PRVD2007-08

Proposed Re-evaluation Decision

Re-evaluation of Triallate

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated triallate for use as an herbicide in terrestrial feed crops, terrestrial food crops and industrial oilseed crops and fibre crops. The PMRA is proposing that the use of triallate and associated end-use products is acceptable for continued registration. Additional mitigation measures to further protect workers and the environment are identified in this document. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing triallate with specific direction on how to address these measures and requirements.

This Proposed Re-evaluation Decision document provides a summary of the data and information reviewed as well as the rationale for the proposed regulatory decision. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. All comments should be forwarded to Publications at the address below.

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Executive Summary

Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the available information on the active ingredient triallate and the associated end-uses on food and non-food areas. The PMRA is proposing that the use of triallate and its end-use products is acceptable for continued registration, with the implementation of additional mitigation measures to further protect workers and the environment.

The followings are the summaries of the health and environmental risk assessments as well as the proposed mitigation measures for the re-evaluation of triallate.

Human Health Risk Assessment: The worker application and postapplication risks are acceptable when using granular formulations. When using emulsifiable concentrate formulations, including for fertilizer admixture, the calculated MOEs are less than the target MOEs. There are no residential products for triallate. Bystander risk from triallate in the air is below the level of concern. Exposure to residues of triallate in drinking water and food are below the level of concern. Aggregation of exposure to triallate through food, water and air is below the level of concern.

Environmental Risk Assessment: The environmental risk assessment indicates triallate exposure to wild birds, small wild mammals, freshwater fish and freshwater invertebrates poses a negligible risk of adverse effects. A risk was identified to terrestrial and freshwater plants from drift of triallate into non-target areas. Mitigation of effects resulting from drift can be achieved through buffer zones. A refined assessment of risk to aquatic plants indicated that the risk from runoff would be low and therefore, not a concern.

Although the agricultural use of triallate results in triallate emissions to the atmosphere through volatilization, the current methods of assessment have identified negligible risk to the environment from the atmospheric loading and subsequent re-deposition to terrestrial and aquatic ecosystems as either dry deposition or in rainfall, from the current use profile. Re-deposition of triallate from atmospheric sources may result in the triallate residues in areas where it is not used.

The proposed major risk-mitigation measures are as follows.

- For emulsifiable concentrate formulations in agricultural field scenarios, mitigation could be achieved by limiting the amount handled per day to 189 kg active ingredient and requiring closed mix/load systems and applying with a closed cab. For fertilizer admixture scenarios, mitigation is not possible based on available information, and specific data to assess this scenario would be required.

- Additional personal protective equipments (PPEs) are required for granular formulations.

- A restricted-entry interval of 12 hours is required to enter or allow worker entry into treated areas.

- Additional precautionary measures to prevent runoff, leaching and volatization are required.

- Terrestrial and aquatic buffer zones for emulsifiable concentrate formulations are required.

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1.0 Introduction

Health Canada's Pest Management Regulatory Agency (PMRA) announced[1] in August 2002 that selected carbamate active ingredients, including triallate, were subject to re-evaluation under the authority of Section 16 of the *Pest Control Products Act*.

This document includes a human health assessment, an environmental assessment and information on the value of triallate to pest management in Canada.

2.0 Re-evaluation of Triallate

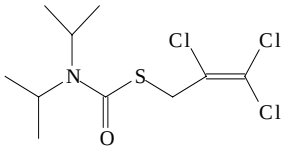
Triallate is a narrow-spectrum herbicide and belongs to the Group 8 (thiocarbamates), which inhibits lipid synthesis (not ACCase inhibition). It works by systemic action. Triallate is registered for the control of wild oats (*Avena fatua*) only.

Much of the scientific information used by the PMRA in its assessment of triallate came from the registrants; the United States Environmental Protection Agency (USEPA) reviews and Reregistration Eligibility Decision (RED) document for triallate, published in March 2001; the National Institute of Public Health and the Environment (Riijksinstituut Voor Volksgezondheid en Milieu—RIVM) review of triallate (Avadex 480) (2000), The Netherlands, CTB opdrachtnummer 99/3431; and previous PMRA reviews. The RED document as well as other information on the regulatory status of triallate in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.1 Chemical Identification

Common name	Triallate
Chemical names	
International Union of Pure and Applied Chemistry (IUPAC)	*S*-2,3,3-trichloroallyl di-isopropylthiocarbamate
Chemical Abstracts Service (CAS)	*S*-(2,3,3-trichloro-2-propenyl) bis(1-methylethyl)carbamothioate
Chemical family	Thiocarbamate
CAS number	2303-17-5
Molecular formula	$C_{10}H_{16}C_{l3}NOS$
Molecular weight	304.7

[1] Re-evaluation Document REV2002-06, *Re-evaluation of Selected Carbamate Pesticides.*

Structural formula	
Purity of active ingredient	96% (limits: 94–98%)
Registration number	19203

Based on the manufacturing process used, no other impurities of toxicological concern are expected to be present in this product, as per Regulatory Directive DIR98-04, *Chemistry Requirement for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, and Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Appendix II of Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

2.2 Physical and Chemical Properties of the Active Substance

Property	Result
Vapour pressure at 25°C	16 mPa
Henry's law constant	1.22 Pa m^3 mol^{-1}
Ultraviolet (UV)/visible spectrum	Not expected to absorb UV at $\lambda > 300$ nm
Solubility in water at 25°C	4 mg/L
n-Octanol–water partition coefficient	log K_{ow} = 4.6
Dissociation constant	Not applicable

2.3 Description of Registered Triallate Uses

Appendix I lists all triallate products that are registered in Canada. Appendix II lists all the uses for which triallate is presently registered. All uses are supported by the registrant and were considered in the health and environmental risk assessments.

Uses of triallate belong to the following use site categories: terrestrial feed crops, terrestrial food crops and industrial oilseed crops and fibre crops.

3.0 Effects Having Relevance to Human Health

3.1 Toxicological Summary

The toxicology data base for triallate is based primarily on studies available from the registrant. Triallate technical product was of low to slight acute toxicity following acute oral exposure to rats, of low acute dermal and inhalation toxicity to rabbits and rats, respectively, it was minimally or moderately irritating to the rabbit eye and skin, respectively, and a skin sensitizer. Signs of acute toxicity induced by triallate are tremors, ataxia, salivation, and convulsions. These signs of neurotoxicity are consistent with the thiocarbamate class of chemicals. Triallate undergoes rapid systemic absorption and distribution following oral exposure, with approximately 85% excreted via the urine and feces within 24 hours. Tissue retention was minimal. Of the 11 metabolites identified, 2,3,3-trichloro-2-propenesulfinic acid (TCPSA) was the most predominant.

In short- and long-term animal studies, the primary effects included changes in kidney, liver and blood parameters. In rats, there was a reduction in survival in both sexes in the long-term study. A number of effects on the nervous system were noted at higher doses, including cholinergic disturbances such as leg weakness, ataxia and convulsions, but there were no effects on acetylcholinesterase inhibition or signs of delayed neurotoxicity in the hen.

There was evidence of carcinogenicity in mice receiving triallate via their diet. An increased incidence of liver carcinomas was observed in male mice at the high dose, which was statistically significant by pair-wise comparison, with a statistically significant trend in both sexes. These hepatic tumours had an apparent early onset, with the first carcinoma noted midway through the two-year treatment period. There was no evidence of carcinogenicity in rats or in hamsters. An assessment of mutagenic potential in a variety of bacterial and mammalian in vitro and in vivo studies included gene mutation, chromosomal aberrations, DNA repair, sister chromatid exchange and micronucleus formation. Triallate tested positive in a number of in vitro mutagenicity studies including the reverse mutation Ames test with or without activation, a forward-mutation assay in mouse lymphoma cells and sister chromatid exchange in Chinese hamster ovary cells. However, triallate was negative for mutagenic activity in the in vivo assays including the mouse micronucleus test, in hamster bone marrow and in a supplemental dominant lethal test.

Triallate caused fetal malformations in rats at doses causing maternal toxicity and was associated with an increased incidence of fused sternebrae in fetal rabbits at a non-maternally toxic dose, indicating the potential for fetal sensitivity. Reproductive toxicity in rats consisted of a reduced gestation period or increase in the number of premature deliveries, which was noted in the second litter of the second generation only.

Reference doses have been set based on no observed adverse effect levels (NOAELs) for the most relevant endpoints, namely cholinergic toxicity, developmental toxicity, body-weight effects and reduced survival. These reference doses incorporate uncertainty factors to account for extrapolating between animals and humans, and for variability within human populations. Additional safety/uncertainty factors have also been employed to take into consideration the severity of effects. For quantitative cancer risk assessment, a cancer potency factor (Q_1*) of 7.17×10^{-2} (mg/kg bw/day)$^{-1}$ was used, which was based on hepatocellular carcinomas in male mice (USEPA 2001).

The toxicology endpoints used in the risk assessment of triallate are summarized in Appendix III.

3.2 Occupational and Residential Risk Assessment

Occupational and residential risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive sub-population. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects. However, MOEs less than the target MOE require risk-mitigation measures.

To estimate the risk from short-term dermal and inhalation exposure (< 30 days), a NOAEL of 5 mg/kg bw/day from a rabbit developmental toxicity study was selected. This NOAEL was based on an increased incidence of fused sternebrae in developing rabbit fetuses at the next highest dose of 15 mg/kg bw/day, a dose that did not produce maternal toxicity. The target MOE is 300. This accounts for interspecies extrapolation (10-fold) and intraspecies variability (10-fold) with an additional factor (3-fold) for fetal sensitivity (fetal effects in the absence of maternal toxicity). The NOAEL for short-term dermal exposure and short-term inhalation exposure is obtained from the same study with the same target MOE; therefore, it is appropriate to combine the route-specific exposures to generate a single risk estimate or a “combined route MOE”.

To estimate the risk from intermediate-term inhalation exposure, a NOAEL of 1.96 mg/kg bw/day from a 7-week inhalation study in the rat was selected. The NOAEL was based on increased renal nephropathy and increased kidney weight in the male at 5.87 mg/kg bw/day. The target MOE is 300. This accounts for interspecies extrapolation (10-fold) and intraspecies variability (10-fold) with an additional factor (3-fold) for fetal sensitivity (fetal effects in the absence of maternal toxicity) and for extrapolating from a short-term study to a longer term scenario.

