Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2004-33

Re-evaluation of Naled

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of naled pursuant to Section 19 of the Pest Control Products (PCP) Regulations. This Proposed Acceptability for Continuing Registration (PACR) document provides a summary of the data and information reviewed, and the rationale for the proposed regulatory decision.

The PMRA has carried out an assessment of available information taking into consideration the proposed risk reduction measures proposed by the registrant. It has concluded that the use of naled and its associated end-use product does not entail an unacceptable risk of harm to human health or the environment provided that the mitigation measures described in this document are implemented and the required data are provided.

By way of this document, the PMRA is soliciting comments from interested parties on the proposed regulatory decision for naled. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed decision. Please forward all comments to the Publications Coordinator at the address below.

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Foreword

The re-evaluation of the available information on the active ingredient naled and the associated end-use product (EP), registered for use on food and non-food areas, has been completed by the PMRA. The registrant of the technical grade active ingredient (TGAI) is Amvac Chemical Corporation.

The PMRA announced in June 1999 that organophosphate (OP) active ingredients, including naled, were subject to re-evaluation under authority of Section 19 of the PCP Regulations.[1]

Subsequent to that announcement, Sergeant's of Canada and Rolf C. Hagan Inc., registrants of domestic class EPs for use on companion animals, voluntarily discontinued their products. In addition, United Agri Products Canada, registrant of the only commercial class EP in Canada, discontinued uses on turf and residential areas (REV2003-02, *Update on the Re-evaluation of Naled in Canada*). Furthermore, United Agri Products Canada proposed risk reduction measures including discontinuation of certain agricultural uses and modes of application as well as limitation of the maximum number of applications per growing season.

The PMRA has carried out an assessment of available information taking into consideration the proposed risk reduction measures proposed by the registrant. It has concluded that the use of naled and its associated end-use product does not entail an unacceptable risk of harm to human health or the environment pursuant to Section 20 of the PCP Regulations, provided that the mitigation measures described in this document are implemented and the required data are provided.

Data have been requested to determine if the existing maximum residue limits (MRLs) can be supported for uses of naled on the following commodities: citrus fruits, spinach, turnip tops, Brussels sprouts, broccoli, cabbages, cauliflowers, lettuce, strawberries, beans, cucumbers, eggplants, melons, peas, peppers, pumpkins, rice, soybeans, squash and tomatoes. Amendments are proposed to the Food and Drug Regulations, Division 15, Table II, that would remove the maximum residue limit of 3 ppm for chard.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for this product.

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[1] See Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*.

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1.0 Purpose

This document describes the outcome of the PMRA's re-evaluation of the available data and information on the insecticide naled and its EPs. It includes a human health assessment, an environmental assessment and information on the value of naled to pest management in Canada. By way of this document, the PMRA is soliciting comments from interested parties on the decisions and mitigation measures proposed.

2.0 General background on re-evaluation

The PMRA is re-evaluating, under Section 19 of the Regulations pursuant to the *Pest Control Products Act*, all pesticides, both active ingredients (a.i.) and formulated EPs, that were registered prior to 1995. As outlined in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, a modern scientific approach is used to determine the continuing acceptability of older active ingredients in relation to human health and the environment. Naled is under reassessment in the United States as a result of the *Food Quality Protection Act*. Therefore, the PMRA is re-evaluating naled under Program 3. The following components are addressed and considered in this re-evaluation.

Risk to human health
The initial focus of the re-evaluation of a pest control product in Program 3 is the risk to human health. As indicated in Regulatory Directive DIR2001-03, a reassessment in Program 3 pays particular attention to the following:

- pest control products with a common mechanism of toxicity;
- aggregate exposure to a pesticide arising from its residues in food and drinking water as well as from non-occupational exposure, such as from treatments in and around homes; and
- susceptibility and exposure of infants and children during critical developmental stages that may be different from that of adults.

Once the non-occupational assessments of all the individual OPs have been completed, a cumulative assessment of all the remaining uses of OPs will be conducted.

The re-evaluation of risks to human health also includes a re-examination of the acceptability of risks resulting from occupational exposure. Occupational risk assessments follow an internationally accepted tiered approach as described in the Organisation for Economic Co-operation and Development's *Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application*. The tiered approach involves increasing levels of refinement through consideration of additional data such as dermal absorption, chemical-specific use-pattern information and biological monitoring data.

For OP compounds, there are often insufficient data available to the PMRA to refine occupational exposure assessments to higher tiers. Such refined assessments are now required for some of the OPs, due in part to the PMRA's policy of applying additional safety factors for workers as required to ensure their protection. It is important to note that the current re-evaluations of OPs were not preceded by a data call-in. As a result, in many cases the PMRA does not have the types of information required to conduct refined, higher tiered occupational exposure assessments. Therefore, in these cases, PMRA has conducted lower tier reviews based on conservative approaches.

