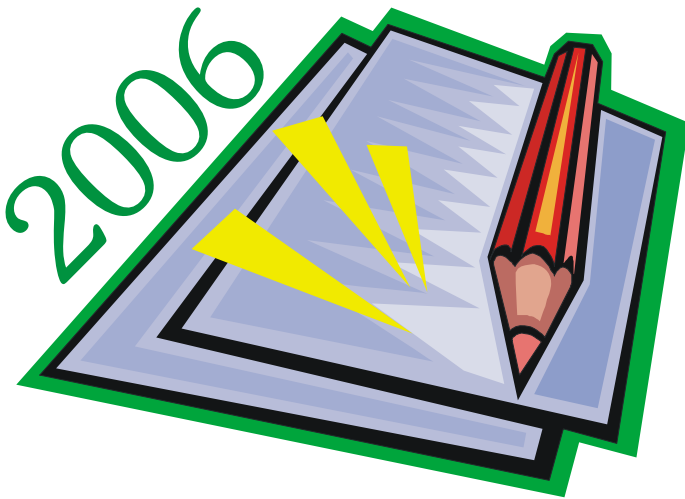




**Registration Renewal for
Pest Control Products
Registered Under the
*Pest Control Products Act***



Health Canada Santé Canada

Canada

General Inquiries

General inquiries regarding the registration renewal or discontinuation process should be directed to the Pest Management Information Service at 1 800 267-6315 or 613 736-3799.

www.pmra-arla.gc.ca
pmra_infoserv@hc-sc.gc.ca

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Notice of Pending Expiry of Registration

This package serves as notice that the registration of one or more of the products registered to you under the *Pest Control Products Act* will expire on 31 December of this year. The enclosed report, List of Products Subject to Renewal, indicates which products are affected at the time of publication¹.

The Pest Management Regulatory Agency (PMRA) must be advised via an Application for Registration Renewal (Form 6000) whether the registrant intends to renew or discontinue the registration of a product.

Amendments to a product label or a Statement of Product Specification Form are not permitted at renewal, except standard updates such as notifiable/non-notifiable amendments (i.e., in Regulatory Directive DIR2001-04, *Notification/Non-notification* or those identified in DIR2006-02, *Formulants Policy*). Registrants will be informed of any unacceptable amendments, **and the product may be refused renewal.**

Failure to respond to this notice will result in expiry of the registration of the products listed in the enclosed report, effective 31 December of this year. The affected products will be assigned a “not eligible for renewal” regulatory status, thereby rendering the manufacture, import, sale and use of these products an offense under the *Pest Control Products Act*.

For those products whose registration is administered by a regulatory representative, please forward this package to the representative.

There may be regulatory action taken prior to December 2006 that could make a product ineligible for renewal (e.g., re-evaluation decision).

¹ Only those products subject to renewal at the end of this calendar year will appear on the report.

REMINDERS

- Upon receipt of an application to renew a product registration, an interim renewal to 31 March of the following calendar year will be granted to allow legal sale and use of the product while the PMRA completes processing of the renewal application. Any product(s) for which an application to renew the registration has not been received by the PMRA by 31 December of the renewal year will be deemed “not eligible for renewal”.
- Form 6000 has been revised to collect registrant’s contact information in a manner more reflective of the PMRA database tracking system and in preparation for the coming into force of the new *Pest Control Products Act* and Regulations.
- Labelling requirements: Applicants must submit an electronic copy of the most recently approved bilingual label text (as separate English and French files) in PDF normal (portable document format). Guidance on the formatting of files to PDF is provided on the enclosed Guidance on Label Requirements for PMRA Registered Product Renewal. The registration renewal will be based on the acceptability of the electronic label text.

Applicants must also submit two hard copies of the product marketplace label, i.e., the label that is found on the actual product container in the marketplace. The marketplace label will be used to verify label integrity, e.g., label presentation, symbols and graphics. It is recognized that the marketplace label text may not be identical to the most recently approved label text e.g., recent approvals that may not yet be reflected in the marketplace label text. However, it is the registrant’s responsibility to ensure that the marketplace label text complies with the most recently approved label text whereby

the text of the marketplace label does not extend beyond that of the most recently approved label text. **NOTE:** Marketplace labels are not required if a product is not currently marketed. Please indicate whether the product is marketed or not in Box 8 of Form 6000.

- In an effort to ensure that the most up-to-date information is available regarding technical grade active ingredients and their site of manufacture, the PMRA is requiring that registrants submit a completed Technical Grade Active Ingredient (TGAI) Site of Manufacture Information—Renewal form.
NOTE: This form is only required to accompany TGAI product renewal applications. Do not submit it for other products.
- A Quality Assurance Renewal Checklist has been developed to assist applicants in ensuring that certain items, sometimes overlooked in completing the renewal application, are addressed. The items on the checklist identify issues that the PMRA has historically noted as frequently requiring clarification. Addressing these items prior to submitting the renewal application will minimize the requirement for clarification and assist in timely product renewal.