A quantitative cancer risk assessment was conducted based on statistically significant increased hepatocellular carcinomas in male mice. Female mice also had a significant positive trend for liver carcinomas. There was no evidence of carcinogenicity in rats. Triallate demonstrated some mutagenic potential in a number of in vitro assays, but was consistently negative in a number of in vivo assays. A Q_1* of 7.17×10^{-2} (mg/kg bw/day)$^{-1}$ was used.

3.2.1 Occupational Exposure and Risk Assessment

Workers can be exposed to triallate through mixing, loading or applying the pesticide. Workers may also be exposed when impregnating fertilizer with triallate and applying the treated fertilizer.

Mixer/Loader/Applicator Exposure and Risk Assessment
There are potential exposures to mixers, loaders, applicators and other handlers. The following supported uses were assessed:

- Groundboom application to barley, wheat (spring, durum), flax, mustard, rapeseed (including canola), sugar beets and dry peas (emulsifiable concentrate formulation).

- Aerial and groundboom application to barley (including spring barley), canary grass, wheat (spring, durum), flax, mustard, rapeseed (including canola) and sugar beets (granular formulation).

- Application of emulsifiable concentrate formulation to dry bulk fertilizer (admixture), and then application of treated fertilizer to fields.

Based on the number of applications, workers applying triallate would generally have a short-term (up to 30 days) duration of exposure. The PMRA estimated handler exposure based on different levels of personal protection:

- Baseline PPE: a long-sleeved shirt and long pants, chemical-resistant gloves (unless specified otherwise) with open mixing and open cab. When specified, respirator worn during mix/load only.

- Mid-level PPE: coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, with open mixing and open cab. When specified, respirator worn during mix/load only.

- Maximum PPE: chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, with open mixing and open cab. When specified, respirator worn during mix/load only.

Mixer/loader/applicator exposure estimates are based on the best available data at this time. The assessment might be refined with exposure data more representative of modern application equipment and engineering controls. Biological monitoring data might also further refine the assessment.

No chemical-specific handler exposure data were submitted for triallate; therefore, dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1. PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and

level of personal protective equipment (PPE). In most cases, PHED did not contain appropriate data sets to estimate exposure to workers wearing chemical-resistant coveralls or a respirator. This was estimated by incorporating a 90% clothing protection factor for chemical-resistant coveralls and a 90% protection factor for a respirator into the unit exposure data. Data also were not available to assess exposure during mix/load using granular formulations in a closed system. In this case, a 90% protection factor for a closed system was applied to the unit exposure value for an open system.

For the fertilizer admixture scenarios, which may occur both on-farm and in commercial facilities, appropriate data to estimate exposure to handlers treating fertilizer are not available. Exposure was estimated using PHED data and data from an on-farm seed treatment study (Fenske 1990). There is great uncertainty in using these data for the fertilizer admixture scenarios as they are not representative of the scenarios.

When handling the granular formulations of triallate using ground equipment, calculated MOEs exceed target MOEs for application, mixing and loading for current label uses, provided that personal protective equipment is used as summarized in Appendix IV. For aerial applications of granular formulations, calculated MOEs are less than target MOEs; however, due to the conservatism in the exposure assessment, the calculated MOEs are considered acceptable. When handling the EC formulations of triallate, calculated MOEs are less than the target MOEs for application, mixing and loading, including application to dry bulk fertilizer. Proposed mitigation measures and regulatory actions are described in Section 7.0.

When handling the granular formulations of triallate using ground equipment, cancer risks were estimated to range from 1×10^{-6} to 1×10^{-5}. Estimated cancer risks are slightly higher for applying granular formulations by aerial equipment (1×10^{-5} to 3×10^{-5}); however, these estimates are considered to be quite conservative. When handling EC formulations for agricultural crops, estimated cancer risks range from 3×10^{-6} to 6×10^{-5}. For fertilizer admixture scenarios, estimates range from 3×10^{-6} to 5×10^{-4}.

Occupational Postapplication Exposure Risk Assessment

Postapplication exposure to workers is expected to be very low because of the timing of applications. Triallate is applied to the soil and/or soil incorporated before plants have emerged from the soil. Therefore, exposure from treated foliage is not expected during harvesting or during any other late season activity. Application in autumn occurs after the crops have been harvested; therefore, postapplication exposure is again expected to be very low because very little activity occurs after harvesting.

A minimum restricted-entry interval (REI) of 12 hours is required. A REI is the minimum length of time required before workers or others can safely re-enter.

3.2.2 Residential Exposure and Risk Assessment

Residential risk assessment is concerned with estimating risks to the general population, including children, during or after pesticide application. Although there are no uses of triallate in residential areas, triallate has been detected in air in the Prairie Region over a period of several months (Kumar 2001, Waite et al. 2005, Environment Canada 2004). Therefore, there is potential for inhalation exposure in rural residential areas, which would be of intermediate-term duration (approximately four months).

The highest detected air concentrations of all years from 1999 to 2004 occurred in 2004 with maximum and mean concentrations of 15.4 and 1.90 ng/m^3, respectively. The maximum air concentration was used for the intermediate-term non-cancer risk assessment, while the mean concentration was used for the cancer assessment. Inhalation exposures and risk estimates for toddlers, youths and adults are presented in Table 3.2.2.1. All are below the level of concern.

Table 3.2.2.1 Inhalation Exposure and Risk Estimates

Population	Daily Exposure[a] for Non-Cancer Assessment (mg/kg bw/day)	Daily Exposure[a] for Cancer Assessment (mg/kg bw/day)	MOE[b]	LADD[c]
Toddler	2.16×10^{-6}	2.66×10^{-7}	9×10^{5}	7×10^{-9}
Youth	7.90×10^{-7}	9.74×10^{-8}	2×10^{6}	3×10^{-9}
Adult	3.73×10^{-7}	4.60×10^{-8}	5×10^{6}	1×10^{-8}
				Total LADD = 2.23×10^{-8} Cancer risk[d] = 1.60×10^{-9}

[a] Where inhalation exposure mg/kg bw/day = air concentration × inhalation rate × exposure time/body weight. Where air concentration = 15.4 and 1.90 ng/m^3 for the non-cancer and cancer assessment, respectively. Inhalation rate = 0.7 m^3/h for toddlers and 1.0 m^3/h for youths and adults. Exposure time is total time spent outdoors, which is 3, 2 and 1.5 hours for toddlers, youths and adults, respectively (USEPA *Exposure Factors Handbook*, USEPA *Child-Specific Exposure Factors Handbook*). Body weight = 15, 39 and 62 kg for toddlers, youths and adults, respectively.

[b] Based on daily exposure for non-cancer assessment and the intermediate-term inhalation NOAEL of 1.96 mg/kg bw/day. Target MOE = 300.

[c] LADD is lifetime average daily dose based on daily exposure for cancer assessment, 120 days exposure/year, a lifetime of 75 years and exposures of 6, 6 and 63 years as toddlers, youths and adults, respectively.

[d] Based on a Q_1* of 7.17×10^{-2} $(mg/kg\ bw/day)^{-1}$

3.3 Dietary Exposure and Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in fruits, vegetables, milk, meat, eggs and processed products may be ingested in the daily diet. These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, assessments take into account differences in children's eating pattern, such as food preferences and greater consumption of food relative to their body weight compared with adults.

The residue of concern includes the TCPSA metabolite; therefore, the sum of triallate and TCPSA is considered in the dietary and drinking water exposure assessments. Chronic, cancer and acute dietary risk assessments (DRAs) were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) as well as with the consumption data from the United States Department of Agriculture's 1994–1998 Continuing Survey of Food Intake by Individuals (CSFII). These DRAs consider all Canadian treated foods and relevant imported food commodities. The available field trial data are used to refine the dietary risk assessment analysis. Anticipated residue values, percent crop treated and processing factors are included in the DEEM-FCID residue files. The drinking water assessment is established based on a comparison of drinking water level of comparison (DWLOC) to estimated environmental concentrations (EEC).

3.3.1 Acute Dietary Exposure and Risk Assessment

Acute dietary risk is calculated using food consumption and food residue values. A deterministic analysis allows all possible combinations of food consumption and residue levels to be combined to estimate a distribution of the amount of triallate residue that might be eaten in a day. An exposure value representing the high end (95^{th} percentile) of this distribution is compared with the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the calculated intake, called the potential daily intake, from residues is less than the ARfD, the intake is not considered to be of concern.

To estimate acute dietary risk (1 day) for the general population, the NOAEL of 60 mg/kg bw from two acute neurotoxicity study in rats was selected. This NOAEL was based on cholinergic signs (leg weakness, flat-footed gait) that were noted at the next highest dose of 100 mg/kg bw. An overall uncertainty factor of 100 is required to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold). The ARfD was calculated to be 0.6 mg/kg bw (60 mg/kg bw ÷ 100). This value is considered protective of the general population including infants and children.

To estimate acute dietary risk (1 day) in the population subgroup, females 13–50 years, a NOAEL of 5 mg/kg bw/day from a rabbit developmental toxicity study was selected. This NOAEL was based on an increased incidence of fused sternebrae in developing rabbit fetuses at the next highest dose of 15 mg/kg bw/day, a dose that did not produce maternal toxicity. An overall uncertainty factor of 300 is required to account for interspecies extrapolation (10-fold)

and intraspecies variability (10-fold) with an additional factor (3-fold) for fetal sensitivity (fetal effects in the absence of maternal toxicity). The ARfD for females 13–50 years was calculated to be 0.017 mg/kg bw (5 mg/kg bw/day ÷ 300).

Deterministic acute dietary exposure analyses were performed to determine the exposure and risk estimates resulting from the use of triallate on domestic and imported agricultural commodities. The general maximum residue limit (MRL) of 0.1 ppm was used for specific Canadian commodities (flax and canola), while the reassessed tolerances in the United States were used for imported or other domestic commodities. Empirical processing factors (DEEM defaults) and a 100 percentage of crop treated were used.

The analysis for triallate for all Canadian population subgroups at the 95th percentile is less than the reference dose and is therefore below the PMRA's level of concern. Risk estimates for the representative population subgroups range from less than 0.15% for the general population and the children 1 to 2 years to 1.6% for the female populations.

3.3.2 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk is calculated by using the average consumption of different foods, and average residue values on those foods, over a 70-year lifetime. This expected intake of residues is compared with the acceptable daily intake (ADI), which is the dose that an individual could be exposed to over a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern.

To estimate the risk from chronic dietary exposure, the NOAEL of 2.5 mg/kg bw/day from a 2-year rat study was selected based on reduced survival, and reduced body weight at the next highest dose of 12.5 mg/kg bw/day. An overall uncertainty factor of 1000 is required to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold) with an additional factor (10-fold) for potential sensitivity of the young and severity of endpoint (reduced survival). The ADI was calculated to be 0.0025 mg/kg bw/day (2.5 mg/kg bw ÷ 1000). This value was considered protective of all populations.