However, the Agricultural Handlers Exposure Task Force and the Agricultural Re-entry Task Force are developing additional proprietary generic databases that will enhance our ability to conduct more refined assessments. Additional data that could be used to refine estimates include residue, dermal absorption and biomonitoring, as well as actual compound specific use-pattern data (e.g., typical versus maximum rates, typical number of applications). These data could also be used in a probabilistic assessment to provide additional refinement. There is currently an international project of the International Life Sciences Institute (ILSI) to develop guidance on probabilistic techniques for worker assessment.

Based on an assessment of the data and information available to the PMRA, the following courses of action may be proposed for OPs where the margins of exposure (MOEs) are less than the target for workers:

1) Where estimated MOEs indicate significant concern, even with maximum feasible mitigation, a phase-out or cancellation would be proposed.

2) Where estimated MOEs are less than the target but where exposure estimates could be refined with additional data, continuing registration for a limited term will be granted conditional upon submission of those data. As an interim measure, maximum feasible personal protective equipment (PPE), engineering controls and restricted entry intervals (REIs) will be implemented pending finalization of the decision. Such measures will substantially reduce exposure and risk. The worker risk estimates will then be revisited before a final re-evaluation decision is made using the submitted data.

Risk to the environment

The environmental assessments will be tiered, with refined environmental risk assessments being conducted only for those active ingredients, products or uses that pass the cumulative health risk assessment or, for unique mechanisms of toxicity, that are acceptable from a human health perspective. At the first tier, based on an identification of hazards to non-target organisms, measures to reduce environmental exposure will be implemented where warranted. These measures may include removing uses that are obsolete, reducing the number of applications, requiring buffer zones to protect sensitive habitats and taking regulatory action against uses that have been determined to be of extremely high risk to organisms in the environment. In general, uses that remain after the

first tier assessment will be revisited when the results of refined environmental assessments are available.

Value

The PMRA seeks to understand, as early as possible in the process, the current uses of the products and their importance for pest management. The PMRA relies to a great extent on provincial and territorial government input. Registrants and users are also an important source of information. Environment Canada, the Department of Foreign Affairs and International Trade, the Canadian Food Inspection Agency, and Agriculture and Agri-Food Canada are also contacted in the process for information specific to their areas of expertise.

The outcome of the re-evaluation of a pesticide, including proposed risk mitigation measures, will be published in a consultation document at the end of the aggregate human health risk assessment and the first tier environmental assessment. In some cases, the PMRA will implement changes in regulatory status of products prior to public consultation, especially where the PMRA considers risk mitigation not effective or practical, or where registrants have opted for voluntary discontinuation of sale of products.

3.0 Re-evaluation of naled

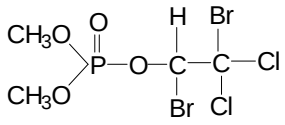
Naled is one of the 27 OP pesticides subject to re-evaluation in Canada. The re-evaluation of naled was announced in Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*. Naled is a broad spectrum OP insecticide that inhibits enzyme acetylcholinesterase, interrupting the transmission of nerve impulses. It works by contact, ingestion and vapour action. Dibrom® Insecticide (Registration Number 7442) is the only currently registered EP supported for continuing registration by the registrant.

Much of the scientific information used by PMRA in its assessment of naled came from United States Environmental Protection Agency (USEPA) reviews. The USEPA Interim Reregistration Eligibility Decision (IRED) document for naled, dated January 2002, can be referenced for further details regarding scientific studies used by the PMRA. This document, as well as other information on the regulatory status of naled in the United States, can be found on the USEPA's website at http://www.epa.gov/pesticides/op/status.htm.

3.1 Chemical identification

Chemical name:	1,2-dibromo-2,2-dichloroethyl dimethyl phosphate
Molecular formula:	$C_4H_7O_4Cl_2Br_2P$

Structural formula:



TGAI manufacturer: Amvac Chemical Corporation

3.2 Description of current registered uses

The following information is based on the currently registered uses of naled.

Type of pesticide: insecticide.

Registered formulation type(s): emulsifiable concentrate

Target pests:
Class Insecta

Coleoptera (beetles)	Colorado potato beetles, flea beetles, willow leaf beetles
Diptera (flies)	fruitflies (*Drosophilia* spp.), gnats, holly leafminers, houseflies, lesser houseflies, adult mosquitoes, onion maggot adults, leafminers
Lepidoptera (butterflies and moths)	alfalfa loopers, cabbage loopers, diamondback moths, imported cabbageworms, leafrollers, tent caterpillars, tomato fruitworms, tomato hornworms
Heteroptera and Homoptera (insects)	aphids, leafhoppers, lygus bugs, mealybugs, spittle bugs, whiteflies
Hymenoptera (bees, wasps, hornets, sawflies)	birch leafminers
Orthoptera (crickets and grasshoppers)	grasshoppers
Thysanoptera (thrips)	thrips
Acari (mites and ticks)	red spider mites, spider mites

3.2.1 Uses of naled supported by the registrant

Summary of supported use sites

The following uses sites are supported by the registrant and considered in the re-evaluation assessment:

Greenhouse food crops	cucumbers, tomatoes
Greenhouse ornamentals	roses, cut flowers
Livestock (indirect exposure only)	beef cattle, dairy cattle, horses, sheep and swine that are present during application (aircraft and/or mist blower application to pastures, feed lots, corrals and holding pens or space spraying of livestock buildings)
Feed crops	alfalfa, clovers, vetch, rangeland, field areas and pastures
Food crops	dry beans (field), broccoli, Brussels sprouts, cabbages, cauliflowers, celery, lettuce, lima beans, onions (bulb, seed), peas (processing), potatoes, spinach, strawberries, sugar beets and tomatoes
Structural sites	dairy barns, livestock barns, pig pens, poultry houses, cider mills and wineries at the lowest registered rate
Commercial outdoor ornamental crops	roses, dahlias, chrysanthemums, Canterbury bells, arborvitae, pittosporum, snowballs, Chinese magnolias, aucuba, zinnia, stocks, azalea, willow, privets and woodlands

Methods and rates of application

Table 3.2.1 summarizes methods and rates of application of naled supported and the risk reduction measures proposed by the registrant of the only commercial class EP, United Agri Products Canada.

Table 3.2.1 Methods and rates of application

Site	Application method	Rate (g a.i.)	Maximum # applications/ year	Preharvest interval (days)
cucumbers (greenhouse), tomatoes (greenhouse)	fogger*	6–12/100 m^3*	2/crop and a third applied post harvest prior to removal of crop residues	4*
roses (greenhouse), cut flower crops (greenhouse)	fogger	6–12/100 m^3		not applicable
corrals, pastures, holding pens (dairy cattle, beef cattle, horses, sheep and swine may be present)	aerial	100–275/ha	2*	0
alfalfa, clover, vetch	aerial, ground	950–1900/ha	2*	4
rangeland, field areas, pastures	aerial, ground	475–864/ha	2*	0
dry beans (field), lima beans, peas (for processing)	aerial, ground	950–1900/ha	2*	4
broccoli, Brussels sprouts, cabbages, cauliflowers, celery, lettuce, spinach	ground	950–1900/ha	2*	4
onions (bulb, seed)	ground	475/ha	2*	4
potatoes	aerial, ground	950/ha	2*	4
strawberries	ground	950/ha	2*	4
sugar beets	ground	1900/ha	2*	5
tomatoes (field)	ground	950–1728/ha	2*	4
in and around dairy barns, livestock barns, pig pens, poultry houses, cider mills, wineries	space spray	259/100 L	2*	0

Site	Application method	Rate (g a.i.)	Maximum # applications/ year	Preharvest interval (days)
woodlands, livestock pastures, feed lots, pastures (including dairy cattle)	aerial, mist blower	110–275/ha	2*	0
roses, dahlias, chrysanthemums, Canterbury bells, arborvitae, pittosporum, snowballs, Chinese magnolias, aucuba, zinnia, stocks, azaleas, willows, privets	ground	1080/1000 L	2*	not applicable

* not specified on the currently registered label. These are proposed by the registrant and included in the re-evaluation assessments.

3.2.2 Risk reduction measures proposed or implemented by the registrant

1) Uses proposed for discontinuation

Greenhouse crops: vapour treatment on cucumbers and tomatoes (to be replaced by fogger treatment).

Food crops: chard, collards, endives, hops, kale, mustard greens

All uses of bait: in and around dairy barns, stables, pig pens, poultry houses, animal hospitals, dog kennels, open air theatres, food processing plants, restaurants and drive-ins.

Application of course spray at the higher rate of 6 mL/10 L solution to food processing plants, loading docks, cull piles, refuse areas, cider mills and wineries.

2) Number of applications/season

When not specified on the label, the supported maximum number of applications per crop per season is two.

3) Phased-out uses

Uses on companion animals (pet collars), turf and residential areas have been phased-out as announced in REV2003-02, *Update on the Re-evaluation of Naled in Canada.*

4) Other label amendments

Product sold by the registrant after 31 August 2003 has label directions direction for aerial application of naled for woodland management under the restricted category as outlined in DIR93-10, *Pesticides for Use in Forest and Woodlands Management*.

All risk reduction measures proposed by the registrant after the announcement of the re-evaluation of naled are taken into consideration in the risk assessments for naled.

3.2.3 Use sites registered in the United States

Naled is currently registered in the United States for the same sites as in Canada, with the exception of clovers, vetch, endives, mustard (greens), onions (bulb, seed) and cut flower crops (greenhouse). Additional crops registered in the United States, but not in Canada, are almonds, cantaloupe, cotton, cucumbers (field), eggplants, grapes, grapefruits, honey dews, lemons, melons, muskmelons, oranges, peaches, peas (dry, succulent), pumpkins, quince, rice, safflower, soybeans, squash, tangerines, tobacco, turnips (greens) and watermelons. Naled is also registered in the United States for outdoor residential use for mosquito control (public health use) and blackfly control.

