



# Proposed Acceptability for Continuing Registration

PACR2004-09

## Re-evaluation of Silicon Dioxide and Silica Gel

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 silicon dioxide and silica gel. The PMRA has determined that silicon dioxide and silica gel are acceptable for continued registration provided that the proposed mitigation measures are adopted.

This Proposed Acceptability for Continuing Registration (PACR) provides a rationale for the proposed regulatory decision for silicon dioxide and silica gel. 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)*

**28 April 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: 0-662-36932-7 (0-662-36933-5)

Catalogue number: H113-18/2004-9E (H113-18/2004-9E-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, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Silicon dioxide and silica gel have 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 silicon dioxide and silica gel and concluded that, based on the health and environmental risk assessment, silicon dioxide and silica gel were eligible for reregistration with implementation of mitigation measures. The PMRA conclusions on the silicon dioxide and silica gel re-evaluation were based on the USEPA RED document for silicon dioxide and silica gel<sup>1</sup>, with consideration of the Canadian use pattern and Canadian-specific issues (e.g., the Canadian Toxic Substances Management Policy [TSMP]).

---

<sup>1</sup> The USEPA RED document for silicon dioxide and silica gel (USEPA 1995) is available from the Chemical Status List on the Office of Pesticide Programs web page at [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration)

## 2.0 Re-evaluation of silicon dioxide and silica gel

|                    |  |
|--------------------|--|
| Active substances: | Silicon dioxide (from diatomaceous earth)<br>Silica gel  |
| Common names:      | Silica, amorphous, diatomaceous earth<br>Silica gel  |
| CAS numbers:       | Silica, amorphous, diatomaceous earth: 61790-53-2, 7631-86-9,<br>606-86-0<br>Silica gel: 7631-86-9 |

In Canada, silica gel was first registered as a powder in 1977 and silicon dioxide, as a dust in 1980. Silicon dioxide and silica gel are both used as insecticides and acaricides.

Currently registered uses for silicon dioxide include the following:

- commercial indoor (stored products such as grains and seeds, grain and seed storage structures, buildings, institutions such as schools and hospitals, transport containers, food processing plants, manure accumulation areas of poultry barns);
- commercial outdoor (around buildings);
- domestic outdoor (garden areas, home structures, garden fruits and vegetables, flowers); and
- domestic indoor (places in the home where insects crawl and hide, sleeping quarters for pets and their surrounding areas and beds).

Currently registered uses of silica gel include the following:

- commercial indoor (food processing plants and other food-related buildings, institutions such as schools, hospitals and transport containers), and
- domestic indoor (crawling insects' hiding spaces, beds).

As of 31 December 2003, Canadian registered products containing silicon dioxide and silica gel are listed in Appendix I.

The USEPA assessment described in the RED document for silicon dioxide and silica gel 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 presented in the RED for silicon dioxide and silica gel.

The federal TSMP<sup>2</sup> and Regulatory Directive DIR99-03<sup>3</sup> were taken into consideration during the review of silicon dioxide and silica gel. Silicon dioxide and silica gel are not considered TSMP Track 1 substances. The only impurity of toxicological concern is crystalline silica, which is present in some currently registered products (up to 8%).

### 3.0 Proposed re-evaluation decision

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

It should be noted that EPs that contain several active ingredients under re-evaluation will not be considered acceptable for continued registration until the re-evaluation of all active ingredients is complete.

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

Based on the USEPA RED and in consideration of the Canadian use pattern, Canadian EP labels should be amended to include the following statements.

- (1) On the “Front Panel” of all silicon dioxide and silica gel products:
  - “Keep out of reach of children.”

---

<sup>2</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>3</sup> *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](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)

- (2) In the “Precautions” section of all commercial EPs containing silica gel as the sole active ingredient:
- “Wear a suitable dust mask approved by NIOSH/MSHA when handling. For applications to stored grain or when using a dust blower, wear a full-face NIOSH-approved respirator during mixing, loading and application.”
- (3) For commercial EPs containing silicon dioxide:
- (a) For products using a source of silicon dioxide with less than 1% crystalline silica, the following is required:
- In the “Precautions” section,  
  
“Wear a suitable dust mask approved by NIOSH/MSHA when handling. For applications to stored grain or when using a dust blower, wear a full-face NIOSH-approved respirator during mixing, loading and application.”
- (b) For products using a source of silicon dioxide with more than 1% crystalline silica, the following is required:
- In the “Precautions” section,  
  
“Wear a suitable dust mask approved by NIOSH/MSHA when handling. For application to stored grain or when using a dust blower, wear a NIOSH-approved supplied-air respirator (SAR) operated in a pressure-demand or other positive-pressure mode during mixing, loading and application.”

