



Re-evaluation Note

REV2001-01

Discontinuation of the Organophosphate Insecticide Methidathion

Methidathion is one of the 27 organophosphate pesticides to be re-evaluated by the Pest Management Regulatory Agency (PMRA), as announced on June 29, 1999, in the Agency's publication REV99-01, *Re-evaluation of Organophosphate Pesticides*.

The purpose of this regulatory note is to notify registrants, pesticide regulatory officials, and the Canadian public that, as of January 23, 1998, the registrant, Novartis, discontinued the sale of products containing methidathion in Canada. Sale at the retail level ended January 23, 1999. Registration of methidathion end-use product will continue until December 31, 2002, to allow for the legal use of any product that may still be in the hands of users. The year 2000 use season was the last year for any significant use of this pesticide in Canada. Information on the phase-out of the sale and use of this pesticide in Canada and the possible need for maximum residue limits (MRLs) to accommodate imports is provided in this note.

Methidathion has been used in Canada as a foliar spray insecticide on the following crops:

canola, mustard, sunflower, alfalfa, apple, blueberry, cherry and potato.

In the U.S., registration of methidathion is being supported by the registrants, Novartis and the Gowan company. Registration appears likely to continue in the U.S. for commodities that are imported into Canada, e.g. citrus, pome fruit and stone fruit.

(publié aussi en français)

October 19, 2001

**This document is published by the Submission Coordination and Documentation Division,
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ISBN: 0-662-31037-3

Catalogue number: H113-5/2001-1E-IN

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1.0 Re-evaluation of organophosphate pesticides

Uses of organophosphate (OP) pesticide products, which are mainly insecticides, include a broad range of use-site categories, such as forests and woodlands, greenhouse food and nonfood crops, livestock, seed treatments, oilseed and fibre crops, stored food and feed, terrestrial feed and food crops, structural uses, outdoor ornamentals and indoor plants, plant scapes and turf.

The re-evaluation of organophosphate pesticides was announced on June 29, 1999, in REV99-01. Under the re-evaluation program, the PMRA uses a modern scientific approach to re-examine older active ingredients and their end-use products to determine their continuing acceptability in relation to human health and the environment.

2.0 Discontinued uses of methidathion

Methidathion (*S*-2,3-dihydro-5-methoxy-2-oxo-1,3,4-triazol-3-ylmethyl-*O,O*-dimethyl phosphorodithionate) has been registered as a foliar spray as Commercial Class products, for the following pest-crop combinations:

flea beetle and red turnip beetle in canola and mustard;

sunflower beetle, sunflower moth, sunflower maggot and painted lady bug in sunflower;

alfalfa weevil, leafhoppers, lygus bug, pea aphid and alfalfa blotch leaf miner in alfalfa (pure or mixed stands);

apple aphid, apple brown bug, European fruit scale, fruittree leafroller, oystershell bug in apple;

blueberry thrips in blueberry;

cherry leafroller in cherry;

Colorado potato beetle, flea beetle, potato leafhopper, and tarnished plant bug in potato.

There is no Domestic Class product containing methidathion registered in Canada.

All uses of methidathion have been discontinued.

3.0 Alternatives for methidathion

The alternative products registered for methidathion uses include other organophosphates, several carbamates and pyrethroids, methoxychlor, imidacloprid, *Bacillus thuringiensis*, mineral oil and insecticidal soap.

4.0 Extent of use and usage

The *Survey of Organophosphate Uses in Canada* conducted in 1998 indicated little use of methidathion on crop-pest combinations for which the product has been registered. Some of the highlights of the reported use of methidathion in Canada are as follows:

- Methidathion was cited as having marginal uses for control of pests in most of the crops listed on the label.
- The only significant use of methidathion appeared to be for sunflowers.