4.0 Effects having relevance to human health

4.1 Toxicology summary

Naled appears to be fully absorbed and metabolized with no sex differences noted. Different dosing regimes had no effect on the absorption, distribution, metabolism and excretion profiles. The bulk of naled was seen to be metabolized to carbon dioxide and excreted via exhaled air. Although dichlorvos (a registered OP) was found in the stomach shortly after dosing, this is considered an intermediary metabolite and was not detected in other tissues. Fecal and urine samples contained only very small amounts of dichlorvos (< 5%). Appreciable amounts of [^{14}C]-tissue residues (20–30% of administered dose) were retained in the carcass at 4 days following exposure. The primary routes of excretion appear to be via the expired air and urine.

Naled is highly acutely toxic by both the oral and dermal routes of exposure as well as moderately toxic via inhalation. It is severely irritating to both the skin and eyes. Naled is also a dermal sensitizer. Clinical signs associated with acute naled intoxication were typical of acetylcholinesterase inhibitors and included, but were not limited to, decreased motor activity, tremors, salivation, ocular and nasal discharge, ataxia, laboured breathing and convulsions, generally beginning within hours of dosing.

There are no apparent species related differences in sensitivity with regard to cholinergic parameters, either acutely or in longer term studies. In acute studies, oral median lethal

doses (LD_{50}s) are slightly lower than dermal LD_{50}s. On repeated dosing, the primary effects of naled are inhibition of acetylcholinesterase and associated clinical signs of toxicity. Generally, plasma cholinesterase as well as erythrocyte and brain acetylcholinesterase were all affected at the same doses, but the degree of inhibition of one parameter relative to the others was inconsistent and depended on the study. Similar levels of cholinesterase inhibition were observed at an oral dose level of 10 mg/kg bw/day (28-day study) and a dermal dose level of 20 mg/kg bw/day. Increasing the length of oral dosing from 1 month to 2 years did not significantly increase the potency of naled to induce cholinergic toxicity (based on a similar degree of cholinesterase inhibition in the rat at 10 mg/kg bw/day after 4 weeks, 6 months and 2 years of dosing). However, hepatic effects were more pronounced with chronic dosing. Other notable effects resulting from repeated oral administration of naled included changes in body weight and food consumption, anemia, liver effects (including pathological changes and increased weights), increased kidney and adrenal weights and changes in some clinical chemistry parameters. The effects seen in the 3-week and 90-day inhalation studies were consistent (clinical signs, nasal pathology as well as cholinesterase enzyme inhibition) and there did not appear to be much impact of length of dosing on the extent of effects noted.

There does not appear to be any clearly consistent differences between males and females in sensitivity to most effects of naled, although females may be somewhat more sensitive to the development of clinical signs of cholinergic toxicity than males.

There was no evidence of delayed neurotoxicity in the hen studies. Naled did not inhibit neuropathy target esterase, an enzyme responsible for the development of OP-induced delayed neuropathy. Furthermore, no neuropathological changes were noted in acute to long-term mammalian toxicity studies.

There was no evidence to suggest that naled resulted in increased sensitivity of the young. Naled did not induce any developmental changes in either rats or rabbits following in utero exposure, even at maternally toxic doses. In a reproductive toxicity study, pup survival was reduced, but only at a dose resulting in significant parental toxicity (mortality in both males and females). The number of pups born per litter (second filial generation) was reduced at a lower dose, but data from the rat chronic study indicate that significant toxicity (including inhibition of plasma, erythrocyte and brain cholinesterases) would be expected in the parental animals at this dose.

There was no evidence in the database to suggest that naled has any adverse effects on the endocrine system of mammals. Moreover, there was no evidence of tumorigenicity in either the mouse or rat following chronic dosing. Although positive responses were seen in Ames tests with two strains of bacteria, the overall weight of evidence from a battery of in vitro and in vivo studies indicates that naled is not genotoxic.

Reference doses have been set based on the no observed adverse effect levels (NOAELs) for the most sensitive indicator of toxicity, namely cholinesterase inhibition, clinical signs of cholinergic toxicity, nasal pathology or liver pathology. These reference doses

incorporate various uncertainty factors to account for extrapolating between rats and humans as well as for variability within human populations.

The toxicology endpoints used in the risk assessment of naled are summarized in Appendix I.

4.2 Occupational risk assessment

Workers can be exposed to naled through mixing, loading or applying the pesticide as well as re-entering a treated site to conduct agronomic activities. Occupational risk is estimated by calculating a MOE based on the potential exposure (in mg a.i./kg bw/day) of workers and the most relevant endpoints from toxicology studies. The calculated MOE is compared to a target MOE that incorporates safety factors protective of the most sensitive sub-populations. The risk exceeds the PMRA's level of concern if the calculated MOE is less than the target MOE.

For workers entering a treated site, REIs are calculated to determine the minimum length of time required before workers or others can safely re-enter.

Based on the use pattern, which precludes application in residential areas, bystander exposure should be minimal. The label states "This product is not to be used in and around homes or other residential areas such as parks, school grounds, playing fields. It is not for use by homeowners or other uncertified users".