OR

- The technical grade active ingredient (TGAI) must contain less than 1% crystalline silica. The registrants have the option to submit a request to change their source of TGAI to a product containing less than 1%.

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 statements.

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

Registrants of EPs containing silicon dioxide, and which are used for the treatment of fleas, carpet beetles, or bed bugs, are required to use a TGAI source that contains less than 1% crystalline silica. Registrants that currently use a TGAI with crystalline silica content greater than 1% are required to submit a request to switch to an alternate source, or remove these uses from the label. This is required within 24 months of finalization of the re-evaluation decision.

Registrants of all EPs are strongly encouraged to use a source of technical silicon dioxide containing less than 1% crystalline silica. Registrants who continue to use the traditional sources (containing up to 8% crystalline silica) may be required to generate use-specific exposure data by the next round of re-evaluation.

Registrants of EPs that are not associated with a registered TGAI are required to submit a request to register a technical source. This is required within 24 months of finalization of the re-evaluation decision.

## **5.0 Additional data requirements**

The technical registrants of silicon dioxide and silica gel are required within 24 months of finalization of the re-evaluation decision:

- to submit all data (as they relate to Canadian use patterns) 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);
- to prepare and submit a comprehensive summary on the health and safety information for the active ingredient. This summary should be based on a contemporary literature review and any available studies conducted on the active ingredient. It is recommended that the document be organized in accordance with the scientific elements addressed by the Data Codes (DACOs) for toxicology and human exposure.

As per normal practice, the PMRA will accept for review, sound, scientifically based waivers and rationales to address any of the data elements.

The above as well as additional data may be required sooner, if expansion of current uses of silicon dioxide and silica gel is requested.

**Appendix I Canadian silicon dioxide and silica gel products currently registered (as of 31 December 2003)**

| <b>Registrant</b>              | <b>Registration number</b> | <b>Guarantee*</b>                              | <b>Product name</b>                           | <b>Class**</b> |
|--------------------------------|----------------------------|--|---|----------------|
| Aerokure International Inc.    | 25533                      | 92.5% SIO                                      | Celite 209 Technical                          | T              |
| Lomas, L.V. & Co.              | 26410                      | 93% SIO  | Celite 209 Food Grade Technical               | T              |
| Lomas, L.V. & Co.              | 27447                      | 93% SIO  | Kenite Eni                                    | T              |
| Lomas, L.V. & Co.              | 27448                      | 93% SIO  | Diafil 610 Food Grade Technical               | T              |
| Bayer CropScience Inc.         | 20943                      | 100% SIL                                       | Silica Gel Insecticide No. 1                  | T              |
| Degussa Canada Inc.            | 25718                      | 99% SIL  | Sipernat Amorphous Silica Technical           | T              |
| Eagle-Piche Minerals Inc.      | 26195                      | 82% SIO  | Celatom Food Grade Diatomaceous Earth         | T              |
| Western Industrial Clay        | 27264                      | 62% SIO  | Barn Fresh Technical Grade Active Ingredient  | T              |
| Valent Biosciences Corporation | 22419                      | 40% SIL  | Pyrenone & Dri-Die Dust Base Insecticide      | M              |
| Aerokure International Inc.    | 21039                      | 86.7% SIO                                      | Insect Stop - Insect Controller               | C              |
| Natural Insecto Products Inc.  | 22489                      | 90% SIO  | Insecto for Control of Grain Insects          | C              |
| Western Industrial Clay        | 27265                      | 62% SIO  | Barn Fresh Insecticide                        | C              |
| Hedley Technologies Inc.       | 24259                      | 10% SIL, 90% SIO                               | Protect-it Ready-to-use Insecticidal Dust     | C              |
| Hedley Technologies Inc.       | 26194                      | 10% SIL, 90% SIO                               | PI2 Ready-to-use Insecticidal Dust            | C              |
| Bayer CropScience Inc.         | 15255                      | 40% SIL, 1% Pyrethrins, 10% Pyperonyl butoxide | Drione Insecticide Powder                     | C              |
| Scotts Canada Ltd.             | 15899                      | 81.7% SIO, 0.9% Rotenone                       | Bug-B-Gone Pure Solutions Outdoor Insect Dust | D              |



