Consumer Product Safety

Proposed Re-evaluation Decision PRVD2010-18 Malathion

Notice to the reader: The online consultation is now closed. Comments and suggestions received during the public consultation period are being considered in the finalization of this document. The final report will be made available as soon as possible.

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This page is a summary of the consultation document. If you would like to comment, please request the full consultation document.

To obtain a full copy of Proposed Re-evaluation Decision PRVD2010-18, *Malathion*, please contact our publications office.

Should you require further information please contact the Pest Management Information Service.

Summary

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Proposed Re-evaluation Decision for Malathion

After a thorough re-evaluation of the insecticide malathion, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing continued registration of products containing malathion for sale and use in Canada. An evaluation of available scientific information found that, under the proposed conditions of use:

- Most uses of malathion products have value in Canada and do not pose unacceptable risks to human health or the environment, that is, commercial products applied in agricultural (such as food and non-food crops in greenhouse or fields, livestock for food) and non-agricultural settings (such as structural, human habitat and recreational areas), other than those noted below. As a condition of the continued registration for these malathion uses, new risk reduction measures are proposed. Additional data are being requested.

- Some uses of malathion are proposed for phase-out because they are not supported by the technical registrant. These uses were not included in the risk assessment:
    - Aquatic non-food sites: mosquito breeding areas and standing water;
    - Greenhouse food crops: mushroom beds and houses (wettable powder and dust formulations and application method of painting on wooden surfaces);
    - Greenhouse non-food crops: carnation, chrysanthemum, geranium, rose, snap dragon and ornamental plants (wettable powder formulation and fogging application method);
    - Seed treatments food and feed and seed treatment non-food: seeds (field and garden);
    - Terrestrial feed crops: ground ULV for alfalfa;
    - Structural: bakeries, canneries, meat processing plants, barns, pig pens, outbuildings, dairies, dairy barns, dwelling foundations (indoor), farm buildings (indoor), food processing plants, poultry houses and shipping crates;
    - Human habitat and recreational areas: farm yards, pens, feedlots, pastures, stabling areas, manure piles, garbage areas and around buildings and undergrowth to control house fly, mosquitoes, stable fly, and small flying insects as a space spray, mist, fog, aerosol and ground ULV;
    - Municipal dumps, refuse areas, sewage lines; and
    - Residential outdoors: yards.

The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment. In 1999, Health Canada announced in Re-evaluation Note REV99-01, *Re-evaluation of Organophosphate Pesticides*, that 27 organophosphate active ingredients, including malathion, would be re-evaluated in Canada. This re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

In 2003, the PMRA published a proposed re-evaluation consultation document (PACR2003-10) for malathion use as an adulticide in mosquito abatement programs, and followed with a document (REV2003-03) which described the mitigation measures to be implemented for malathion use as an adultcide. The required label changes for related end-use products have been implemented as described in REV2003-03. The PMRA received comments following the release of PACR2003-10. These comments were considered and the PMRA's response to these comments are summarized in Appendix XXIII of Proposed Re-evaluation Decision PRVD2010-18, *Malathion*.

The technical registrant of malathion in Canada, Cheminova Inc., has voluntarily discontinued a number of residential uses including structural (pet quarters, indoor uses); companion animals (pet treatment); turf (broadcast turf/lawn treatment); and residential outdoors (broadcast/turf lawn treatment). The changes to the related product labels have been completed.

The technical registrant of malathion in Canada, Cheminova Inc., has voluntarily discontinued a number of residential uses including structural (pet quarters, indoor uses); companion animals (pet treatment); turf (broadcast turf/lawn treatment); and residential outdoors (broadcast/turf lawn treatment). The changes to the related product labels have been completed.

As discussed in Proposed Re-evaluation Decision PRVD2010-18, *Malathion*, the PMRA has completed the risk and value assessments for malathion on the remaining food and non-food uses. All relevant end-use products containing malathion registered in Canada are affected by this proposal. Once

the final re-evaluation decision is made, registrants will be instructed on how to address any new requirements.