For **short-term and intermediate-term dermal exposures** (exposures < 3 months), the toxicity endpoint selected is from a 28-day dermal toxicity study in rats. The NOAEL in this study was 10 mg/kg bw/day, based on inhibition of erythrocyte and brain cholinesterase activity and clinical signs observed at the lowest observed adverse effect level (LOAEL) of 40 mg/kg bw/day. A **target MOE of 100** is required. This target MOE is comprised of a 10-fold uncertainty factor for interspecies extrapolation and a 10-fold uncertainty factor for intraspecies variability; it is thus considered protective of all population subgroups. This 28-day NOAEL is considered appropriate for both short- and intermediate-term exposures as the data do not suggest that toxicity differs significantly following short- or intermediate-term treatment with naled.

For **inhalation exposures** (all durations), the selected toxicity endpoint is from a 90-day inhalation study in rats with a LOAEL of 0.23 µg/L, equivalent to 0.065 mg/kg bw/day, based on the observation of clinical signs and nasal tissue pathology (i.e., chronic rhinitis, epithelial dysplasia). A **target MOE of 300** is required for the inhalation occupational risk assessment of all durations and includes the conventional uncertainty factor of 100× as well as an additional uncertainty factor of 3× because a NOAEL was not achieved in this study. The available toxicology database suggests that increased duration of inhalation exposure would not significantly increase the toxicity of naled; therefore, this study is appropriate for use in the risk assessment of short and intermediate-term inhalation exposure to naled.

4.2.1 Mixer/loader/applicator exposure and risk assessment

Naled may be applied using the following equipment: aircraft, ground boom, airblast (mist blower), fogging, low-pressure handwand, high-pressure handwand or backpack. Based on the naled use pattern, mixer/loader/applicator exposure scenarios were considered to be short to intermediate term (< 3 months). Dermal and inhalation exposure were estimated for the various application methods using the Pesticide Handlers' Exposure Database Version 1.1 (PHED 1.1). The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software that facilitates the generation of scenario-specific exposure estimates, based on formulation type, application equipment, mix/load systems and level of PPE.

Three exposure scenarios were generated based on different levels of PPE and engineering controls as a tiered approach.

a) Mid-level PPE: cotton coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, with and without respirator, with open mixing and open cab.
b) Maximum PPE: chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves and a respirator with open cab and open mixing.
c) Engineering controls: closed mixing, closed cab, and baseline PPE (a long-sleeved shirt, long pants, no gloves unless otherwise indicated). Engineering controls are not applicable for hand-held application equipment.

In most cases, the PHED did not contain appropriate data sets to estimate exposure to workers wearing cotton coveralls, chemical-resistant coveralls or a respirator. This was estimated by incorporating a 75% clothing protection factor for cotton coveralls, 90% protection factor for chemical-resistant coveralls and a 90% protection factor for a respirator into the unit exposure data.

Exposure is calculated as the product of the PHED unit exposure for a given scenario, the label application rate(s) and the area treated per day for a specific crop divided by the body weight. The average body weight of an adult handler used in all assessments is 70 kg.

Exposure was not estimated for applicators using fogging equipment because the Dibrom® label explicitly states the following: "Apply with stationary (automated) fogging equipment ONLY. All workers must vacate the premises during fogging operation and must not re-enter until the greenhouse has been ventilated." Since application is automated and no workers are present during fogging, applicator exposure is not considered to be a concern for this use scenario. As such, only mixer/loader exposure was considered for fogging.

Mixer, loader and 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 spray equipment and engineering controls.

Combined dermal and inhalation MOEs for naled were not calculated because the route specific NOAELs had different toxicity endpoints. The target MOE for dermal exposure is 100 and for inhalation exposure is 300.

Dermal and inhalation MOEs for mixing, loading and applying naled are summarized in Appendix II.

For most applications, calculated dermal and inhalation MOEs exceed the target MOE, provided cotton coveralls and a respirator are worn.

Engineering controls (closed mixing and loading as well as closed cab) are required to mitigate exposure for some applications.

For a few uses, calculated MOEs are below target MOEs even with maximum PPE or engineering controls. These uses are as follows:

- aerial application to alfalfa, clovers, vetch, rangeland, field areas, pastures, peas, beans, lima beans and potatoes;
- aerial application to tomatoes at the maximum application rate; and
- high-pressure handwand application to outdoor ornamentals as well as in and around dairy barns, livestock barns, pig pens, poultry houses, cider mills and wineries.

Although ground application to alfalfa, clovers, vetch, peas, beans, lima beans and sugar beets at the high-end hectarage and the maximum label rate result in calculated inhalation MOEs below the target MOEs, these calculated MOEs are considered highly conservative. However, these are minor uses, and it is unlikely that a worker would repeatedly apply naled to large areas. For typical scenarios in Canada, the calculated MOEs exceed the target MOEs.

All proposed protective equipment, engineering controls and other mitigation measures are described in detail in Section 8.0, Proposed regulatory actions.

4.2.2 Postapplication exposure and risk assessment

Workers who re-enter treated sites to conduct agronomic activities involving foliar contact (e.g., pruning, thinning, harvesting or scouting) may be exposed to naled and dichlorvos. Naled metabolizes to dichlorvos, both of which are registered pesticides in Canada. To properly assess exposure from the use of naled, the postapplication assessment must be conducted for both exposure to naled and exposure to dichlorvos. Based on the naled use pattern, postapplication exposure is expected to be intermediate to

long term (< 3 months) for greenhouse workers and short to intermediate term (< 3 months) for all outdoor crops (Appendix III).

