Proposed Acceptability for Continuing Registration

PACR2004-30

Re-evaluation of Lithium Hypochlorite

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 lithium hypochlorite. The PMRA has determined that lithium hypochlorite is acceptable for continued registration. Additional data requirements are identified.

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

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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 <u>DIR2001-03</u>, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Lithium hypochlorite has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in <u>DIR2001-03</u>. 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.

The USEPA conducted a re-evaluation of lithium hypochlorite and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration. These conclusions were published in a 1993 RED document for lithium hypochlorite. In its re-evaluation of lithium hypochlorite, 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]). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of lithium hypochlorite

Active substance: Lithium hypochlorite Chemical name: Lithium hypochlorite

CAS number: 13840-33-0

In Canada, lithium hypochlorite was first registered in 1978. It is registered as a technical grade active ingredient (Pest Control Product Number 23738) and is used in "scheduled" swimming pool and spa products. A "scheduled" product is exempt from registration as per Section 5(1)(c) of the Pest Control Products Regulations, provided that all applicable conditions are met as set out in Schedule II of the Regulations. Information on scheduled pool and spa chemicals can be found in the Regulatory Directive <u>DIR93-05</u>, *Scheduling of Selected Pool and Spa Chemicals*.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for lithium hypochlorite is considered to be an adequate

basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the USEPA RED for lithium hypochlorite.

The federal TSMP and Regulatory Directive <u>DIR99-03</u> were taken into consideration during the review of lithium hypochlorite, and it was concluded that lithium hypochlorite is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive <u>DIR98-04</u> or TSMP Track 1 substances as identified in Appendix II of <u>DIR99-03</u>.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for lithium hypochlorite addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of lithium hypochlorite that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that lithium hypochlorite is acceptable for continued registration. Additional data requirements are identified in Section 4.0.

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.

4.0 Additional data requirements

The technical registrant of lithium hypochlorite is required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in prior to the reregistration in the United States and USEPA Data Evaluation Reports (DERs);
- 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 for Use-site Category (USC) # 29. The registrant is required to address the following sections of DACO tables:
 - for the TGAI: DACOs 2 and 4
 - for the EP: DACO 5

The above data and additional data may be required sooner if expansion of current uses of lithium hypochlorite is requested.

5.0 Supporting documentation

PMRA documents, such as <u>DIR2001-03</u>, <u>DIR93-05</u> and DACO tables, can be found on our website at <u>www.hc-sc.gc.ca/pmra-arla</u>. 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: <u>pmra_infoserv@hc-sc.gc.ca</u>.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document (*Lithium Hypochlorite*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.