattle and as a surface spray in their quarters as well as a space spray or fog in any farm buildings are no longer being supported in Canada. Therefore, this reevaluation decision is proposed only for the remaining uses of MGD on horses (that are not intended for slaughter), ponies and dogs as well as a surface spray in horse stables and barns.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for MGD is considered to be an adequate basis for the proposed Canadian re-evaluation decision.

The federal Toxic Substances Management Policy and Regulatory Directive <u>DIR99-03</u> were taken into consideration during the review of MGD, and it was concluded that MGD 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 <u>DIR98-04</u> or Toxic Substances Management Policy Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed Re-evaluation Decision

The USEPA published a RED document for MGD addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of MGD that are also registered in Canada. The PMRA is proposing that MGD is acceptable for continued registration with the implementation of the mitigation measures specified in Section 4.0.

It should be noted that for end-use products that contain more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

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 MGD should not apply for label amendments during this comment period; they will be informed by letter of the specific instructions for addressing label changes once the re-evaluation decision has been finalized.

4.0 Proposed Regulatory Actions

Use of MGD on cattle and as a surface spray or fog of their quarters as well as a space spray or fog in any farm buildings are no longer being supported; therefore, these uses must be removed from the relevant product labels.

Canadian end-use product labels must also be amended as follows to further protect human health and environment.

- A "PRECAUTIONS" section must appear on labels of end-use products and must include:
 - For all commercial products:
 - "Do not use on horses intended for slaughter."
 - For all products intended to be used as a surface spray:
 - "Remove animals from quarters before treating premises and ventilate area thoroughly before re-admitting animals."
- On the primary display panel of the labels of products intended to be used as a surface spray, the wording "farm buildings", "barns" or "stables" must be replaced by "horse stables and barns".
- An "ENVIRONMENTAL HAZARD" section must appear on all end-use product labels and must include the following statements:
 - "Toxic to fish. Do not apply this product directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats. Do not contaminate irrigation or drinking water supplies, or aquatic habitats by cleaning of equipment or disposal of wastes."

The registrants must update their product labels in order to meet the requirements of <u>DIR2002-01</u>, Canadian Label Improvement Program for Pesticides Used on Companion Animals, published on 22 February 2002.

Some end-use products labelled for use for horse stables and farms do not have directions for this use; therefore, a complete description of the directions for use, including application rates, must be added to these labels.

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

5.0 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) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca.

The USEPA RED document (<i>Di-n-propyl isocinchomeronate</i>) is available on the Offic of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemic Status.							

Appendix I Products Containing Di-n-propyl isocinchomeronate Registered in Canada as of 1 March 2006

Registrant	Product Name	Registration Number	Guarantee	Class
Air Guard Control (Canada) Ltd	Konk Insecticide ABS Air Spray For Horses	24693	1.2%	Domestic
Can-Vet Animal Health Supplies Ltd	Dairy Fly Shield and Fogging Solution	22606	0.3%	Commercial
Can-Vet Health Supplies Ltd	Can-Vet Equine Fly Shield	22607	0.3%	Commercial
Davis & Lawrence	D&L Fly Kill Spray or Wipe On For Horses	23898	0.15%	Commercial
Farnam Companies Inc.	Roll-on Fly Repellent Insecticide	13438	1%	Domestic
Farnam Companies Inc.	Farnam Wipe Liquid Wipe-on Fly Repellent	10375	1%	Domestic
Farnam Companies Inc.	Swat Fly Repellent Cream For Wounds and Sores	13922	1%	Domestic
Farnam Companies Inc.	Clear Formula Swat Fly Repellent Cream For Wounds and Sores	26403	1%	Domestic
McLaughlin Gormely King Company MGK Repellent 326		18526	99.41%	Technical
Vétoquinol NA. Inc. DISVAP III Insecticide Solution		15967	0.3%	Commercial
Vétoquinol NA. Inc.	Wipe On For Horses	22889	0.3%	Commercial