Deterministic chronic dietary exposure analyses were performed to determine the exposure and risk estimates resulting from the use of triallate on domestic and imported agricultural commodities. Anticipated residues were calculated from field trials when available or the general MRL was used for specific Canadian commodities (flax and canola). Processing factors and Canadian average weighted percent crop treated were used as refinement criteria. The analysis for triallate for all Canadian population subgroups is less than the reference dose and is therefore below the PMRA's level of concern. Risk estimates for the representative population subgroups is less than 0.3% for all the Canadian subpopulations.

3.3.3 Cancer Dietary Exposure and Risk Assessment

A quantitative risk assessment was conducted based on statistically significant increased hepatocellular carcinomas in male mice. Female mice also had a significant positive trend for liver carcinomas. There was no evidence of carcinogenicity in rats. Triallate demonstrated some mutagenic potential in a number of in vitro assays, but was consistently negative in a number of in vivo assays. A Q_1* of 7.17×10^{-2} $(mg/kg\ bw/day)^{-1}$ was used.

Deterministic cancer dietary exposure analyses were performed in order to determine the exposure and risk estimates which result from the use of triallate on domestic and imported agricultural commodities. Lifetime cancer risks in the range of 10^{-6} or less are not of concern.

Cancer dietary risk assessment indicated that the cancer dietary risk assessment of triallate from exposure through from food, associated with the uses supported data registration, is under the PMRA's level of concern for food alone. The lifetime cancer risk estimate, based on the Q_1* approach was approximately 2×10^{-7} for the general population and 5×10^{-7} for children 1–2 years.

3.3.4 Drinking Water Exposure

Acute and chronic aggregate risks from food and drinking water exposure are addressed by calculating DWLOCs. These are calculated based on the difference between the appropriate reference dose and the non-drinking water exposure and can be directly compared to estimated concentrations in drinking water. DWLOCs can only be determined if all other sources of dietary exposure are acceptable.

The acute DWLOC values ranged from 520 µg/L for the most affected subpopulation of females to 20 995 µg/L for the general population. The chronic DWLOC values ranged from 25 µg/L for the most affected subpopulation of infants to 87 µg/L for the general population. Cancer risk is based on exposure in the total population over the entire lifetime, which is the relevant timeframe. The cancer DWLOC was calculated to be 0.4 µg/L.

Based on the available surface water monitoring data for both triallate and TCPSA, estimated residues of triallate in drinking water (1.1 µg/L—acute; 0.09 µg/L—chronic and cancer) are below the acute, chronic and cancer DWLOCs. The triallate residues determined from a single groundwater monitoring study (0.2 µg/L) was lower than the DWLOCs but, did not include measurements of TCPSA. However, given the concentrations predicted for triallate from the groundwater modelling (0.001 µg/L) and the low levels of TCPSA in surface water monitoring, exposure to triallate and TCPSA in drinking water obtained from groundwater will be minimal and therefore, not of concern.

Complete EEC values are presented in Section 4.3.

3.4 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

Triallate is not registered for residential uses; however, inhalation exposure is possible because triallate has been detected in air for a period of several months in rural areas. Inhalation exposure may co-occur with background (chronic) dietary exposure for toddlers, youths and adults. The duration of aggregate exposure would be intermediate-term.

Kidney toxicity was observed in short-term repeat dosing studies via oral, dermal or inhalation routes of exposure. The most relevant studies to assess short-term aggregate exposure were the repeat-dose 7-week inhalation toxicity study, and the 90-day oral toxicity study, both in rats. The NOAEL/LOAEL (lowest observed adverse effect level) for kidney toxicity (increased renal lesions, renal nephropathy and increased kidney weight in the males) was 1.96/5.87 mg/kg bw/day in the inhalation study and 5/25 mg/kg bw/day in the 90-day oral study. A target MOE of 300 was based on standard uncertainty factors (10-fold for interspecies variation, 10-fold for intraspecies variation), with an additional 3-fold safety factor to account for potential sensitivity to the young noted in a rabbit developmental toxicity study and for extrapolating from a short-term study to a longer term scenario. This assessment is protective of all populations including females of child-bearing age (females 13–50 years).

The aggregate MOEs and cancer risks are below the level of concern. Aggregate MOEs, based on dietary and inhalation exposures only, for adults, youths and toddlers were above the target of 300; therefore, they are not considered to be of concern. Aggregate DWLOCs calculated for the intermediate-term risk assessment were 250, 325 and 517 µg/L for toddlers, youths and adults, respectively. The corresponding EECs are less than the aggregate DWLOCs; therefore, they are not of concern. The cancer risk from aggregate exposure (dietary and inhalation only) was less than 1×10^{-6}. Because inhalation exposure to the total aggregate exposure was so low as to be negligible when calculating the LADD, the DWLOC for aggregate cancer risk would essentially be the same as when calculated with dietary exposure only (see Section 3.3.3).

4.0 Environmental Assessment

In assessing the environmental risk of triallate, a deterministic approach was used for the screening level assessment. In this standard PMRA approach, risk was characterized by the quotient method, the ratio of the estimated environmental concentration to the effects endpoint of concern. Risk quotient (RQ) values less than one are considered indicative of a low risk of adverse effects on non-target organisms, whereas values greater than one are considered to indicate that some degree of risk exists.

Initial and cumulative EECs were calculated for soil, water and wildlife food sources for the spray formulations of triallate. A range of application rates from high to low were used to calculate the EECs along with the maximum number of applications and minimum intervals between applications. The cumulative EECs were estimated by adjusting the sum of the

applications for dissipation between applications using the time for 50% decline (DT_{50}) for the appropriate environmental media. To assess the risk to aquatic organisms from runoff, concentrations of triallate were predicted using the Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM/EXAMS). Effects endpoints included both acute and chronic, where chosen from the available toxicity studies. Effects endpoints, chosen from the most sensitive species, were used as surrogates for the wide range of species that can be potentially exposed following treatment with triallate.

Granular formulations of triallate were also assessed. The calculated EECs were based on the concentrations of active ingredient in a granule. These granular formulations provide a unique exposure scenario as birds may consume granules as grit to aid in digestion of food. In this assessment the number of granules required to reach the lethal dose to 50% (LD_{50})for a particular size of bird and the number of granules available per m^2 were compared to determine risk.

Air monitoring data for triallate were provided by Environment Canada (Waite et al. 2005, Environment Canada 2004). These data were used for an inhalation risk assessment as the EEC in calculating the RQ. Because air quality monitoring data does not distinguish between formulation type, the RQ calculated apply to both the spray and granular formulations.

Refinements were made to the aquatic screening level assessment. Using the aquatic EEC refinements a simple probabilistic approach was taken to further assess the risk to those species groups for which a risk from runoff was identified in the aquatic environment. This approach determined the probability of the predicted EECs in runoff exceeding the effects endpoint of concern. Distributions of EECs were generated from multiyear annual peak, maximum yearly 96-h, 21-d, 60-d rolling averages predicted by PRZM/EXAMS using Crystal Ball 2000. A mathematical fit was performed to determine the set of parameters for each distribution that best describe the characteristics of the data. The Kolmogorov-Smirnov method was used to judge the quality or goodness of fit of each probability distribution. The distribution with the highest ranking fit was chosen to represent the data. The chosen probability distribution was then used as the basis of the Monte Carlo simulation. The Monte Carlo analysis uses the parameters of the chosen probability distribution to generate a range of possible results (20 000 trials) for the chosen probability distribution. Using this generated probability distribution of concentrations, it is then possible to calculate the proportion of EECs which will exceed the specified effects endpoint concentration.

4.1 Environmental Fate

The physicochemical properties indicate that triallate has low solubility (4 mg/L at 25°C) and has the potential to bioaccumulate (USEPA 1975) (log K_{ow} = 4.55). The potential to bioaccumulate was supported by the results of a fish bioconcentration factor (BCF) study (BCF's of 700 in edible tissue, 2700 in visera and 1600 in whole fish). The depuration of triallate from fish is relatively quick (> 90% within 14 days following the end of the exposure); therefore, bioconcentration will only occur in situations with continued or repeated exposure.

The vapour pressure (1.2×10^{-4} mm Hg) and the Henry's law constant (1.2×10^{-5} atm m^3/mol) indicate that triallate is volatile and likely to volatilize from water and moist soil (Kennedy and Talbert 1977, USEPA 1975b). This conclusion is supported by environmental fate studies in which high rates of volatilization of triallate were observed and by monitoring studies which show triallate detection in air samples within Canada.

Two laboratory volatilization studies and one field volatilization study confirm that triallate volatilizes following application to soil. In one laboratory study, 39 to 51.6% of the triallate applied as an EC formulation and mixed with a sand soil, maintained at 25°C, volatilized over a 30-day period. The volatilization in this study did not reach a plateau. In an additional laboratory study using triallate in the granular formulation, volatilization increased with temperature. At 4°C, 6.1% volatilized versus 30.7% at 20°C, which is similar to the rate for the EC formulation. In this study, it was noted that volatilization of triallate decreased in soil with lower moisture levels and higher organic matter. Based on these laboratory volatilization studies, differences in volatilization rates between the two formulations of triallate are negligible.

A field volatilization study conducted with the granular formulation of triallate confirmed that triallate volatilizes under field conditions. At study termination, 28 days, 21% of the applied triallate had volatilized from the treated field. Within the first 7 days, 15% of the applied triallate volatilized, which represented 71% of the total triallate that volatilized. Consistent with laboratory studies the volatilization was enhanced with precipitation. It was noted that the amount of volatilization was highest closest to the application and decreased with time. This decrease may have been a result of increased adsorption of triallate to soil organic matter.

Air sampling conducted by Environment Canada in the Canadian Prairies, the area of Canada where triallate is primarily used, resulted in a confirmation of the potential for triallate to volatilize. Ten currently used herbicides were analyzed in this study, with triallate being detected at higher frequency and concentration than the other herbicides (Waite et al. 2005). The sampling was conducted in a north-south transect in Saskatchewan in order to sample areas of higher and low agriculture activity. The concentrations of triallate increased in the southern sampling sites at areas of more intense agricultural activity during all sampling weeks. At one sampling site (Bratt's Lake) air samplers were set up at three heights (1 m, 10 m and 30 m). The highest concentrations of triallate were always detected at the 1-m elevation and decreased with increasing elevation although, triallate was still detected at 30-m elevation. The results of this study indicate that local application of triallate highly influence the detection in air samples. The highest concentrations (15.4 ng/m^3–1-m height; 8.95 ng/m^3–10-m height; 4.55 ng/m^3–30-m height) of triallate was detected in 2004, during the week of June 2nd (Environment Canada 2004). Application of triallate in the prairie provinces typically occurs between the last week of April to the last week of May (Saskatchewan Agriculture, Food and Rural Revitalization 2003 and 2004 *Final Crop Report*).