Potential risk to re-entry workers is estimated using activity specific transfer coefficients (TCs) from the Agricultural Re-entry Task Force and a dislodgeable foliar residue (DFR) study on leaves of broccoli plants treated with naled. The TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from the data generated in field exposure studies.

Postapplication risk is managed by establishing an REI for specific tasks. Pesticide residues dissipate and/or breakdown over time, an REI is the length of time required for the dislodgeable pesticide residues to dissipate to such a level that entry into a treated area does not result in unacceptable exposure.

Due to the rapid dissipation of naled and dichlorvos, dislodgeable residue levels for all outdoor crops were sufficiently low two days following the second application. As such, REIs are proposed at 48 hours.

There are no DFR data available to generate a risk assessment for workers in greenhouses. However, due to the rapid dissipation of naled and dichlorvos, re-entry should be acceptable in greenhouses with ventilation and an REI of 48 hours.

4.3 Dietary risk assessment

In a dietary exposure assessment, the PMRA determines how much pesticide residue, including residues in fruits, vegetables, milk, meat, eggs and processed products, may be ingested with 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.

Acute and chronic dietary exposure and risk estimates were generated using the Dietary Exposure Evaluation Model and updated consumption data from the United States Department of Agriculture's Continuing Survey of Food Intakes by Individuals (1994–1998). Although naled metabolizes to dichlorvos and dichlorvos residues could be present as a result of the application of naled, only naled residues were considered in this risk assessment. Dichlorvos is being assessed independently and the risk assessment will include residues as a result of naled having been applied.

Acute dietary risk is calculated using food consumption and food residue values. A probabilistic statistical analysis allows all possible combinations of food consumption and residue levels to be combined to estimate a distribution of the amount of naled residue that might be eaten in a day. An exposure value representing the high end (99.9^{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), the **NOAEL of 1.0 mg/kg bw/day** from the 28-day oral toxicity study in rats was selected for risk assessment based on clinical signs of toxicity during the first week of the study at the LOAEL of 10 mg/kg bw/day. These results were supported by the findings of the 1 year oral toxicity study in the dog, where the acute NOAEL was 0.2 mg/kg bw/day with clinical signs of toxicity observed during the first week of treatment at 2 mg/kg bw/day. An overall **uncertainty factor of 100** was required to account for interspecies extrapolation (10×) and intraspecies variability (10×). The ARfD was calculated to be 0.01 mg/kg bw (1.0 mg/kg bw ÷ 100). This value was considered to be protective of all populations including infants and children.

The acute dietary exposure was calculated using a refined probabilistic assessment. Refinements for commodities on which use of naled is registered in Canada or the United States include generating residue distribution files that incorporated the following, where appropriate:

- empirical data from magnitude of residue (MOR) studies,
- processing studies,
- percent commodity treated estimates, and
- American generated anticipated residues.

Residues on food items from the mosquitocide use of naled were not considered in the naled acute analysis. Acute dietary risk from foods treated with naled was not a concern for the general Canadian population and all population subgroups (i.e., less than 100% of the ARfD is consumed). At the 99.9th percentile of exposure, the most highly exposed population subgroups, all infants (< 1 year old) and children (1–6 years old), consume 37 and 43% of the ARfD, respectively, in their food. All other subpopulations had potential dietary intakes less than 25% of the ARfD in their food.

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 dietary risk from the repeat or chronic exposure, the **NOAEL of 0.2 mg/kg bw/day** from the 2-year chronic study in rats was selected for risk assessment. The NOAEL was based on inhibition of plasma, erythrocyte and brain cholinesterase and liver pathology at the LOAEL of 2.0 mg/kg bw/day. This is supported by the results of the 2-generation reproduction study, which also had a LOAEL of 2.0 mg/kg bw/day based on decreased parental body weights. An overall **uncertainty factor of 100** was required to account for interspecies extrapolation (10×) and intraspecies variability (10×). No

additional uncertainty or safety factors were deemed necessary as the database was considered adequate and there was no evidence of sensitive populations. The ADI was calculated to be 0.002 mg/kg bw/day (0.2 mg/kg bw/day ÷ 100). This value was considered to be protective of all populations including infants and children.

The chronic dietary exposure was calculated using a refined deterministic assessment. Refinements for commodities on which naled is registered in Canada or the United States include incorporating the following, where appropriate:

- mean residue from MOR studies,
- processing studies,
- percent commodity treated estimates, and
- American generated anticipated residues.

Chronic dietary risk from foods treated with naled is not a concern for the general Canadian population and all population subgroups (i.e., less than 100% of the ADI is consumed). The most highly exposed population subgroups, non-nursing infants, consume 4% of the ADI in their food, followed by all infants (< 1 year) and children (1–6 years) at 3% each.

