Re-evaluation Decision

Trichlorfon

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Overview

Re-evaluation Decision for Trichlorfon

After a re-evaluation of the insecticide trichlorfon, Health Canada’s Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of some uses of trichlorfon in Canada and phasing out the uses with risk concerns.

An evaluation of available scientific information found that, under the revised conditions of use, certain uses of products containing trichlorfon that do not involve a level of concern to human health or the environment have value in the food and crop industry. These uses include ground application on Balsam fir and spruce trees in farm woodlots, rights-of way and Christmas tree plantations as well as uses on beef and non-lactating dairy cattle. As a condition of the continued registration for these particular uses, new risk-reduction measures must be included on the labels of all products. Certain uses of trichlorfon are to be phased-out because of the human health risks and/or risks to the environment. These are using trichlorfon in municipal parks and on outdoor ornamentals as well as applying trichlorfon by air. In addition, registrants must submit additional scientific information.

The regulatory approach for the re-evaluation of trichlorfon was first presented in the Re-evaluation Note REV2007-05, *Preliminary Risk Assessment of Trichlorfon* and the Proposed Re-evaluation Decision PRVD2008-14, *Trichlorfon*.1 This Re-evaluation Decision2 describes this stage of PMRA’s regulatory process for the re-evaluation of trichlorfon as well as summarizes the Agency’s decision and the reasons for it. No comments were received during either of the consultation processes. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-14, *Trichlorfon*. To comply with this decision, registrants of products containing trichlorfon will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-14, *Trichlorfon*.

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

1 “Consultation statement” as required by subsection 28(2) of the *Pest Control Products Act*.

2 “Decision statement” as required by subsection 28(5) of the *Pest Control Products Act*. 
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 rigorous, modern hazard and risk assessment methods and policies. These methods consider the unique characteristics of sensitive populations in humans (e.g. children) and organisms in the environment (e.g. 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 on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA’s website at www.pmra-arla.gc.ca.

What Is Trichlorfon?

Trichlorfon is a broad spectrum, Resistance Management Group 1B (organophosphate) insecticide that inhibits the enzyme acetylcholinesterase and interrupts the transmission of nerve impulses. It works by contact and ingestion action. Products containing trichlorfon are registered under the following use-site categories: Forest and Woodlots, Livestock for Food, Terrestrial Food Crops, Terrestrial Feed Crops, Ornamentals Outdoors, Greenhouse Food Crops, Industrial Oil Seed and Fibre Crops, Structural, and Human Habitat and Recreational Areas.

Following the re-evaluation announcement for trichlorfon, Bayer CropScience Inc., the registrant of the technical grade active ingredient, indicated it intended to discontinue all uses except for those on Balsam fir and spruce trees in farm woodlots, rights-of way, Christmas tree plantations and municipal parks, on beef and non-lactating dairy cattle and on ornamentals. Only uses the registrant supported were considered in the health and environmental risk assessments of trichlorfon.

Health Considerations

Can Approved Uses of Trichlorfon Affect Human Health?

Trichlorfon is unlikely to affect your health when used according to the revised label directions.

Exposure to trichlorfon may occur through diet (food and water), by mixing, loading or applying the pesticide, or when entering a treated site. The PMRA considers two key factors when assessing health risks: the dose levels at which no health effects occur and

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3 “Acceptable risks” as defined by subsection 2(2) of the Pest Control Products Act.

4 “Value” as defined by subsection 2(1) of the Pest Control Products Act: “the product’s actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product’s (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.”
the dose levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Trichlorfon is highly to moderately toxic via the oral route and of low toxicity via the dermal and inhalation routes of exposure. Trichlorfon is moderately irritating to eyes, non-irritating to skin and is considered a skin sensitizer.

Following oral exposure, trichlorfon is readily absorbed and rapidly eliminated with little accumulation in the tissues. Exposure to trichlorfon in adult animals produced inhibition of acetylcholinesterase, progressing to clinical signs at higher doses. Effects on pup development, including transient behavioural changes and brain-weight effects, have been observed at doses resulting in maternal toxicity. Several studies from the published literature have also raised concerns regarding the neurotoxic effects of trichlorfon on prenatal brain development in guinea pigs and pigs.

In the environment, trichlorfon degrades to dichlorvos, which is also an organophosphate. Dichlorvos is also a mammalian metabolite and is a more potent acetylcholinesterase inhibitor than trichlorfon. Thus, the risk assessment took dichlorvos into consideration. Acetylcholinesterase is an enzyme responsible for the proper functioning of the nervous system and is inhibited following an overexposure via oral, dermal or inhalation routes. Symptoms including tremors, salivation, diarrhea and shortness of breath may occur in animals and humans.