Atmospheric loading of triallate in the prairies was determined by Environment Canada and was calculated to be 603, 1430 and 1214 kg for 2002, 2003 and 2004, respectively (Environment Canada 2004) during the week of the maximum detected concentration. These amounts of triallate were estimated using a hemi-ellipsoid model that encompasses the prairie provinces and contains an air volume of 439 879 km^3. The hemi-ellipsoid area included an east-west transect of 1400 km, a north-south transect of 600 km and a height of 1 km (Waite et al. 2005).

This evidence of volatilization suggests that triallate is available for redeposition from atmospheric sources and may result in the presence of triallate in areas not subject to use of this active ingredient.

Triallate dissipation from the terrestrial and aquatic environments is not likely to be affected greatly by abiotic transformation. Available laboratory studies indicate that triallate was stable to hydrolysis and phototransformation. Laboratory biotransformation studies indicate that triallate is slightly to moderately persistent in both the terrestrial (half-time = 18–62 d) and aquatic (half-time = 14–46 d) environment. The dissipation times determined in these studies included both biotransformation and volatilization and were dependent on the temperature. At lower temperatures, the dissipation was decreased, which was attributed to a decrease in volatilization of triallate. Dissipation of triallate from water in the presence of sediment increased as a result of adsorption to the sediment. The major transformation product identified was carbon dioxide, and TCPSA was identified as a minor transformation product. A DT_{50} under anaerobic conditions was not available. TCPSA has been identified as a residue of concern with regard to human health.

Terrestrial field dissipation studies conducted in the states of South Dakota, North Dakota, Idaho, Montana and Washington demonstrate that triallate is classified as slightly persistent to persistent (DT_{50} = 20–190 d), depending on where the study was carried out. The variation in the DT_{50}s at the different sites may be related to the extent to which volatilization is favoured, which can be influenced by soil moisture content, temperature, wind, etc.

An adsorption study indicated that triallate has high adsorption (K_{oc} = 1305–2377); therefore, triallate has a low potential to contaminate groundwater sources. An aged soil leaching study detected 7% of the applied radioactivity in the leachate although the residues were not identified. In an unaged leaching study 1.9–2.5% of the applied radioactivity was detected in the leachate. Although not identified, it is suspected that these residues were TCPSA. Using a longest soil half-life (62 d) and the lowest K_{oc} (1305) a groundwater ubiquity score (GUS) score of 1.6 was calculated which indicates that triallate is a non-leacher (Gustafson 1989). Despite triallate being identified as a non-leacher, it was detected in one groundwater study conducted in Canada (Waite et al. 1992). This study indicated a maximum concentration of 0.63 µg a.i./L and a detection frequency of 7%. Thus, the PMRA concludes that, under conditions that promote leaching, there is a potential that triallate may reach groundwater sources.

4.2 Environmental Toxicology

Acute toxicity studies for honeybees reported LD_{50} and lethal concentration to 50% (LC_{50}) of > 25 µg a.i./bee and > 1000 µg a.i./kg diet, respectively. A LC_{50} of 549 mg a.i./kg soil was reported following acute exposure of earthworms (*Eisenia foetida*) to triallate. A study investigating the reproduction of earthworms indicated that effects on earthworm reproduction are unlikely to occur at soil concentrations less than 1.9 mg a.i./kg soil. For birds species acute toxicity studies reported an acute oral LD_{50} of 2251 mg a.i./kg bw and a dietary LC_{50} = > 5620 mg a.i./kg diet. Effects on reproduction in birds were not observed at dietary concentrations of 500 mg a.i./kg diet or less. Avian inhalation data are not available. Acute toxicity testing with mammals reported LD_{50}s ranging from 1100 to 3455 mg a.i./kg bw. Effects on reproduction of mammals were not observed at dietary concentrations of 150 mg a.i./kg diet or less. A 7-week mammalian inhalation study reported a NOAEL of 1.96 mg/kg bw/day based on a number of subchronic endpoints including hyperactivity, swollen conjunctive, rapid and/or laboured breathing and salivation. Given the lack of inhalation toxicity data for birds, this mammalian inhalation endpoint will be considered in the inhalation risk assessment for birds.

With the exception of the crop species ryegrass, oat and cucurbit related species, toxicity to terrestrial plants appears to be low with effect concentrations resulting in 25% reduction (EC_{25}) ranging from 257 to 1681 g a.i./ha. The most sensitive plant species tested was oats, with an EC_{25} of 22 g a.i./ha for seedling emergence and 37 g a.i./ha for vegetative vigour.

Acute toxicity studies for aquatic invertebrates reported LC_{50}s of 91 to 430 µg a.i./L. There appears to be no difference in the toxicity of the formulated product and the technical active ingredient to freshwater invertebrates. Chronic effects to freshwater invertebrates were not observed at water concentrations of 13 µg a.i./L or less. LC_{50}s ranging from 698 to 1300 µg a.i./L were reported in acute toxicity studies for freshwater fish. Chronic effects in freshwater fish were not observed at concentrations of 38 µg a.i./L or less. No data were available to assess the toxicity of triallate to estuarine and marine invertebrates and fish, and data on the toxicity are required unless the use is restricted to the prairies provinces thus, eliminating the potential exposure for estuarine and marine organisms. A no observed effect concentration (NOEC) for freshwater algae of 12.5 µg a.i./L and the EC_{25} for aquatic vascular plants of > 10 000 µg a.i./L were available (Fairchild et al. 1997).

4.3 Estimated Environmental Concentrations

4.3.1 Terrestrial

Table 4.3.1.1 summarizes the terrestrial EECs used in the current assessment. The EEC of triallate on soil was calculated based on a soil density of 1.5 g/cm^3, soil depth of 15 cm, and a range of Canadian label rates. The EECs of triallate on food sources that may be ingested by wild mammals and birds were estimated based on correlations in Hoeger and Kenaga (1972) as modified by Fletcher et al. (1994) using the range of Canadian label rates for each use.

Table 4.3.1.1 Estimated Environmental Concentrations Used in Risk Assessment

Application Rate (g a.i./ha)	Soil (mg a.i./kg soil)	EEC in Diet (mg a.i./kg diet)		
		Bobwhite Quail	Mallard Duck	Rat
2200	0.98	385.2	74.4	1109.9
1700	0.76	297.6	57.5	857.6
1400	0.62	245.1	47.4	706.3

4.3.2 Aquatic

4.3.2.1 Drinking Water

The Level 1 concentration of triallate in drinking water was estimated using PRZM/EXAMS for surface water and the Leaching Estimation and Chemistry Model (LEACHM) for groundwater (PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*). EECs in drinking water were determined by modelling the highest application rate of 2.2 kg a.i./ha applied once a year using scenarios specific to the prairie provinces, which is the major triallate Canadian use area. There are two major sources for surface drinking water in Canada, reservoirs and dugouts, EECs were calculated for both. The acute and chronic EEC determined for reservoirs were 16.4 µg/L and 2.9 µg/L, respectively. For dugouts, the acute and chronic EECs were 21.0 µg/L and 3.7 µg/L, respectively. Some communities in Canada obtain their drinking water from groundwater; therefore, the PMRA also estimated Level 2 EECs for groundwater. The acute and chronic EECs for groundwater are presented in Table 4.3.2.1.1.

The available monitoring data were considered while determining the potential exposure to triallate in drinking water in Canada. Detections of triallate were reported in groundwater and surface water in the prairie provinces, the main use area of triallate (Environment Canada 2005; Saskatchewan Environment and Resource Management 2002; Alberta Environment 2002; Grover et al. 1997; National Contaminants Information System 2002; Alberta Environment Protection 2001; Anderson et al. 1998). In some instances, detections were in known drinking water sources. The available monitoring data did not include analysis of the triallate transformation product, TCPSA, which was identified as a residue of concern by the USEPA's Health Effects Division. A drinking water monitoring study that included the analysis of TCPSA was conducted by the registrant in the United States and was considered in this assessment. The concentrations from the monitoring data are presented in Table 4.3.2.1.1. Concentrations of triallate reported in groundwater from one monitoring study (Waite et al. 1992) are higher than the concentrations predicted by the models for groundwater. The model does not take into consideration preferential flow or particularly shallow water tables. In some instances, depending on the vulnerability of aquifer, detections of pesticides may be possible even though not predicted by models.

The modelling results for surface water are one to two orders of magnitude higher than the monitoring. Predicted concentrations of triallate are for a receiving water body (reservoir or dugout) adjacent to the treatment field. The predicted concentrations in surface water are modelled assuming yearly application to the same drainage area for 20 years. This differs from water surveillance data in that the samples are likely to be taken some distance downstream from the treatment field, which will result in time for adsorption, volatilization and dilution of the concentration. The detectable levels of a particular pesticide are determined by a number of factors including timing of application and runoff events in relation to sampling activities. Unless sampling is event based, it is unlikely that samples will coincide with peak concentrations. The inclusion of the drinking water monitoring study from the United States increased the PMRA's confidence in the water surveillance data as the triallate transformation product, TCPSA, was monitored in this study.

Table 4.3.2.1.1 Upper and Lower Bound Concentrations Estimated From Models and Monitoring Data

		Groundwater		Surface Water			
		Acute Concentration (µg/L)	Chronic Concentration (µg/L)	Acute Concentration (µg/L)		Chronic Concentration (µg/L)	
				Reservoirs	Dugouts	Reservoirs	Dugouts
Upper bound (models)		0.001 ¶	0.001 ‡	16.4 †	21.0 †	2.9 ‡	3.7 ‡
Lower bound (monitoring)	**Triallate**	0.6 §	0.2 °	1.2 **		0.09 *	
	TCPSA	N/A	N/A	0.45 ** (United States drinking water monitoring study)		0.08 * (United States drinking water monitoring study)	
	Triallate + TCPSA	N/A	N/A	1.1***		0.09 ***	

* 95th percentile of the mean concentration for each study site including ½ level of concern for non-detects

** 95th percentile of the maximum detected concentrations from surface water monitoring studies

*** 95th percentile of triallate and TCPSA concentrations (acute—maximum concentrations; chronic—average concentrations)

§ Maximum detected value taken from one groundwater monitoring study

° Arithmetic mean of all samples (including ½ the limits of detection) from one groundwater monitoring study

¶ 90th percentile of daily average concentration predicted by LEACHM

† 90th percentile of the annual peak concentrations predicted by PRZM/EXAMS

‡ 90th percentile of the annual average concentrations predicted by PRZM/EXAMS for surface water and LEACHM for groundwater

4.3.2.2 Aquatic Ecosystems

Screening Scenario

Screening level EECs for triallate in water were calculated assuming a reasonable worse-case scenario of a direct application into a body of water 30-cm deep, where the pesticide is assumed to be instantaneously and completely mixed within the water body. Screening EECs, immediately following one application, were calculated for a variety of application rates spanning the use pattern for triallate. The EECs are presented in Table 4.3.2.2.1.

