



# Proposed Acceptability for Continuing Registration

**PACR2004-14**

## **Re-evaluation of 10,10'-oxybis(phenoxarsine)**

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 10,10'-oxybis(phenoxarsine). The PMRA has determined that 10,10'-oxybis(phenoxarsine) is acceptable for continued registration provided that the proposed mitigation measures are adopted and data requirements are addressed.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for 10,10'-oxybis(phenoxarsine). 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)*

**4 June 2004**

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

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

**Internet: [pmra\\_publications@hc-sc.gc.ca](mailto:pmra_publications@hc-sc.gc.ca)  
[www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)**

**Information Service:  
1 800 267-6315 or (613) 736-3799  
Facsimile: (613) 736-3798**



ISBN: 0-662-37342-1 (0-662-37343-X)

Catalogue number: H113-18/2004-14E (H113-18/2004-14E-PDF)

**© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services  
Canada 2004**

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 (EPs), that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03<sup>1</sup>, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

10,10'-oxybis(phenoxarsine) 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 foreign 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 10,10'-oxybis(phenoxarsine) and concluded that, based on the health and environmental risk assessments, 10,10'-oxybis(phenoxarsine) was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 1993 USEPA RED document for 10,10'-oxybis(phenoxarsine)<sup>2</sup>. In its re-evaluation of 10,10'-oxybis(phenoxarsine), the PMRA based its conclusions on this 1993 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]).

---

<sup>1</sup> Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, 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](mailto:pmra_infoserv@hc-sc.gc.ca); or through our website at [www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)

<sup>2</sup> The USEPA RED document for 10,10'-oxybis(phenoxarsine) [*10, 10'-oxybisphenoxarsine (OBPA)*, USEPA 1993] is available from the Chemical Status List on the Office of Pesticide Programs' webpage at [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration)

## 2.0 Re-evaluation of 10,10'-oxybis(phenoxarsine)

Common name: 10,10'-oxybis(phenoxarsine)

CAS number: 58-36-6

10,10'-oxybis(phenoxarsine) was first registered in 1973. In Canada, it is currently registered for use as a material preservative in vinyl manufactured products intended for use indoors (shower curtains, wall coverings, upholstery, etc.) or outdoors (awnings, ditch liners, tarpaulins, etc.). Currently registered products containing 10,10'-oxybis(phenoxarsine) in Canada are listed in Appendix I.

The USEPA assessment described in the RED document for 10,10'-oxybis(phenoxarsine) is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and environmental assessments conducted by the USEPA are presented in the RED document for 10,10'-oxybis(phenoxarsine).

Additional environmental fate data are required to evaluate whether 10,10'-oxybis(phenoxarsine) meets the Track 1 substance criteria that are based on the federal TSMP<sup>3</sup> and Appendix II of Regulatory Directive DIR99-03<sup>4</sup>.

## 3.0 Proposed re-evaluation decision

The USEPA RED document for 10,10'-oxybis(phenoxarsine) addresses the main science areas that are necessary for Canadian regulatory decisions. This document also addressed uses of 10,10'-oxybis(phenoxarsine) registered in Canada. Based on the USEPA RED document and the Canadian use pattern, the PMRA has determined that 10,10'-oxybis(phenoxarsine) is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 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.

---

<sup>3</sup> The federal Toxic Substances Management Policy is available through Environment Canada's website at [www.ec.gc.ca/toxics](http://www.ec.gc.ca/toxics)

<sup>4</sup> Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, 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](mailto:pmra_infoserv@hc-sc.gc.ca); or through our website at [www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)

## 4.0 Proposed regulatory action

Labels of EPs must be updated as follows to protect workers and the environment.

- For all EPs, the following statement must be added in the “**Environmental Hazards**” section:

“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.”

- According to the chemistry information submitted to the PMRA in the past, 10,10'-oxybis(phenoxarsine) may contain arsenic as an impurity from the manufacturing process or may be formed from thermal decomposition of 10,10'-oxybis(phenoxarsine). Therefore, arsenic may be released during the plastic manufacturing process. Based on this, the following statement must be added in the “**Precautions**” section for all EPs:

“Arsenic can be released during the use of this product. It is recommended that this product must not be used in circumstances that would result in arsenic air concentrations in the workplace exceeding the exposure levels established by occupational health and safety authorities in your jurisdiction. If values exceed this level, it is recommended that NIOSH approved respiratory protection be worn.”