Proposed Re-evaluation Decision PRVD2010-18, *Malathion* is a consultation document that summarizes the science evaluation for malathion and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information in Proposed Re-evaluation Decision PRVD2010-18, *Malathion* is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessment of malathion.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of Proposed Re-evaluation Decision PRVD2010-18, *Malathion*. Please forward all comments to Publications.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration. The Act also requires that products have value when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information, please refer to the following:

- Protecting Your Health and the Environment
- Pesticide Registration Process
- Pesticide Risk Reduction Program

Before making a re-evaluation decision on malathion, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision on malathion, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this summary, please refer to the Science Evaluation section of Proposed Re-evaluation Decision PRVD2010-18, *Malathion*.

What is Malathion?

Malathion is a group 1B Resistance Management Mode of Action (MoA) non-systemic, broad-spectrum organophosphate insecticide and acaricide. It disrupts nervous system function by inhibiting the acetylcholinesterase enzyme. It is used to control a broad range of insect pests on a wide variety of sites including: aquatic non-food sites; empty food storage areas; greenhouse (food and non-food crops); human habitat and recreational areas; industrial oilseed and fibre crops; livestock for food; seed treatment; stored food and feed; structural sites; terrestrial feed and food crops; outdoor ornamentals; and residential outdoor sites.

It is applied using conventional ground and aerial application equipment by farmers, farm workers,

professional applicators and the general public.

Health Considerations

Can Approved Uses of Malathion Affect Human Health?

Additional risk-reduction measures are required on malathion labels. Malathion is unlikely to affect your health when used according to the revised label directions.

Potential exposure to malathion may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when malathion products are used according to label directions.

The target for malathion is the nervous system including effects on neurobehavioural parameters and acetylcholinesterase, an enzyme necessary for normal functioning of the nervous system. Overexposure may produce a variety of symptoms in animals and humans including nausea, dizziness, sweating, salivation, runny nose and watery eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. Cholinesterase inhibition has been observed with oral, dermal and inhalation exposure. Young animals have been shown to be more sensitive to this effect of malathion.

Malathion was not found to be genotoxic or teratogenic. Based on the scientific evidence, malathion is unlikely to pose a carcinogenic risk for humans. Following administration to pregnant rabbits, an increase in resorptions (embryo-fetal loss) has been observed in the presence of maternal toxicity. Due to the nature of this endpoint and its potential implications on the health of the unborn child, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to malathion. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

In its evaluation of risk from the exposure of malathion and malaoxon, the PMRA has adopted protective and conservative estimates of residues to compensate for the high potency factor of the malaoxon metabolite in food and water and for data gaps. In particular, the PMRA has compensated for malaoxon residues that were, for the most part, below analytical detection.

The PMRA has also considered the special case of exposure arising from on-site consumption during Pick-Your-Own operations.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Acute dietary risk for children and infants was the highest and reached 101% of reference dose,

but is considered below the level of concern due to the conservative assumptions. Chronic risk for children reached 66% of reference dose and is not of concern.

Dietary exposure from Pick-Your-Own operations were estimated by adding the acute exposure from all forms of fresh fruit to the chronic exposure, in this case, apple and strawberry. Calculated MOEs exceed the target MOE for all sub-populations, and are not of concern.

Overall, the PMRA has concluded that risk to health from dietary residues is not of concern.

Risks in Residential and Other Non-Occupational Environments

Residential risks from the use of malathion on vegetable gardens, ornamentals, and in mosquito abatement programs are not of concern.

Malathion is registered for use on residential ornamental and vegetable gardens, and on exterior wall surfaces, around foundations, under fences and shrubs, and around buildings. Malathion is also registered for use in mosquito abatement programs, where bystanders could potentially be exposed by the inhalation route or by being exposed to malathion residues on turf. Estimates of exposure reach the target Margin of Exposure (MOE) for adults and children for all application exposure scenarios and most postapplication, and are therefore not of concern.