Table 4.3.2.2.1 Expected Environmental Concentrations in Water (30-cm deep) as a Result of Direct Application From the Application Field

Application Rate (g a.i./ha)	EEC (µg a.i./L)
2200	**733.3**
1700	566.7
1400	466.7

Runoff Model Results

Concentrations of triallate in a one-hectare receiving water body with an average EXAMS depth of 0.8 m (equivalent to 1.25-m deep parabolic shaped pond) and a 10-ha drainage area were estimated using PRZM/EXAMS (Table 4.3.2.2.2). The EECs of triallate in surface water were calculated using a multiyear period (20–81 years), which simulate pesticide transport from a field into an adjacent water body and the fate of a pesticide within that water body. For the modelling, it is assumed that triallate is applied yearly over the entire multiyear run. The model input parameters are provided in Appendix V.

Table 4.3.2.2.2 Predicted Triallate Runoff EECs in a Wetland of One Hectare

		Concentration (µg a.i./L)[a]					
		Peak	**96-h**	**21-day**	**60-day**	**90-day**	**Yearly Average**
Water	**Manitoba**	14.6	12.2	8.0	6.5	6.2	4.7
	Saskatchewan	22.5	17.5	10.5	7.1	6.4	4.5

[a] Concentrations represent the 90th percentile of the highest yearly EECs predicted at the times identified.

4.4 Terrestrial Risk Assessment

4.4.1 Emulsifiable Concentrate Formulation

Triallate does not pose a risk to bees and other pollinating insects. Negligible risk (RQ = 0.04–0.05) was identified on an acute oral basis for birds exposed to triallate whereas, a low risk (RQ = 0.5–0.8) was identified for chronic exposure. Given the volatile nature of triallate and the detections of triallate in air in the prairie provinces (Waite et al. 2005, Environment Canada 2004), the PMRA determined the risk to birds as a result of exposure via inhalation. The PMRA does not routinely receive inhalation toxicity data for birds; therefore, a toxicity endpoint for birds was estimated using the mammalian inhalation exposure data. Using the highest detected concentration of 15.4 ng/m^3 (Environment Canada 2004) the risk from inhalation to birds is negligible (RQ = 1.7×10^{-7}).

Using an exposure scenario that assumes 100% of an organism diet consists of food from treated fields, a moderate risk to small mammals was identified for both acute (RQ = 1.1–1.7) and chronic (RQ = 4.7–7.4) effects. Given that triallate is used as a pre-emergence herbicide, it is unlikely there would be enough food sources available to attract small wild mammals to the field. As a result, it is unlikely that small wild mammals would feed on 100% contaminated diet. Therefore, the PMRA concludes that small wild mammals are not at risk of acute effects from consumption of food contaminated with triallate. Even though the calculated RQ for chronic exposure indicates a moderate risk, it is unlikely that small wild mammals would be exposed to triallate at the concentrations predicted on food sources chronically. Triallate is applied once per year and is classified as slightly to moderately persistent in soil, dependent on the temperature. Therefore, the PMRA concludes that the chronic risk to small wild mammals is low. Using the 7-week whole body exposure inhalation study (NOAEL = 1.96 mg a.i./kg bw/day) and the highest detected concentration of 15.4 ng/m^3 (Environment Canada 2004) the risk to small wild mammals from inhalation of volatilized triallate is negligible (RQ = 1.6×10^{-5}).

Non-target plants can be exposed to triallate via spray drift. A high to very high risk was identified for non-target terrestrial plants (using the most sensitive crop species (oats) as a surrogate for sensitive non-target plants) from exposure to triallate (RQ = 64–100, depending of the application rate). The potential for effects resulting from drift was examined by determining the percent of the application rate that is required to reach the threshold of effects for terrestrial plants (EC_{25} = 22 g a.i./ha). Values < 100% indicate mitigation by buffer zones may be required in order to protect the most sensitive terrestrial plant species. For triallate, 0.5 to 0.7% of the application rate is required to reach the threshold of effects for the most sensitive species.

There is a potential exposure to terrestrial plants from off target atmospheric transfer due to volatilization and re-deposition. The potential risk to non-target terrestrial plants was calculated by using concentrations in rainfall and dry deposition determined by Waite et al. (2005). The maximum concentration detected in rain fall was 20 ng/L. In order to determine if this concentration could potentially pose a risk to terrestrial non-target plants, the 20-year maximum measured rainfall in Regina was used in order to convert the concentration in rainfall to an equivalent application rate (0.027 g a.i./ha). When compared to the threshold of effects (22 g a.i./ha) it was determined that there is negligible risk (RQ = 0.001) of adverse effects

resulting from re-deposition of triallate in rain. In order to exceed the threshold of effects it would require 837 days of continuous rain with the concentration of 20 ng/L. The maximum concentration of triallate determined in the dry deposition samples reported by Waite et al. (2005) was 2455 ng/m^2/day. Using this information, it was determined that this amount of triallate falling on one hectare of land would be equivalent to an application rate of 0.025 g a.i./ha. When compared to the threshold of effects for non-target terrestrial plants (EC_{25} = 22 g a.i./ha) it was determined that non-target terrestrial plants are at negligible risk (RQ = 0.001) from concentrations of triallate determined in dry deposition.

4.4.2 Granular Formulation

Granular forms of pesticides pose a unique risk to wildlife as the granules can be directly consumed by organisms. This usually occurs when organisms mistake granules as food sources, inadvertently consuming the granules attached to other food sources or in the case of birds consuming the granules as grit. The risk assessment determined negligible to low risk of acute effects to wild birds and mammals. It was determined that an individual would need to consume a large number of granules in order for adverse effects to occur (189 169 granules for birds; 76 230 granules for small wild mammals). The laboratory volatilization studies indicate that the rate of volatilization is not affected by the formulation type. The application rate for the spray and granular formulations is the same; therefore, the results of the inhalation risk assessment for the spray formulation apply to the granular formulation. There is negligible risk to birds and small mammals from inhalation of volatilized triallate.

Similarly, the exposure of non-target terrestrial plants/habitats from off-target transfer of volatilized triallate from the granular form may occur. The rate of volatilization is not affected by the formulation type; therefore, the risk assessment of the volatilized triallate from the emulsifiable concentrate applies to the granular formulation. There is negligible risk to non-target terrestrial plants from volatilized triallate.

Insufficient data (fertilizer granule size, granule size distribution and % a.i. per granule) was available to assess the risk from triallate emulsifiable concentrate blended with fertilizer granules. Therefore, a risk assessment for this use was not completed. It is assumed that the calculated risk from this pesticide-fertilizer combinations will be similar to the granular form of triallate therefore, based on this information it is assumed that the potential risk to birds, mammals and non-target plants will be negligible. If this use is to be maintained on the product labels, information on the fertilizer granule size and distribution are required in order to confirm that a risk to birds and mammals does not exist.

4.5 Aquatic Risk Assessment

4.5.1 Freshwater

The aquatic screening level assessment indicated that the threshold of effects was exceeded for freshwater invertebrates, fish and plants based on screening level EECs. A refined assessment was done to characterize the potential risk from drift and runoff.

The potential for effects resulting from drift was examined by determining the percent of the application rate that is required to reach the threshold of effects. For the most sensitive aquatic species (*Selenastrum capricornutum*) drift of 1.7 to 2.6% of the spray application rate, depending on the application rate, would result in aquatic concentrations that exceed the threshold of effects (NOEC = 12.5 µg a.i./L). Therefore, spray drift of triallate to aquatic environments poses a potential risk to aquatic organisms, and mitigation with buffer zones may be required.

Refined EECs for runoff were predicted by PRZM/EXAMS using a scenario that represents the use pattern of triallate in the prairies. The concentrations predicted represent EECs that would occur in a 1-ha edge of field receiving water body that is 0.8-m deep. The refined assessment indicated a low risk for freshwater invertebrates (RQ = 0.4) and freshwater fish (RQ = 0.14). A moderate risk (RQ = 1.4) was identified for algae.

This was further refined using a simple probabilistic approach to determine the probability of the predicted EECs from runoff exceeding the NOEC for freshwater aquatic plants. The EEC probability distributions in surface water resulting from runoff for the 96-h values generated by Monte Carlo simulations using the PRZM/EXAMS output indicate there is a 10.5% chance of exceeding the NOEC for freshwater acute plants. Given that algae are resilient and are capable of recovering from such an impact, the PMRA concludes that the risk to freshwater algae from runoff of triallate following application is low.

Detections of triallate in air and rain indicate there is a possibility of redeposition of this active into non-target bodies of water. In order to assess the potential risk to non-target aquatic plants, it was assumed that the concentration in a 30-cm deep, 1-ha pond was equivalent to the maximum concentration detected in rain (20 µg a.i./L). This is a conservative scenario that assumes the pond is filled completely with rain water. When compared to the threshold of concern (NOEC = 12.5 µg a.i./L), non-target aquatic plants are at negligible risk (RQ = 0.002) from exposure to volatilized triallate redeposited in rain.

4.5.2 Marine/Estuarine

Data on toxicity were not available to assess the risk of triallate exposure to marine and estuarine organisms. These data are required unless the use of triallate is restricted to the prairie provinces where there is no possibility of estuarine and marine systems being exposed.

4.6 Environmental Assessment Conclusions

The environmental risk assessment indicates triallate exposure to wild birds, small wild mammals, freshwater fish and freshwater invertebrates poses a negligible risk of adverse effects. A risk was identified to terrestrial and freshwater plants from drift of triallate into non-target areas. Mitigation of effects resulting from drift can be achieved through buffer zones (see Section 4.7). A refined assessment of risk to aquatic plants indicated that the risk from runoff would be low and would not be a concern.