4.4 Drinking water exposure

Drinking water exposure was addressed by calculating drinking water levels of comparison (DWLOCs). DWLOCs can only be calculated if all other exposures are not of concern to the PMRA, as the DWLOC simply expresses the difference between the reference dose and the non-drinking water exposure. The DWLOC values were compared to model estimates of potential drinking water exposure.

The acute DWLOC values ranged from 62.9 µg/L for the most sensitive sub-population of all infants (< 1 year), to 262.2 µg/L for the total population general population. The chronic DWLOCs ranged from 19.4 µg/L for the most sensitive sub-population, all infants (< 1 year), to 68.8 µg/L for the total population. Exposure estimates from drinking water were based on estimated environmental concentrations (EECs) values calculated from the screening models. These estimates were 0.0 µg/L for ground water (acute and chronic), 62.0 µg/L for acute surface water and 0.36 µg/L for and chronic surface water. As none of the exposure estimates for drinking water exceed the relevant DWLOC, all drinking water exposure estimates are acceptable.

4.5 Aggregate exposure assessment

Aggregate risk assessment looks at the combined potential risk associated with exposures from food, drinking water and residential uses of a pesticide. Generally, when the combined risks from these exposures are less than 100% of the relevant reference doses, the aggregate risk is not considered a health concern. As residential use of naled is not permitted, the aggregate risk assessment for naled would consider food and water only, as described above.

Drinking water, chronic and acute dietary risk assessments demonstrated that there were no health concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors. In addition no dietary health concerns were evident for nursing or pregnant females, or based on gender in general.

5.0 Environmental assessment

This assessment was based mainly on the USEPA environmental risk assessment presented in the IRED document for naled.

In characterizing the environmental risk of naled, the PMRA utilized a deterministic approach that characterizes the risk by quotient method. In this method, a risk quotient (RQ) is calculated as the ratio of the EEC to the effects endpoint of concern. RQs less than one are considered as a low risk to non-target organisms, whereas, RQs greater than one indicate some degree of risk.

In the assessment, EECs for aquatic and terrestrial ecosystems were based on various label rates (0.11–1.9 kg a.i./ha) and one application/season. Toxicity endpoints (acute and/or chronic) were chosen for the most sensitive species and used as surrogates for the range of species that may potentially be exposed following treatment with naled.

5.1 Environmental fate

Available data indicate that naled is moderately persistent in the environment. In soil, biotransformation was an important route in transformation of naled in aerobic as well as in anaerobic soil; the half-life was less than one day for both systems. In water, hydrolysis and phototransformation were important routes of transformation, with the half-life being less than five days.

Naled is rapidly lost from moist soil and water surface as indicated by its Henry's Law constant (9.9×10^{-4} atm·m^3·mole^{-1}). The log K_{ow} is not available. However, static bioaccumulation studies indicated that naled applied at 0.031, 0.063 and 0.127 mg a.i./L to tanks inhabited with killifish, *Fundulus heteroclitus*, did not accumulate in whole body tissue over a 7-day exposure period.

Under field conditions, naled is expected to be slightly mobile in soil.

5.2 Environmental toxicology

Laboratory studies demonstrated that naled was acutely and chronically toxic to a wide variety of organisms, including birds, mammals, fish and aquatic invertebrates.

Naled was classified as highly toxic to honey bees (LD_{50} = 0.48 µg a.i./bee). It was very highly toxic to freshwater invertebrates (EC_{50} = 0.3–92 µg a.i./L), and moderately to very highly toxic to estuarine/marine organisms (LC_{50} = 9.3–1200 µg a.i./L) and fish

(LC_{50} = 160–3300 µg a.i./L). Naled was highly to very highly toxic to algae (EC_{50} = 0.012–0.64 mg a.i./L) and moderately toxic to aquatic vascular plants (no observed effect concentration [NOEC] > 1.8 mg a.i./L). It was moderately to highly toxic to birds (LD_{50} = 26.75–64.9 mg a.i./kg) on an acute basis and slightly toxic (LC_{50} > 2117 mg a.i./kg) on a dietary basis. Naled was moderately toxic to mammals on an acute basis (LD_{50} = 92–371 mg a.i./kg). Naled has chronic adverse effects on freshwater invertebrates and fish at levels greater than 0.098 and 6.9 µg a.i./L, respectively, and on marine/estuarine invertebrates and fish at levels greater than 0.33 and 40 µg a.i./L, respectively.

5.3 Drinking water concentrations

Residues of naled in drinking water sources in Canada were estimated using Level 1 LEACHM and PRZM/EXAMS models. LEACHM was used to estimate the residues in ground water, whereas the residues in dugouts and reservoirs were estimated using PRZM/EXAMS. For residues in ground water, the concentration was estimated to be 0 µg a.i./L. For residues in reservoirs, the acute and chronic exposure concentrations were estimated to be 62 and 0.36 µg a.i./L, respectively. For dugouts, the acute and chronic exposure concentrations were estimated to be 21 and 0.13 µg a.i./L, respectively. These concentrations represent the maximum upper bound exposure concentration.