Residential risks from potential exposure to malaoxon on decks and playstructures are not of concern.

Malaoxon is a degradation product of malathion, which forms on hard surfaces such as decks and playstructures. Estimates of exposure for children, adolescents, and adults using default assumptions and chemical-specific monitoring data reach the target MOE, and are therefore not of concern.

Aggregate risk from exposure incurred at "Pick Your Own" orchard or berry facility is not of concern.

"Pick Your Own (PYO)" facilities are considered commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled malathion products. Estimates of exposure that aggregate the dermal exposure incurred during harvest and the dietary exposure from consuming fresh fruit reach the target MOE for orchard and berry crops, and are therefore, not of concern.

Occupational Risks from Handling Malathion

Occupational (mixer/loader/applicator) risks are not of concern when products are used according to revised label directions.

Most occupational risks due to malathion are not of concern for agricultural scenarios. Based on the precautions and directions for use on current labels, risk estimates associated with certain, mixing, loading and applying activities reach target MOEs, and are not of concern. For those uses that do not reach the targeted MOEs, mitigation measures such as additional personal protective equipment, engineering controls, or restrictions on amount handled per day are required to reduce potential exposure and protect worker's health.

Occupational postapplication risks are not of concern.

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture. Most occupational postapplication risks are not of concern if proposed protective measures are followed. When the proposed mitigation measures such as lengthened restricted-entry intervals (REIs) are considered, the risk estimates for postapplication workers meet the target MOE, and are not of concern.

Environmental Considerations

What Happens When Malathion is Introduced Into the Environment?

Malathion poses a potential risk to terrestrial and aquatic organisms, therefore additional risk reduction measures need to be observed.

When malathion is released into the environment some of it can be found in soil and surface water. Malathion is very soluble in water and does not adsorb strongly to soils and therefore may leach into groundwater and enter surface water in runoff. Water monitoring has revealed malathion residues in groundwater as well as surface water, albeit infrequently and at low concentrations.

Malathion breaks down into several transformation products through hydrolysis and biotransformation at rates that depend on environmental conditions. The major transformation products, identified in biotransformation studies (mono- and dicarboxylic acid of malathion, demethyl mono and di-carboxylic acid of malathion), are expected to be non-persistent in the environment. Malaoxon, the oxidation transformation product that is primarily responsible for the toxicity of malathion, is also expected to be non-persistent. Under neutral and alkaline conditions, both malathion and malaoxon readily hydrolyse and are increasingly stable under acidic conditions. In soil, malathion is not expected to phototransform, but may photolyze in natural waters containing photosensitizing agents. Malathion is not expected to volatilize significantly and is demonstrated to have low potential for bioaccumulation in fish.

Malathion poses a risk to both terrestrial and aquatic organisms. Birds are at risk in and around the site of application due to the consumption of contaminated food items, and the risk cannot be mitigated. In order to minimize the potential exposure to aquatic organisms, strips of land between the agricultural field and the aquatic areas (buffer zones) will be left unsprayed. The width of these buffer zones will be specified on the product label.

Value Considerations

What is the Value of Malathion?

Malathion is registered for use on a broad spectrum of sites for the control of a wide range of pests.

In Canada, malathion is registered to control a broad range of pests including beetles, bugs, butterflies, crickets, earwigs, flies (including black flies, face and horn flies and mosquitoes), grasshoppers, lice, mites, moths, spiders, thrips and ticks on a wide variety of sites.

Malathion for the control of a wide variety of chewing pests.

Malathion is a non-systemic insecticide and acaricide with contact, stomach, and respiratory action. Malathion is suited for control of a wide variety of chewing insects.

IPM compatibility and short pre-harvest interval

Malathion has short pre-harvest intervals (PHI). It is frequently used in berry production and is considered as IPM compatible.