5.0 U.S. Environmental Protection Agency status of methidathion

Registrants in the U.S. (Novartis Crop Protection Inc. and the Gowan company) are supporting continued use of methidathion in the U.S. According to a *Methidathion Summary* published December 8, 1999, by the Environmental Protection Agency (EPA), methidathion is used in the U.S. on a variety of nuts, citrus, stone and pome fruit crops, artichokes, olives, cotton, alfalfa (grown for seed), safflower, etc. The U.S. summary document indicated that the estimated dietary, drinking water, and aggregate risks were found by the EPA to be low for the U.S. uses. Risks to workers were considered high. Mitigation measures, identified in the *Methidathion Summary* for workers, include increased personal protective equipment or engineering controls. Risks to the environment were also considered high.

6.0 The PMRA's regulatory position

6.1 Registration

As of January 23, 1998, the registrant, Novartis, discontinued the sale of products containing methidathion in Canada. Retail sale of these products ceased on January 23, 1999. Use of the products is to end on December 31, 2002, when the registrations will be cancelled.

The products affected in Canada are:

Methidathion Technical Agricultural Insecticide (Registration No. 22800) and Supracide 240 EC (Registration No. 18550).

6.2 MRLs

The following are the current Canadian MRLs:

Table II, Division 15, Food and Drug Regulations

Chemical	MRL	Foods
methidathion	2.0	citrus fruits
	0.5	apples, pears
	0.2	cherries, grapes, peaches, plums

A reassessment of the definition of the residue of concern (ROC), based on plant and metabolism studies, indicates that the ROC should be defined as methidathion for plant commodities and, for animal commodities, redefined from methidathion to methidathion, methidathion oxon, methidathion sulfoxide, and methidathion sulfone. This ROC could be harmonized with that used in the U.S. by the EPA and the U.S. Food and Drug Administration. This change in the ROC will be communicated to the Canadian Food Inspection Agency (Agriculture and Agri-Food Canada) to ensure the monitoring for these residues in imported foods.

As indicated, the registrant of technical grade methidathion has voluntarily discontinued sale of the product in Canada and indicated that they have no further interest in providing data in support of this pesticide in Canada. The PMRA therefore has no plans to schedule this pesticide for an updated risk assessment under the re-evaluation program.

The *Food and Drugs Act* prohibits the sale of food containing pesticide residues at levels in excess of the MRLs established in the Regulations under that Act. The decision to establish, maintain or modify an MRL must be based on an assessment of information that is sufficient to determine the safety of the permitted level of residues.

Because methidathion is not being scheduled for an updated risk assessment, the PMRA will recommend the revocation of all methidathion MRLs established in Table II, Division 15 of the Food and Drug Regulations, including those that were originally established to cover both domestic uses and imports, and those that were established to cover imports only.

The PMRA will consider requests to modify or maintain the MRLs established for methidathion to cover imports from other countries. Interested parties should petition the PMRA for the establishment of MRLs to cover residues (ROCs) in treated imported raw agricultural commodities and their processed products. The interested party may identify or provide existing domestic or foreign data and the PMRA will determine whether they are sufficient.

In cases such as this, where there is no remaining domestic use for the product and there is interest in import MRLs, the toxicology data would be reviewed (as per the process currently in place, i.e. a peer review of the EPA and other international data evaluations where available and suitable). Any necessary use information, and chemistry and residue data would also be reviewed. The PMRA may request additional data. Data requirements will be similar to those for establishing a MRL to cover domestic use of the pesticide (see Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*).

The PMRA is also considering adopting the proposals that the EPA has under consideration for import tolerances that are outlined in their document entitled *Pesticides: Guidance on Pesticide Import Tolerances and Residue Data for Imported Food; Request for Comment* (Federal Register, Vol. 65, No. 106, Thursday, June 1, 2000). These proposals include a possible reduction to the standard data requirements, depending on the conditions described.

6.3 Conclusion of Re-evaluation

The decisions and actions outlined in this Re-evaluation Note conclude the re-evaluation of methidathion by the PMRA.