The human data on trichlorfon indicate that acute exposure to high doses of trichlorfon results in those effects typically associated with acute organophosphate intoxication. Trichlorfon has been shown to cause neuropathology in hens and humans directly exposed. The occurrence of neuropathy in humans with low-level exposure heightens the concern for this compound, particularly because the neuropathy is of a persistent enough nature to render severe consequences in a subpopulation of aged individuals.

As some concerns were noted with the current use pattern for trichlorfon, the PMRA is requiring the phase out of uses in municipal parks and is requiring further protective measures, such as product use changes, protective equipment and improved work practices, to further reduce the level of human exposure to trichlorfon. In addition, specific toxicity information regarding symptoms of overexposure are required in the Toxicological Information section of the product labels.

**Risks in Residential and Other Non-Occupational Environments**

**Residential risks are of concern. Therefore, residential uses are to be phased-out.**

Exposure may occur after trichlorfon is used in outdoor residential and recreational areas. Given trichlorfon degrades to dichlorvos, adults and children can be exposed to both when entering a treated site. Adults and children could experience short-term exposure
when or immediately after it is used, for example people walking in treated municipal parks. There are insufficient data to estimate residues of trichlorfon and dichlorvos in municipal parks. It was assumed the exposure of hikers would be similar to scouters entering a treated forest. Based on this re-entry activity, the risk estimates associated with the residential uses do not meet current standards. Toddlers are expected to experience greater exposure to trichlorfon than adults after the product is applied because the activities associated with toddlers are considered more intensive. As well, these estimates do not include potential inhalation exposure to dichlorvos. Currently, no data are available to estimate the concentration of dichlorvos in the air after trichlorfon is applied on to spruce and fir trees in municipal parks.

As restricted-entry intervals calculated for adults are not considered feasible for municipal parks, a postapplication assessment for children was not pursued. Children’s exposure is expected to be higher. Consequently, the PMRA is requiring the phase-out of uses in residential settings such as municipal parks.

**Occupational Risks From Handling Trichlorfon**

**Exposure risks for mixers, loaders and applicators are not of concern provided additional risk-reduction measures are observed.**

Workers can be exposed to trichlorfon when mixing, loading or applying the pesticide. Worker exposure estimates are based on the best available data at this time. The assessment may be refined with exposure data that are more representative of modern application equipment and engineering controls. Biological monitoring data could also further refine the assessment. No specific handler exposure data were submitted for trichlorfon. Therefore, dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1.

The risk estimates associated with mixing, loading and applying activities for current label uses meet current standards and are not of concern, provided engineering controls and/or personal protective equipment are used.

**Postapplication risks are of concern for workers performing high exposure activities.**

As trichlorfon degrades to dichlorvos, workers can be exposed to both when entering a treated site to conduct activities such as handling treated ornamentals and Christmas trees, or when handling treated livestock. The postapplication occupational risk assessment considered exposures to workers entering treated sites, including forests, nurseries and Christmas tree plantations. It is expected that exposure of livestock handlers would be less than that of individuals applying product. Therefore, a quantitative postapplication exposure assessment was not conducted. However, mitigation measures are recommended to protect people handling treated animals.
Restricted-entry intervals are calculated to determine the minimum length of time required before workers or others can safely enter a treated site. An restricted-entry intervals is the amount of time that must elapse before residues on surfaces or in air decline to a level at which performing a specific activity results in acceptable exposures.

The length of time it takes for trichlorfon and dichlorvos residues to reach acceptable levels is not considered feasible for all uses; therefore, the PMRA is requiring that uses on outdoor ornamentals be phased out.

**Residues in Water and Food**

**Dietary risks from food and water are not of concern.**

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 and chronic dietary exposure to trichlorfon was estimated using anticipated residue data from dermal application studies with livestock. The use on livestock is the only supported food use of trichlorfon. The acute potential daily intake of trichlorfon accounts for 1.3% (99.9th percentile) of the acute reference dose for the general population, and 2.1% of the acute reference dose for the highest exposed population group, children three to five years of age. The chronic dietary exposure as a percentage of the acceptable daily intake is 7% for the general population and 13% for the highest exposed population groups, children one to two and three to five years of age. Therefore, the acute and chronic dietary risk from trichlorfon is not considered to be of concern.