- For products with registration numbers 14607, 12320, 15422 and 14516, the following statement must be added in the “**Precautions**” section:

“Wear goggles or a face shield, chemical-resistant gloves, long pants, a long sleeve shirt, shoes and a chemical-resistant apron during mixing/loading, clean up, repair and other handling activities.”

- For the product with registration number 24744, the following statement must be added on the principal display panel:

“To be used only in the manufacture of a pesticide that is registered under the PEST CONTROL PRODUCTS ACT.”

The statement “commercial liquid” must also be replaced by “manufacturing concentrate”.

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

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 this technical grade active ingredient (TGAI), 10,10'-oxybis(phenoxarsine), is required to submit the following within 12 months of finalization of the re-evaluation decision.

1) Additional chemistry data:

For Registration Number 21021,

- DACO 2.13.4—Impurities of Toxicological Concern (including arsenic; they must be specified at any level)
- DACO 2.14.11—Octanol/Water Partition Coefficient

For Registration Number 22141,

- DACO 2.12.2—Statement of Product Specification Form
- DACO 2.13.3—Batch Data, five recent batches to 0.1%
- DACO 2.13.4—Impurities of Toxicological Concern (including arsenic; they must be specified at any level)
- DACO 2.14.11—Octanol/Water Partition Coefficient

2) Data and/or information to characterize potential arsenic exposure of industrial workers handling 10,10'-oxybis(phenoxarsine) treated vinyl products or vinyl coated fabrics, and of consumers in contact with finished products or coated fabrics that have been manufactured using 10,10'-oxybis(phenoxarsine) treated vinyl.

The registrant of 10,10'-oxybis(phenoxarsine) is also required to submit the following within 24 months of finalization of the re-evaluation decision.

- 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 10,10'-oxybis(phenoxarsine); and

- 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<sup>5</sup> for Use-site Category # 18 (Material). The relevant sections of the DACO tables in which registrants are required to address are:

**For the TGAI: DACOs 2 through 9, inclusive**

**For the EP: DACOs 5 through 9, inclusive**

The above data and additional data may be required sooner if expansion of current uses of 10,10'-oxybis(phenoarsine) is requested.

The PMRA is currently undertaking initiatives to address the labelling deficiencies for certain kinds of antimicrobial products, especially with respect to the "Directions for Use" section of the product labels. The PMRA will announce in the near future the nature of these initiatives and any requirements to be addressed by registrants.

---

<sup>5</sup> Use-site category DACO tables are available through the Pest Management Information Service or through the PMRA website at [www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)

## Appendix I      Currently registered 10,10'-oxybis(phenoxarsine) products in Canada (as of 31 March 2004)

Registration number	Product name	Registrant	Guarantee (%)	Class
21021	OBPA for Manufacturing Fungicides & Bactericides	Morton International Inc.	96	Technical
22141	Policida P-4 (A Technical Grade Powder)	AKZO Nobel Functional Chemicals LLC	97	Technical
24744	Vinyzene BP 5-5 DIDP Bacteriostatic & Fungistatic Additive	Morton International Inc.	5	Manufacturing concentrate
14607	Vinyzene SB-1 Granular Bacteriostatic & Fungistatic Additive	Morton International Inc.	5	Commercial
12320	Vinyzene BP-5-2 Bacteriostatic & Fungicstatic Additive	Morton International Inc.	2	Commercial
14516	Vinyzene BP-5-2 DIDP Bacteriostatic & Fungistatic Additive	Morton International Inc.	2	Commercial
15422	Vinyzene BP-5-2 PG Bacteriostatic & Fungistatic Additive	Morton International Inc.	2	Commercial
24747	Intercede ABF-5 DIDP	AKCROS Chemicals America	4.94	Commercial
24748	Intercede ABF-2 DIDP	AKCROS Chemicals America	1.98	Commercial
26929	Intercede ABF-2	AKCROS Chemicals America	2	Commercial