| <b>Registrant</b>           | <b>Registration number</b> | <b>Guarantee*</b>  | <b>Product name</b>   | <b>Class**</b> |
|-----------------------------|----------------------------|--|---|----------------|
| Scotts Canada Ltd.          | 18687                      | 79.5% SIO,<br>0.2% Pyrethrins,<br>1.0% Pyperonyl<br>butoxide | Bug-B-Gone Pure Solutions<br>Indoor/outdoor Insect Dust       | D              |
| Woodstream Canada Corp.     | 19216                      | 80% SIO  | Insectigone Crawling Insect<br>Killer                         | D              |
| Aerokure International Inc. | 21038                      | 100% SIO   | Insect Stop 100% Natural                                      | D              |
| Hedley Technologies Inc.    | 21149                      | 97% SIO  | Insecolo All Purpose Insecticide<br>(Home & Garden)           | D              |
| Woodstream Canada Corp.     | 21340                      | 80% SIO  | Insectigone Cockroach & Ant<br>Killer                         | D              |
| Woodstream Canada Corp.     | 21341                      | 80% SIO  | Insectigone Earwig Killer                                     | D              |
| Woodstream Canada Corp.     | 21342                      | 80% SIO  | Insectigone Ant Killer  | D              |
| Nu-Gro IP Inc.              | 21936                      | 97% SIO  | Greenearth Dio Bug & Slug<br>Killer                           | D              |
| Aerokure International Inc. | 21951                      | 80% SIO  | Insect Stop II (Indoors &<br>Outdoors)                        | D              |
| Aerokure Int'l Inc.         | 21951.02                   | 80% SIO  | Stop Insect Insect Controller                                 | D              |
| Hedley Technologies Inc.    | 22870                      | 97% SIO  | Insecolo Flea Control   | D              |
| Wilson Laboratories Inc.    | 23329                      | 97% SIO  | C-I-L Mother Earth<br>Indoor/outdoor Insect Dust              | D              |
| Watkins Inc.                | 24921                      | 97% SIO  | Watkins Multi-purpose Insect<br>Control                       | D              |
| Nu-Gro IP Inc.              | 25366                      | 97% SIO  | C-I-L Mother Earth Ant &<br>Roach Killer                      | D              |
| Aerokure International Inc. | 25596                      | 100% SIO   | Indoor & Outdoor Insect Stop<br>Cockroach & Ant Killer        | D              |
| Aerokure International Inc. | 25597                      | 100% SIO   | Indoor & Outdoor Insect Stop<br>Silverfish & Cockroach Killer | D              |
| Aerokure International Inc. | 25598                      | 100% SIO   | Indoor & Outdoor Insect Stop<br>Earwig Killer                 | D              |
| Aerokure International Inc. | 25599                      | 100% SIO   | Indoor & Outdoor Insect Stop<br>Ant Killer                    | D              |

| <b>Registrant</b>        | <b>Registration number</b> | <b>Guarantee*</b>                                    | <b>Product name</b>                    | <b>Class**</b> |
|--------------------------|----------------------------|--|--|----------------|
| Nu-Gro IP Inc.           | 25801                      | 97% SIO  | CIL Mother Earth Slug Dust             | D              |
| Nu-Gro IP Inc.           | 26622                      | 97% SIO  | Green Earth Indoor/outdoor Insect Dust | D              |
| Nu-Gro IP Inc.           | 26679                      | 97% SIO  | Green Earth Ant & Roach Insect Dust    | D              |
| S.C. Johnson & Son, Ltd. | 27185                      | 97% SIO  | Raid Earthblends Ant & Earwig Dust     | D              |
| Bayer CropScience Inc.   | 14431                      | 40% SIL,<br>1% Pyrethrins,<br>10% Pyperonyl butoxide | Drione Insecticide Powder              | D              |

\*SIO = silicon dioxide; SIL = silica gel

\*\*T = Technical; M = Manufacturing; C = Commercial; D = Domestic