The supported uses of trichlorfon are not expected to result in any significant drinking water exposure. Therefore, drinking water risks are not of concern.

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Currently, there is no definition for the residue of concern for trichlorfon, and no MRLs are specified. The supported food uses of trichlorfon are on beef cattle and non-lactating dairy cattle. Where no specific MRL is established for a pest control product, subsection B.15.002(1)(a) of the Food and Drug Regulations applies. This requires that residues do not exceed 0.1 ppm, which is considered a general MRL for enforcement purposes.
However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. A transition strategy will be established to allow permanent MRLs to be promulgated prior to the revocation of the general MRL.

The general MRL of 0.1 ppm will apply for enforcement purposes with respect to the residues of trichlorfon in food for all commodities, including beef cattle and milk.

**Environmental Considerations**

**What Happens When Trichlorfon is Introduced Into the Environment?**

*Trichlorfon poses a potential risk to certain terrestrial and aquatic organisms; therefore, additional risk-reduction measures must be observed.*

Trichlorfon is not expected to persist in soil or aquatic environments. There is a high potential for mobility due to the very high solubility in water and weak adsorption to soil. Trichlorfon has a minimal potential for bioaccumulation. Dichlorvos is a major transformation product when trichlorfon decomposes in water.

The forestry use as well as the livestock and ornamental outdoor uses of trichlorfon are not expected to contaminate drinking water sources. In addition, the relatively short half-lives for dichlorvos and trichlorfon in surface water further decreases the potential for contamination of drinking water sources. Therefore, drinking water risks are not of concern.

Estimated environmental concentrations for water and land ecosystems were determined for the forestry and ornamental outdoor uses of trichlorfon based on the range of application rates and number of applications listed on the current labels of registered products. The uses on livestock were not expected to result in appreciable exposure to non-target organisms found on land and in the water; therefore, an assessment was not conducted for this use-pattern.

Birds, small wild mammals, bees and aquatic organisms such as fish and aquatic invertebrates can be affected when trichlorfon is used. To reduce exposure of these organisms, it is important that additional risk-reduction measures be observed.

Aerial application in forestry is of particular concern because the risk to pollinators, birds and small wild mammals cannot be mitigated. The buffer zones calculated for aerial application are large and believed to be operationally unfeasible. Therefore, aerial applications of trichlorfon are to be phased-out.
Value Considerations

What is the Value of Trichlorfon?

No additional information with respect to the value of trichlorfon was provided in response to the preliminary assessment published in Re-evaluation Note REV2007-05 or Proposed Re-evaluation Decision PRVD2008-14.

The registered chemical alternatives for unsupported uses of trichlorfon or for the supported uses of trichlorfon that have risk concerns are listed in Appendix V of PRVD2008-14.

Measures to Minimize Risk

The labels of registered pesticides 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 required to address potential risks that were identified in the assessment. These measures, in addition to those already on existing trichlorfon product labels, are designed to further protect human health and the environment. As a result of the re-evaluation of trichlorfon, the PMRA is requiring further risk-reduction measures on product labels.

Additional Key Risk-Reduction Measures

• As per the registrant’s original agreement, all unsupported uses must be removed from the Dylox 80% Soluble Powder (Registration Number 9827) label and Dylox 420 Liquid Insecticide (Registration Number 16387) must be discontinued.

Human Health

• Label updates to the Toxicological Information section, which will provide information about symptoms and treatment for exposed individuals.

• Engineering controls (water-soluble packaging for soluble powder formulations), additional personal protective equipment, restricted-entry intervals and restrictions on number of applications to protect mixers/loaders/applicators and workers entering treated sites.

• Phase-out of residential use (municipal parks) and the use on outdoor ornamentals.
Environment

- Changes to label statements—including precautionary statements for bees, birds, small wild mammals and aquatic organisms as well as restrictions on field sprayer and airblast applications—to reduce release of trichlorfon into the environment.
- The observance of buffer zones to mitigate the entry of spray drift into aquatic systems.
- The phase-out of aerial applications of trichlorfon to protect aquatic habitats that may contain sensitive species.

Appendix I lists all the required label amendments.

What Additional Scientific Information is Being Requested?

The human health risks and/or risks to the environment for certain uses of trichlorfon were found to be acceptable and additional confirmatory scientific information is being requested from registrants as a result of this re-evaluation. Appendix II lists the additional data requirements.