User Requested Minor Use Label Expansions

Malathion has several uses that were registered through the User Requested Minor Use Label Expansion (URMULE) program. These uses have few viable alternative active ingredients or no registered alternatives.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed

by law.

Risk-reduction measures are being proposed to address potential risks identified in this assessment. These measures, in addition to those already identified on existing malathion product labels, are designed to further protect human health and the environment. The following key risk-reduction measures are being proposed.

Additional Key Risk-Reduction Measures

Human Health

To protect mixer/loader/applicators using commercial products:

- Additional personal protective equipment
- Restrictions on amount of active handled per day
- Packaging of all malathion wettable powder products in water soluble packaging

To protect workers entering treated sites, restricted-entry intervals are to be implemented:

To protect homeowners using domestic products:

- specification that the higher application rate of 30 g a.i./L is to only be used for dwelling foundation applications

Environment

- Additional advisory statements to protect non-target terrestrial and aquatic organisms and to reduce the potential for malathion residues in runoff to adjacent aquatic habitats

- Buffer zones for aquatic habitats (the PMRA is seeking comments on the feasibility of the buffer zones proposed for aerial applications.)

- A statement advising that the use of malathion may result in contamination of groundwater, particularly in areas where soils are permeable and/or the depth to the water table is shallow.

What Additional Scientific Information is Being Requested?

The human health risks and risks to the environment were found to be acceptable for most uses of malathion with the additional mitigation measures. However, additional information is being requested to help refine the risk assessments.

The following studies or suitable scientific rationale would be required to support continued registration as per section 12 of the *Pest Control Product Act*:

- Use Description - Qualitative information to more fully characterize exposure from grape vines (nursery), livestock, stored grain, structural uses, and mushroom houses.

- Postapplication Worker - Passive Dosimetry or Biological Monitoring, and/or Dislodgeable/Transferable Residue - Data are needed to provide estimates of postapplication worker exposure in mushroom houses.

- Postapplication Worker - Passive Dosimetry or Biological Monitoring, and/or Dislodgeable/Transferable Residue - Data are needed to provide estimates of postapplication worker exposure in structural sites (for example, flour mills).

- Dislodgeable/Transferable Residues - Residue studies that measure the formation and dissipation of malaoxon in airborne spray and, particularly, on deposited surfaces such as

hard surfaces and turf over a 10- to 30- day period following application of ULV malathion.

- Residue data to confirm the assumptions made in the dietary risk assessment. In particular, metabolism and magnitude of residues resulting from direct application on livestock, and magnitude of residues from treating stored grain.

- Immunotoxicity study.

Next Steps

Before making a re-evaluation decision on malathion, the PMRA will consider all comments received from the public in response to Proposed Re-evaluation Decision PRVD2010-18, *Malathion*. In particular, the PMRA is seeking comments on the feasibility of some of the larger buffer zones proposed for aerial applications. In addition, the PMRA is looking for information related to Value, including:

- efficacy data or scientific rationale to show that the coarse droplet size sprays and other conditions used to obtain feasible buffer zones still result in adequate product performance.

- quantitative and/or qualitative data on the economic and social importance of malathion to specific industries.

- feedback on the viability of alternative chemical and non-chemical pest management practices for the registered site and pest combinations for malathion.

The PMRA will then publish a Re-evaluation Decision, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

Other Information

At the time that the re-evaluation decision is made, the PMRA will publish an Evaluation Report on malathion in the context of this re-evalulation decision (based on the Science Evaluation section of Proposed Re-evaluation Decision PRVD2010-18, *Malathion*). In addition, the test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Once all organophosphate pesticides have been re-evaluated, a cumulative risk assessment will be conducted, which will consider potential exposure to all chemicals causing toxicity in the same manner. The results of the cumulative risk assessment may result in updates to any previous re-evaluation decision.

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