RENEWAL PACKAGE CONTENTS

This package contains the following documents necessary for completion of the registration renewal application:

- A report of affected products: List of Products Subject to Renewal
- Notice of Pending Expiry of Registration of Pest Control Products
- The booklet *Registration Renewal for Pest Control Products Registered Under the Pest Control Products Act*

- Guidance on Label Requirements for PMRA Registered Product Renewal
- Other guidance may have been included in your package at the time of mailing.

NOTE: Paper forms have not been included in this year's renewal package. The renewal package and the official copy of all required forms is available on the PMRA's website at:

www.pmra-arla.gc.ca/english/appregis/renewal-e.html.

Transfer of Ownership

The List of Products Subject to Renewal included in this renewal package reflects those recorded on the PMRA's product register on the date of issue. If a transfer of ownership of the product's registration has been initiated but is not yet complete, i.e., the new registrant is not recorded on the PMRA's product register, the onus to renew the registration remains with the registrant recorded on the PMRA's product register. The PMRA urges interaction between parties involved in the transfer of ownership to ensure that the registration of any affected product does not lapse.

Initial and Private Label Products

Initial product registrants are responsible for renewing the registration of the initial product **and** any private label products associated with the initial product. The registration of private label products is dependent on the continued registration of the initial product. Therefore, initial product registrants must inform the private label product registrants of their decision to renew or discontinue the registration of the product. Furthermore, initial product registrants must ascertain whether the private label registrant intends to renew or discontinue the registration of the private label product and inform the PMRA of such a decision. The requirements and conditions for renewing initial product and

private label registrations are set out in Renewing a Product's Registration and Discontinuing the Registration of a Control Product, below. Note that each initial and private label product is processed as an individual product for the purposes of renewal; therefore, a renewal fee of C\$154 will be applied to each product.

Renewing a Product's Registration

The following steps must be completed to apply for **renewal** of a product's registration:

- Verify the accuracy of the information contained in the List of Products Subject to Renewal included in the renewal package mailed to you, and report any discrepancies **immediately** to the Pest Management Information Service at 1 800 267-6315.
- For each product being renewed, complete and return a renewal application that comprises:
 - Form 6000: Application for Registration Renewal Form
 - Form 6011: Fee Form
 - A renewal fee of C\$154
 - Form 6003: Statement of Product Specification (separate forms for each formulation).
 - Two hard copies of the marketplace label. For products with multiple container sizes, only the label components from one size of container are required.
 - An electronic copy of the most recently approved bilingual label text (as separate English and French text files) in PDF normal (portable document format). (See enclosed Guidance on Label Requirements for PMRA Registered Product Renewal.)
 - Form 6116: Technical Grade Active Ingredient (TGAI) Site of Manufacture Information—Renewal (ONLY required to be submitted with TGAI product renewals.)

Submit your Renewal Applications in Electronic Format

Registrants are encouraged to prepare and submit their renewal applications in electronic format. In addition to reducing paper, the electronic format allows the PMRA to efficiently manage the renewal applications once received. For information on preparing and submitting renewal applications in electronic format, please refer to the enclosed guidance Submitting Renewal Applications in Electronic Format.

Registrants are requested to submit applications for registration renewal as soon as possible to allow for the smooth processing of the expected 1600 renewal submissions.

To ensure ongoing registration status for your products, all applications are to be received by **15 September 2006**. Applications may be submitted by mail or courier to:

Health Canada
Pest Management Regulatory Agency
RENEWAL 2006
2720 Riverside Drive
Ottawa ON K1A 0K9
CANADA

During the review of the renewal process, minor clarification may be required of the registrant and will be done by telephone, facsimile or e-mail. If an acceptable reply is received within the time frame identified to the applicant (up to 10 calendar days), the renewal process will continue. If an acceptable reply to a request for clarification is **not** received within the allotted time frame, the renewal application will be withdrawn and the product registration will expire.

Discontinuing the Registration of a Control Product via the Renewal Process

The following step must be completed to apply for **discontinuation** of a product's registration:

- Complete and return the enclosed Form 6000, ensuring that section 9 is completed. (A label, fee, or statement of product specification form are not required)

Registrants will be informed in writing once the application to discontinue has been processed.

Registration Expiry

Failure to respond to this notice will result in the expiry of the registration of the products listed on the enclosed List of Products Subject to Renewal report, effective 31 December of this year. The affected products will be assigned a “not eligible for renewal” regulatory status, thereby immediately rendering the manufacture, import, sale and use of these products an offense under the *Pest Control Products Act*.

A lapsed product registration may be reinstated administratively, provided an application to reinstate the registration is received by the PMRA within one year of the 31 December expiry date. Reinstatement submissions will be classified as Category C submissions with respective timelines.

For further information, please contact the Pest Management Information Service at 1 800 267-6315.

DEADLINE FOR RENEWAL APPLICATIONS

To ensure ongoing registration status for your products, all applications are to be received by **15 September 2006**.

Applications may be submitted by mail or courier to:

Health Canada
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RENEWAL 2006
2720 Riverside Drive
Ottawa ON K1A 0K9
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