Based on the current assessment, the PMRA has not identified a risk to non-target organisms resulting from loadings to the atmosphere, primarily as the result of volatilization, and subsequent redeposition to terrestrial and aquatic ecosystems as either dry deposition or in rainfall. Redeposition of triallate from atmospheric sources may result in the presence of triallate in areas where it is not used. Although the agricultural use of triallate results in triallate emissions into the atmosphere through volatilization, the current methods of assessment have identified negligible risk to the environment from the atmospheric loading resulting from the current use profile.

4.7 Environmental Risk Mitigation

4.7.1 Buffer Zones

Emulsifiable Concentrate
The buffer zones for aquatic environments were calculated using the NOEC of 12.5 µg a.i./L for *Selenastrum capricornutum*, the most sensitive non-target aquatic freshwater species, based on available data. Buffer zones for the terrestrial environments were calculated using the EC_{25} for Oat of 22 g a.i./ha, the most sensitive terrestrial plant species, based on available data. Spray drift information from Wolf and Caldwell (2001) was used to calculate the buffer zones for ground applications on field crops. Buffer zones were calculated for 3 water body depths (< 1m, 1–3 m, 3 m). The applicator will be required to determine the depth of the body of water adjacent to the treatment field prior to application and apply the appropriate buffer zone. The listed ground buffer zones can be reduced by 70% with the use of shrouds and 30% with the use of cones. The resulting buffer zones calculated are listed in Appendix VI. For triallate products coformulated with another active ingredient that has not been re-evaluated, the buffer zones for triallate must be observed until the coformulant(s) are reviewed. If buffer zones are determined for the coformulant to be larger than those for triallate then the product label will be modified at that time to reflect the more restrictive buffer zone.

Granular Formulation
Drift of granules is minimal; therefore, buffer zones for granular formulations are not required.

4.7.2 Volatilization

Triallate was determined to volatilize and has been detected in air, rain and dry deposition in the prairie provinces. Volatilization of triallate is dependent upon two factors, the soil temperature and moisture. The most effective way of decreasing the volatilization rate of a pesticide is to ensure it is incorporated into the soil as quickly as possible following application. Even though no risk was identified from concentrations of triallate detected in air primarily as a result of volatilization, atmospheric transport and the subsequent redeposition of triallate from atmospheric sources may result in the presence of triallate, in areas not subject to use of the active ingredient. To reduce the atmospheric loading of triallate efforts should be made to reduce the volatilization. This can be achieved by doing the following:

- incorporation into the soil concurrently with application; and

- application should occur when soil temperatures are less than 4°C or less as indicated on the current label.

4.7.3 Runoff

Evidence of surface water contamination was identified by water surveillance data along with predicted EECs in water by PRZM/EXAMS. As a result a statement must be added to each end-use product label warning of the potential for runoff.

4.7.4 Leaching

Although, the leaching potential of triallate based on results of laboratory studies was identified as low, detections of triallate in groundwater indicate that leaching of triallate may occur under specific conditions. Therefore, a statement must be added to each end-use product label warning of the potential for leaching.

5.0 Value

5.1 Commercial and/or Restricted Class Products

All triallate uses are supported by the registrant. No uses have risk concerns after consideration of mitigation measures. Consequently, no alternatives to the use of triallate were listed.

5.2 Domestic Class Products

There are no Domestic Class products containing triallate.

5.3 Value of Triallate

Triallate controls one of the most troublesome weeds, wild oats, in several major crops including wheat (spring and durum), barley, rapeseed (including canola), flax, dry peas, mustard, sugar beets, and canary seed. It is the only selective herbicide registered for use on canary seed for the control of wild oats (another product registered for the same use, difenzoquat, was discontinued in 2006). Triallate can be coformulated or tank-mixed with other herbicides to broaden weed control spectrums. Although populations of triallate-resistant wild oats have been identified in Canada, triallate can be readily used in rotation with other herbicide groups including Group 1, 2, 3, 9, 10, 11 or 16 to mitigate resistance development in wild oats populations. The mode of action of triallate plays a role in managing resistance development to other herbicide groups.

6.0 Other Assessment Considerations

6.1 Toxic Substances Management Policy

During the review of triallate, the PMRA has taken into account the federal Toxic Substances Management Policy[2] and has followed its Regulatory Directive DIR99-03[3]. It has been determined that this active ingredient does not meet the TSMP Track 1 criteria for the following reasons.

- The log *n*-octanol–water partition coefficient (log K_{ow}) of triallate is 4.55, which is below the TSMP Track 1 cut-off criterion of log $K_{ow} \geq 5.0$.

- Triallate does not meet the criteria for persistence as its DT_{50} values in water (4–25 days), and soil (18–62 days) are below the TSMP Track 1 cut-off criteria for water (≥ 182 days), sediment (≥182 days) and soil (≥ 182 days). No data were provided for persistence of triallate in air.

- The toxicity of triallate is described in Sections 3.0 and 4.0.

- The major transformation product, CO_2, does not meet TSMP Track 1 criteria.

- Based on the chemical structure of triallate it is not expected to be contaminated with TSMP Track 1 contaminants. Triallate may be contaminated with di-iso-propylnitrosamine. However, based on historical data submitted to the PMRA this contaminant was not detected at a detection limit of 0.02 ppm.

6.2 Formulant Issues

Formulants issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Program and Implementation Guidance Document*, published on 31 May 2006.

7.0 Proposed Regulatory Actions

The PMRA is proposing that the use of triallate and its end-use products are acceptable for continued registration, with the implementation of additional risk-mitigation measures to further protect workers and the environment.

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[2] The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics.

[3] Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca; or through our website at www.pmra-arla.gc.ca.

All proposed label amendments for the uses of triallate products proposed for continuing registration are presented in Appendix VI.

7.1 Proposed Regulatory Actions Relating to Human Health

The PMRA has determined that the worker application and postapplication risks are acceptable when using granular formulations. When using emulsifiable concentrate formulations, including for fertilizer admixture, the calculated MOEs are less than the target MOEs.

7.1.1 Proposals Pertaining to Mixer/Loader/Applicator and Postapplication Exposure

For EC formulations in agricultural field scenarios, mitigation could be achieved by limiting the amount handled per day to 189 kg a.i./day and requiring closed mix/load systems and application with a closed cab (see Appendix VI).

For EC fertilizer admixture scenarios, mitigation is not possible. Exposure data specific to this scenario are required, and acceptable risk must be demonstrated or these uses need to be removed from the labels.

For granular formulations, mitigation could be achieved by requiring chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear to be worn during mixing, loading, application, clean-up and repair. In addition, a respirator must be worn during mixing, loading, clean-up and repair activities (see Appendix VI).

For aerial application of granular formulations, human flaggers are not permitted.

A restricted-entry interval of 12 hours is required for all formulations.

7.1.2 Residue of Concern Definition

The residue of concern for triallate is defined as triallate and its metabolite 2,3,3-trichloroprop-2-enesulfonic acid (TCPSA).

7.1.3 Maximum Residue Limits of Triallate in Food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian maximum residue limits (MRLs) and to remove MRLs that are no longer supported. The Agency recognizes, however, that interested parties may want to retain an MRL in the absence of a Canadian registration to allow legal importation of treated commodities into Canada. The PMRA requires similar chemistry and toxicology data for such import MRLs as those required to support Canadian food use registrations. In addition, the PMRA requires residue data representative of use conditions in exporting countries, in the same manner that representative residue data are required to support domestic use of the pesticide. These requirements are necessary so that the Agency may determine whether the requested MRLs are needed and to ensure they would not result in unacceptable health risks.

Where no specific MRL for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for enforcement purposes.

The food uses of triallate supported by the registrant are barley, wheat, dry peas, flax, mustard, rapeseed and sugar beets. Currently, residues of triallate in all agricultural commodities, including those approved for treatment in Canada, are regulated by subsection B.15.002(1). However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

7.2 Proposed Regulatory Actions Relating to Environment

Terrestrial and aquatic buffer zones for emulsifiable concentrate formulation are proposed (see Appendix VI).

8.0 Data Requirements

8.1 Data Requirements Related to the Occupational Exposure Assessment

Should the registrant wish to maintain registration of the fertilizer admixture scenarios, the following data would be required as condition for continued registration:

- DACO 5.2 Use Description/Scenario (including extent of use)
- DACO 5.4/5.5 Mixer/Loader/Applicator—Passive Dosimetry Data or Biological Monitoring Data

8.2 Data Requirements Related to the Dietary Exposure Assessment

Sufficient data are available to assess the dietary risks from the existing use pattern; however, additional data may be required to support any expansion of use.

8.3 Data Requirements Relating to Environmental Risks

If triallate will continue to be blended with fertilizer granules, the following data would be required as condition for continued registration.

- Data on the mass of a single granule and size distribution of the fertilizer granules that can be impregnated with triallate, to confirm no risk to birds and mammals from this use.

The following data are also required if the use continues to be not restricted to the prairie provinces.

- DACO 9.4.2 Estuarine/marine invertebrate toxicity (not required if use restricted to prairie provinces)
- DACO 9.5.2.4 Estuarine/marine fish toxicity (not required if use restricted to prairie provinces)
- DACO 9.8.3 Estuarine/marine algae toxicity (not required if use restricted to prairie provinces)

9.0 Proposed Re-evaluation Decision

The PMRA has re-evaluated the available information on the active ingredient triallate and the associated end-uses on food and non-food areas. The PMRA is proposing that the use of triallate and its end-use products is acceptable for continued registration, with the implementation of additional mitigation measures to further protect workers and the environment. Additional data are required as condition for continued registration if triallate continues to be blended with fertilizer granules.