Other Information

For trichlorfon, the summary of assessments found in PRVD2008-14 serves as an evaluation report. A list of references considered by the PMRA in support of the registration decision are found in this Re-evaluation Decision (Appendix III). The relevant test data on which the decision is based are available for public inspection, upon application, in the PMRA’s Reading Room (located in Ottawa). For more information, please contact the PMRA’s Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection\(^5\) regarding this decision on trichlorfon within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA’s website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA’s Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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

\(^5\) As per subsection 35(1) of the Pest Control Products Act.
Appendix I Label Amendments for Commercial and Restricted Class Products Containing Trichlorfon

Label Amendments Relating to Human Health
The use of water-soluble packets for soluble powder formulations is required to reduce exposure when mixing or loading the product. Canadian end-use product labels must be amended to include the following statements to further protect workers.

General (all)

Not to be used in conjunction with products containing naled or dichlorvos.

TOXICOLOGICAL INFORMATION:

Trichlorfon is an organophosphate that is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician.

For products that contain greater than 10% petroleum distillates, the following text must also be added to the Toxicological Information section (placed at the end of the paragraph presented above), as an additional aid to the attending physician.

NOTE: Product contains a petroleum distillate solvent.

Neguvon Pour-On Cattle Insecticide (Registration Number 9419)

Wear long, chemical-resistant gloves or gauntlets during use.

Wear chemical-resistant gloves when handling treated cattle.

Dylox 80% Soluble Powder (Registration Number 9827)

Wear coveralls over long-sleeved shirt and long pants during mixing, loading and application.

Wear respirator for high-pressure handwand and airblast applications.
Limit of 2 applications per year, 7 days apart.

REI of 10 days for Balsam fir and spruce trees in farm woodlots, rights-of-way, Christmas tree plantations.

Not for use in greenhouse or other enclosed areas.

**Label Amendments Relating to the Environment**
The following additional label statements are required to further protect the environment.

**ENVIRONMENTAL HAZARDS**

**TOXIC** to aquatic organisms, birds, and small wild mammals.

**TOXIC** to bees exposed to direct treatment, drift or residues on flowering crops or weeds. **DO NOT** apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.

**DIRECTIONS FOR USE**

**Field sprayer application:** **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine/medium/coarse classification. Boom height must be 60 cm or less above the crop or ground.

**Airblast application:** **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

**DO NOT** apply by air.

**Buffer zones**

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.
Buffer Zones Required for the Protection of Aquatic Habitat Following Applications of Trichlorfon

<table>
<thead>
<tr>
<th>Method of application</th>
<th>Crop</th>
<th>Buffer Zones (metres) Required for the Protection of</th>
<th>Freshwater Habitat of Depths:</th>
<th>Estuarine/Marine Habitats of Depths:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Less than 1 m</td>
<td>Greater than 1 m</td>
</tr>
<tr>
<td>Airblast (early growth stage)</td>
<td>Forests, woodlots</td>
<td>50</td>
<td>40</td>
<td>50</td>
</tr>
<tr>
<td>Airblast (late growth stage)</td>
<td>Forests, woodlots</td>
<td>40</td>
<td>30</td>
<td>40</td>
</tr>
</tbody>
</table>
Appendix II Additional Data Requirements

The following confirmatory data are required to support the continued registration of trichlorfon.

DACO 6.2 The nature of the residue in livestock is not understood. Complete identification of metabolites is required to fully depict the metabolism in livestock.

DACO 7.6 (a) The registrant is required to explain the difference between the concentration of trichlorfon found in magnitude of residue study and that which was found in the nature of the residue study.

(b) The registrant is required to provide all available studies related to the magnitude of residues that may be incurred in milk.
References

A. Studies/Information Provided by the Applicant/Registrant (Unpublished)

Toxicology


Residue Chemistry


Occupational

References


B. Additional Information Considered for Trichlorfon Re-evaluation (Published Information)

Toxicology


EPA. 1999. Memorandum. Jess Rowland and Pauline Wagner, Hazard Identification Assessment Review Committee, Health Effects Division to W. Phang, Reregistration Branch 1,


**Residue Chemistry**


**Occupational**


Environment


EPA. 1997. Environmental Fate and Effects Division Re-Registration Eligibility Decision Document (EPA 738-R-96-017)


**Use Analysis**

Bennett, K. (date unknown). *Caterpillar pests of cole crops in home gardens.*
http://www.extension.umn.edu/yardandgarden/ygbriefs/e253caterpillarpests-cole.html


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Soroka, J.J. 1971. *Insect Pests of Legume and Grass Crops in Western Canada.* Agriculture and Agri-Food Canada, Publication 1435E.