List of Abbreviations

µg	microgram(s)
ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
ASABE	American Society of Agricultural and Biological Engineers
atm	atmospheres
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
CSFII	Continuing Survey of Food Intake by Individuals
d	day
DACO	data code
DEEM	Dietary Exposure Evaluation Model
DT_{50}	dissipation time to 50%
DWLOC	drinking water level of comparison
DNA	deoxyribonucleic acid
DRA	dietary risk assessment
EC	emulsifiable concentrate
EC_{25}	effect concentration resulting in 25% reduction
EEC	expected environmental concentration
EXAMS	Exposure Analysis Modeling System
FCID	Food Commodity Intake Database
g	gram(s)
GR	granular
GUS	groundwater ubiquity score
h	hour
ha	hectare(s)
Hg	mercury
IUPAC	International Union of Pure and Applied Chemistry
K_d	adsorption coefficient
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	octanol–water partition coefficient
L	litre(s)
LADD	lifetime average daily dose
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LEACHM	Leaching Estimation and Chemistry Model
LOAEL	lowest observed adverse effect level
m	metre(s)
m^3	metre(s) cubed
mg	milligram(s)
mm	millimetre(s)
mm Hg	millimetre(s) mercury

MOE	margin of exposure
N/A	not applicable
ng	nanogram(s)
nm	nanometre
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRZM	Pesticide Root Zone Model
Q_1*	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RQ	risk quotient
SF	safety factor
TCPSA	2,3,3-trichloro-2-propenesulfinic acid
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USC	Use-Site Category
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration
UV	ultraviolet

Appendix I Triallate Products Currently Registered (excluding discontinued products or products with a submission for discontinuation) as of 28 March 2007

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee	
					Triallate	Trifluralin
19203	Technical	Gowan Company LLC	Triallate Technical	Solid	96%	—
8167	Commercial		Avadex BW Herbicide Emulsifiable Concentrate	Emulsifiable Concentrate	400 g/L	—
16759	Commercial		Extra Strength Avadex BW Herbicide	Emulsifiable Concentrate	480 g/L	—
19521	Commercial		Fortress Herbicide	Granular	10%	4%
25112	Commercial		Avadex Microactiv Herbicide	Granular	10%	—
28120	Technical		Triallate Technical	Solid	96%	—

Appendix II Registered Commercial Class Canadian Uses of Triallate as of 1 March 2006[a]

Use-Site Category	Site(s)	Pest	Formulation Type	Application Methods and Equipment	Application Rate (kg a.i./ha)	Maximum Number of Applications Per Year[b]
13—Terrestrial Feed Crop	Canary seed (stated as Canary grass on the label)	Wild oats	Granular	Ground spreader, aerial application	1.10–1.70	1
13 and 14—Terrestrial Feed and Food Crops	Barley		Emusifiable Concentrate or Granular	Ground sprayer, ground spreader, aerial application (for granules only)	1.10–1.70	1
	Spring and durum wheat		Emusifiable Concentrate or Granular	Ground sprayer, ground spreader, aerial application (for granules only)	1.10–1.70	1
	Dry peas[c]		Emusifiable Concentrate	Ground sprayer	1.68–1.70	1
	Mustard		Emusifiable Concentrate or Granular	Ground sprayer, ground spreader, aerial application (for granules only)	1.39–2.21	1
	Sugar beets		Emusifiable Concentrate or Granular	Ground sprayer, ground spreader, aerial application (for granules only)	1.39–2.21	1
7, 13, 14—Industrial Oilseed Crops and Fibre Crops, Terrestrial Feed and Food Crops	Flax		Emusifiable Concentrate or Granular	Ground sprayer, ground spreader, aerial application (for granules only)	1.39–2.21	1
	Rapeseed (including canola)		Emusifiable Concentrate or Granular	Ground sprayer, ground spreader, aerial application (for granules only)	1.39–2.21	1

[a] All uses are supported by the registrant.

[b] This is not stated on the labels, but has been provided by the registrant (letter from Monsanto to the PMRA, 5 May 2003).

[c] EC formulation can also be sprayed on granular fertilizer that is going to be applied by means of a ground spreader.

Appendix III Toxicology Endpoints for Health Risk Assessment for Triallate

Exposure Scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE
Acute Dietary General Population	NOAEL = 60	Clinical signs neurotoxicity	Acute oral neurotoxicity—Rat	100
	ARfD = 0.06 mg/kg bw			
Acute Dietary Females 13–50	NOAEL = 5	Fused sternebrae—rabbit fetuses	Developmental Toxicity—Rabbit	300
	ARfD = 0.017 mg/kg bw			
Chronic Dietary	NOAEL = 2.5	Decreased body weight, reduced survival	Two-year dietary chronic / carcinogenicity—Rat	1000
	ADI = 0.0025 mg/kg bw/day			
Short-Term[a] Dermal[b] and Inhalation[b]	Oral NOAEL = 5	Fused sternebrae—rabbit fetuses	Developmental Toxicity—Rabbit	300
Intermediate-Term Inhalation[c]	Inhalation NOAEL = 1.96	Kidney toxicity	Inhalation toxicity—Rat	300
Aggregate[c] oral and inhalation	Oral NOAEL = 5 Inhalation NOAEL = 1.96	Kidney toxicity	Inhalation and 90-day oral toxicity—Rat	300
Cancer		Liver tumours in male mice	Two-year dietary chronic / carcinogenicity—Mouse	Q_1* = 7.17 × 10^{-2} (mg/kg bw/day)$^{-1}$

[a] Duration of exposure is > 1–30 days

[b] A dermal absorption factor of 20% and an inhalation absorption factor of 100% was used in route-to-route extrapolation to an oral NOAEL.

[c] Duration of exposure is 1–6 months

Appendix IV Summary of Occupational Risk Estimates for Triallate

Table 1 Mixer/Loader/Applicator: Exposure Estimates and Margins of Exposure (non-fertilizer admixture scenarios)

Crop	Formulation/ Application Method	Rate (kg a.i./ha)	Applicator	Area Treated (ha/day)	PPE/System[a]	Daily Exposure (µg/kg bw)		Margins of Exposure (MOE)		
						Dermal[b]	Inhalation[c]	Dermal[d]	Inhalation[d]	Combined[e]
Barley, wheat, dry peas	EC / groundboom	1.7	Farmer	100	Baseline PPE, closed mix/load, closed cab	14.57	0.41	343	12 111	334
			Custom	300		43.71	1.24	114	4037	111
Flax, mustard, rapeseed, canola		2.21	Farmer	100		18.94	0.54	264	9316	257
			Custom	300		56.83	1.61	88	3105	86
Sugar beets		2.21	Farmer	80		15.15	0.43	330	11 645	321
			Custom	300		56.83	1.61	88	3105	86
Barley, canary grass, wheat	Granular / solid broadcast spreader	1.7	Farmer	80	Maximum PPE, open mix/load, open cab	3.08	3.54	1625	1414	756
			Custom	130		5.00	5.75	1000	870	465
Flax, mustard, rapeseed, canola		2.2	Farmer	80		3.98	4.58	1255	1093	584
			Custom	130		6.47	7.44	773	672	360
Sugar beets		2.2	Farmer	80		3.98	4.58	1255	1093	584
			Custom	130		6.47	7.44	773	672	360
Barley, canary grass, wheat	Granular / aerial	1.7	Custom– m/l	400	Maximum PPE, open mix/load	7.81	2.14	640	2340	503
			Custom– appl.		Baseline, no gloves	18.77	0.68	266	7353	257
Flax, mustard, rapeseed, canola, sugar beets		2.2	Custom– m/l	400	Maximum PPE, open mix/load	10.11	2.77	495	1808	388
			Custom– appl.		Baseline, no gloves	24.29	0.88	206	5682	199

[a] Baseline PPE = long pants, a long-sleeved shirt and chemical-resistant gloves; no gloves during application. Maximum PPE = long pants, long-sleeved shirt chemical-resistant coveralls and chemical-resistant gloves; respirator worn during mix/load only.

[b] Where dermal exposure (µg/kg/day) = (unit exposure × area treated × rate)/70 kg bw * 20% dermal absorption

[c] Where inhalation exposure (µg/kg/day) = (unit exposure × area treated × rate)/70 kg bw

[d] Based on an oral NOAEL of 5 mg/kg/day; target MOE = 300

[e] Combined MOE = 5 mg/kg/day / (dermal exposure + inhalation exposure); target MOE = 300

Table 2 Mixer/Loader/Applicator: Exposure Estimates and Margins of Exposure for Fertilizer Admixture Scenarios

Crop	Formulation/ Application Method	Rate (kg a.i./ha)	Area Treated (ha/day)	PPE/System[a]	Daily Exposure (ug/kg bw)		Margins of Exposure		
					Dermal[b]	Inhalation[c]	Dermal[d]	Inhalation[d]	Combined[e]
On-Farm Treatment and Application Based on PHED Data									
Barley, wheat, dry peas	EC / solid broadcast spreader	1.7	65	Maximum PPE, open mix/load, open cab	10.42	2.78	480	1800	379
Flax, mustard, rapeseed, canola, sugar beets		2.2	65		13.54	3.61	369	1384	292
On-Farm Treatment and Application based on Fenske data (fertilizer admixture) and PHED data (solid broadcast spreader)									
Barley, wheat, dry peas	EC / solid broadcast spreader	1.7	65	Maximum PPE, open mix/load, open cab	1750.53	3.07	3	1628	3
Flax, mustard, rapeseed, canola, sugar beets		2.2	65		2275.68	3.99	2	1253	2
Coating of Dry Bulk Fertilizer at a Commercial Facility									
Barley, wheat, dry peas	EC / closed mix/load	1.7	5141 kg a.i./day[f]	Baseline PPE, closed mix/load	287.35	8.08	18	619	17
Flax, mustard, rapeseed, canola, sugar beets	EC / closed mix/load	2.2	4990 kg a.i./day[g]		270.17	7.84	19	638	18
Custom Application to Fields									
Barley, wheat, dry peas	Solid / solid broadcast spreader	1.7	130	Maximum PPE without a respirator / open cab	2.46	5.05	2030	990	665
Flax, mustard, rapeseed, canola, sugar beets		2.2	130		3.2	6.57	1562	761	511

[a] Baseline PPE = long pants, a long-sleeved shirt and chemical-resistant gloves. Maximum PPE = long pants, a long-sleeved shirt, chemical-resistant coveralls, chemical-resistant gloves and respirator.

[b] Where dermal exposure (µg/kg/day) = (unit exposure × area treated × rate)/70 kg bw * 20% dermal absorption

[c] Where inhalation exposure (µg/kg/day) = (unit exposure × area treated × rate)/70 kg bw

[d] Based on an oral NOAEL of 5 mg/kg/day; target MOE = 300

[e] Combined MOE = 5 mg/kg/day / (dermal exposure + inhalation exposure); target MOE = 300

[f] To estimate the amount of active ingredient handled in a commercial facility, the maximum label rate of triallate application on that crop (1.7 kg a.i./ha) and the minimum fertilizer rate (150 kg/ha) were considered. In one hectare, 1.70 kg of triallate and 150 kg of fertilizer would be applied. Therefore, 1.70 kg a.i. is applied to 150 kg fertilizer. Assuming that a commercial facility would treat 453 592 kg of fertilizer per day, then 5141 kg of triallate would be used per day.

[g] To estimate the amount of active ingredient handled in a commercial facility, the maximum label rate of triallate application on that crop (2.2 kg a.i./ha) and the minimum fertilizer rate (250 kg/ha) were considered. In one hectare, 2.2 kg of triallate and 250 kg of fertilizer would be applied. Therefore, 2.2 kg a.i. is applied to 250 kg fertilizer. Assuming that a commercial facility would treat 453 592 kg of fertilizer per day, then 4990 kg of triallate would be used per day.

Table 3 Cancer Exposure and Risk Estimates for Occupational Handlers (non-fertilizer admixture scenarios)

Crop	Formulation/ Application Method	Rate (kg a.i./ha)	Applicator	Area Treated (ha/day)	PPE/ System[a]	Absorbed Daily Dose[b] (µg/kg bw/day)	Lifetime Average Daily Dose[c] (mg/kg bw/day)	Risk[d]
Barley, wheat, dry peas	EC / groundboom	1.7	Farmer	100	Baseline PPE, closed mix/load, closed cab	14.98	0.0000438	0.000003
			Custom	300		44.95	0.000657	0.00005
Flax, mustard, rapeseed, canola		2.21	Farmer	100		19.48	0.0000569	0.000004
			Custom	300		58.44	0.000854	0.00006
Sugar beets		2.21	Farmer	80		15.58	0.0000455	0.000003
			Custom	300		58.44	0.000854	0.00006
Barley, canary grass, wheat	Granular / solid broadcast spreader	1.7	Farmer	80	Maximum PPE, open mix/load, open cab	6.61	0.0000193	0.000001
			Custom	130		10.75	0.000157	0.00001
Flax, mustard, rapeseed, canola		2.2	Farmer	80		8.56	0.000025	0.000002
			Custom	130		13.91	0.000203	0.00001
Sugar beets		2.2	Farmer	80		8.56	0.000025	0.000002
			Custom	130		13.91	0.000203	0.00001
barley, canary grass, wheat	Granular / aerial	1.7	Custom– m/l	400	Maximum PPE, open mix/load	9.95	0.000145	0.00001
			Custom– appl.		Baseline, no gloves	19.45	0.000284	0.00002
Flax, mustard, rapeseed, canola, sugar beets		2.2	Custom– m/l	400	Maximum PPE, open mix/load	12.87	0.000188	0.00001
			Custom– appl.		Baseline, no gloves	25.17	0.000368	0.00003

[a] Baseline PPE = long pants, a long-sleeved shirt and chemical-resistant gloves; gloves not worn during application. Maximum PPE = long pants, a long-sleeved shirt, chemical-resistant coveralls and chemical-resistant gloves; respirator worn during mix/load only.

[b] Absorbed daily dose = daily dermal dose + daily inhalation dose, as determined by PHED scenarios. Dermal absorption factor of 20% applied.

[c] LADD = average daily dose × treatment frequency × working duration/ (365 days × 75 years). Treatment frequency = 2 and 10 days/year for farmers and custom applicators, respectively. Working duration = 40 years.

[d] A Q_1* value of 0.0717 $(mg/kg/day)^{-1}$ was considered appropriate to use in the cancer risk assessment.

Table 4 Cancer Exposure and Risk Estimates for Occupational Handlers for Fertilizer Admixture Scenarios

Crop	Formulation/ Application Method	Rate (kg a.i./ha)	Area Treated (ha/day)	PPE / System[a]	Absorbed Daily Dose[b] (µg/kg bw/day)	Lifetime Average Daily Dose[c] (mg/kg bw/day)	Risk[d]
On-Farm Treatment and Application Based on PHED Data							
Barley, wheat, dry peas	EC / solid broadcast spreader	1.7	65	Maximum PPE, open mix/load, open cab	13.19	0.0000386	0.000003
Flax, mustard, rapeseed, canola, sugar beets		2.2	65		17.15	0.0000501	0.000004
On-Farm Treatment and Application Based on Fenske Data (fertilizer admixture) and PHED Data (solid broadcast spreader)							
Barley, wheat, dry peas	EC / solid broadcast spreader	1.7	65	Maximum PPE, open mix/load, open cab	1753.60	0.00512	0.0004
Flax, mustard, rapeseed, canola, sugar beets		2.2	65		2279.67	0.00666	0.0005
Coating of Dry Bulk Fertilizer at a Commercial Facility							
Barley, wheat, dry peas	EC / closed mix/load	1.7	5141 kg a.i./day[f]	Baseline PPE, closed mix/load	286.43	0.00126	0.00009
Flax, mustard, rapeseed, canola, sugar beets	EC / closed mix/load	2.2	4990 kg a.i./day[g]		278.01	0.00122	0.00009
Custom Application to Fields							
Barley, wheat, dry peas	Solid / solid broadcast spreader	1.7	130	Maximum PPE without respirator, open cab	7.51	0.00011	0.000008
Flax, mustard, rapeseed, canola, sugar beets		2.2	130		9.77	0.000143	0.00001

[a] Baseline PPE = long pants, a long-sleeved shirt and chemical-resistant gloves. Maximum PPE = long pants, a long-sleeved shirt, chemical-resistant coveralls, chemical-resistant gloves and respirator.

[b] Absorbed daily dose = daily dermal dose + daily inhalation dose, as determined by PHED scenarios or Fenske study. Dermal absorption factor of 20% applied.

[c] LADD = average daily dose × treatment frequency × working duration/ (365 days × 75 years). Treatment frequency = 2, 3 and 10 days/year for farmers, operators at a commercial facility and custom applicators, respectively. Working duration = 40 years.

[d] A Q_1* value of 0.0717 $(mg/kg/day)^{-1}$ was considered appropriate to use in the cancer risk assessment.

Appendix V Input Parameters Used to Predict EECs of Triallate in Water

Item		Value
Name of the Crop That Uses the Maximum Label Rate		**Flax, Mustard, Canola, Sugar Beets**
Maximum allowable rate per year (kg a.i./ha)		2.2
Maximum number of applications per year		1
Minimum interval between application		N/A
Timing of applications		Spring application— last week in April; Fall application — October 1
Method of application		EC— ground boom and then incorporation into the soil GR— broadcast or aerial application and then incorporation into the soil
Solubility in water at pH 7		4 mg/L at 25°C
Vapour pressure		1.2×10^{-4} mm Hg
Henry's law constant		1.2×10^{-5}
Hydrolysis half life	**pH 4**	Stable
	pH 7	Stable
	pH 8	Stable
Phototransformation half-life in water		Stable (> 30 d)
Aerobic soil biotransformation DT_{50}		62 d
Aerobic aquatic biotransformation DT_{50}		25 d
Anaerobic aquatic biotransformation DT_{50}		N/A
Adsorption K_d		5.3
Adsorption K_{oc}		1305

Appendix VI Summary of Label Amendments for Commercial Class Products Containing Triallate

(**Note:** The information presented below does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements, and supplementary PPE that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in summary.)

COMMON NAME: Triallate

CHEMICAL NAME: *S*-(2,3,3-trichloro-2-propenyl) bis(1-methylethyl)carbamothioate

FORMULATION TYPE: Emulsifiable Concentrate or Granular

USE-SITE CATEGORY: USC # 7, Industrial Oil Seed Crops and Fibre Crops
USC # 13, Terrestrial Feed Crops
USC # 14, Terrestrial Food Crops

Personal Protective Equipment

For EC formulations of triallate in agricultural field scenarios, the following statements must be included on the labels:

> Wear a long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear during mixing, loading, application, clean-up and repair. In addition, during clean-up and repair, wear either a respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE-approved canister approved for pesticides.

For granular formulations of triallate, the following statements must be included on the labels:

> Wear chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear during mixing, loading, application, clean-up and repair. In addition during mixing, loading, clean-up and repair, wear either a respirator with a NIOSH/MSHA/BHSE-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE-approved canister approved for pesticides.

Aerial Application (granular ONLY)

"Do not use human flaggers."

In addition, labels must be updated for aerial application directions for use as per Regulatory Directive DIR96-04.

Restricted-Entry Interval

"Do not enter or allow worker entry into treated areas during the restricted-entry interval of 12 hours."

Environmental Hazards

Runoff

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted or fine textured such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Leaching

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

Volatilization

The active ingredient contained in this product is known to volatilize. To reduce the atmospheric loading of triallate, effort should be made to reduce the volatilization such as the following.

- Incorporation into the soil concurrently with application.
- Application should occur when soil temperatures are less than 4°C or less.

DIRECTIONS FOR USE

DO NOT apply more than one application per year.

DO NOT apply this product directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries and marine habitats.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

For **emulsifiable concentrate** formulation, the following *additional* statements must be included on the labels.

> **DO NOT** handle more than 189 kg a.i./day (473 L and 394 L for products #8167 and #16759, respectively). Mixtures must be prepared by using a closed mix/load system. Applicators using ground equipment must use a closed cab.
>
> **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 and Biological Engineers medium classification.

Buffer Zones

The buffer zones specified below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, pastures, rangeland and shrub lands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine or marine habitats.

Method of Application	Buffer Zone (metres) Required for the Protection of:			
	Aquatic Habitat at Water Depths:			Terrestrial Habitat
	< 1 metre	1–3 metres	> 3 metres	
Ground sprayer*	5	2	1	5
Ground sprayer with shrouds	2	1	0	2
Ground sprayer with cones	4	1	0	4

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

Clarifications/Revisions for Direction for Use:

- For label of Registration Number 25112, the designation of “canary grass” must be replaced by “canary seed” [canary grass (*Phalaris canariensis*) can be easily confused with reed canary grass (*Phalaris arundinacea*)];

- For labels of Registration Number 19521 and 25112, the rate(s) for aerial application must be specified so as to be in agreement with the statements listed in the second paragraph under the **DIRECTIONS FOR USE** heading in the AERIAL APPLICATION section, which read "Apply only at the rate(s) recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment." Note that none of these product labels have specified rate(s) for aerial application;

- For the label of Registration Number 25112, the following amendments must be made to the table "Avadex Microactiv Herbicide Rates (kg/ha) - Spring Treatment (Incorporated)" under the Spring Treatment (Incorporated) heading in the DIRECTIONS FOR USING AVADEX MICROACTIV HERBICIDE IN CONVENTIONAL TILLAGE SYSTEMS section:
  - "Flax **" must be replaced by "Flax ***" to refer to the correct footnote.
  - The second footnote (**) is not properly referenced in the table. "Spring and Durum Wheat" must be replaced by "Spring and Durum Wheat**".

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