5.4 Terrestrial assessment

The results of this screening assessment identified various levels of risk to non-target terrestrial organisms exposed to naled.

Bees and other beneficial insects may be exposed to naled through spray deposit. Based on the acute contact toxicity (LD_{50} = 0.54 kg a.i./ha), moderate to high acute risk to bees is anticipated from the use of naled when use involves application to crops in blossom (RQ = 2–35). The extent of the residual hazard will vary with application rate, weather conditions and the formulation of the specific product applied.

Birds could be exposed to naled drift or by consumption of contaminated food (e.g., seeds, insects or grasses). Based on the acute oral toxicity of naled to birds (LD_{50} = 26.75 mg a.i./kg; no observed effect level [NOEL] = 2.675 mg a.i./kg) and using standard PMRA exposure scenarios, it was determined that birds would have to consume contaminated food sources for 0.4 to 7 days for their population to be reduced by 50% (LD_{50}). For no observable effects on a population, birds can consume contaminated food for 0.04 to 0.7 days (NOEL). As the number of feeding days required for adverse effects is less than one, there is an acute risk to birds consuming contaminated food sources.

Similarly, wild mammals could be exposed to naled by consumption of contaminated food (e.g., grass, seeds and leafy plants). Based on the acute oral toxicity of naled to small mammals (LD_{50} = 92 mg a.i./kg; NOEL = 9.2 mg a.i./kg) and using standard PMRA exposure scenarios, it was determined that animals would have to consume contaminated

food sources for 1.3 to 22 days for their population to be reduced by 50% (LD_{50}). For no observable effects on population, animals can consume contaminated food for 0.1 to 2.2 days (NOEL). As the number of feeding days required for adverse effects is less than one, at application rates ≥ 275 g a.i./ha, there is an acute risk to small mammals consuming contaminated food. Assessment of chronic (reproduction) toxicity to mammals resulted in risk quotients ranging from 0.6 to 11. Based on this scenario, chronic toxicity of naled is classified as high risk for small mammals.

5.5 Aquatic assessment

The results of this screening assessment identified various levels of risk to non-target aquatic organisms exposed to naled.

Aquatic organisms can be exposed to naled that enters aquatic systems through spray drift. For the laboratory-derived data, RQ values were based on estimates of the acute NOEC for the most sensitive species (e.g., 1/10 LC_{50}). For freshwater invertebrates (NOEC = 0.03 µg a.i./L), algae (NOEC = 1.2 µg a.i./L) and fish (NOEC = 8.7 µg a.i./L) risk quotients ranged from 1200 to 21000, from 30 to 525, and from 0.04 to 0.07, respectively. For the most sensitive estuarine invertebrates (NOEC = 0.9 µg a.i./L) risk quotients ranged from 39 to 677. The assessment concluded that for all aquatic invertebrates and plants acute risks from use of naled was high to extremely high at all application rates. Naled has chronic adverse effects on freshwater invertebrates and fish at levels greater than 0.098 and 6.9 µg a.i./L, respectively, and on marine/estuarine invertebrates and fish at levels greater than 0.33 and 40 µg a.i./L, respectively.

5.6 Environmental assessment conclusions

Naled poses the greater risk to aquatic organisms. There is a high to extremely high risk (RQ = 14–21 000) for aquatic invertebrates and plants. There is no risk for fish (RQ ≤ 0.07).

For terrestrial organisms, there are low levels of acute risk to birds. Some levels of acute risk to small mammals were identified; however, the magnitude of this risk can not be determined at present. There is high chronic risk for small mammals (RQ = 11). A moderate to high risk was determined for bees (RQ = 2–38).

5.7 Environmental risk mitigation

Mitigation of potential impacts on terrestrial ecosystems is difficult given that the non-target organisms frequent treated areas. In the case of bees, it may be possible to reduce the risk by restricting the application of naled to when bees are not actively foraging. For small mammals, there are no available options to effectively reduce the risk that results from ingestion of contaminated food sources in treated areas.

Naled can enter aquatic ecosystems through spray drift. The observance of buffer zones, however, can effectively mitigate the risk to off-site non-target organisms. Based on the spray drift predictions and the most sensitive toxicity endpoint, NOEC of 0.03 µg a.i./L (*Daphnia magna*), buffer zones for waterbodies of different depths were calculated for mitigating the entry of naled into aquatic habitats (Section 8.1.4).

6.0 Value

6.1 Evaluation method

6.1.1 Agricultural uses of naled

The importance of naled end-use products in managing specific pests on specific crops in Canada was evaluated based on the availability of registered alternative pesticides that are potential substitutes. The recent field use of naled in agriculture in Canada was assessed by a survey of OP use conducted in 1998 (the "1998 OP Survey") with the cooperation of provincial governments. This use was also assessed after 1998 from consultations with crop production specialists as well as expert opinion of provincial agricultural officials, grower groups and other stakeholders. Recent (2001) usage data for naled was provided by the end-use product registrant, United Agri Products Canada.

Uses of naled were classified into two value classes as follows.

Key uses
Some uses of naled were considered "key uses" because they matched one or more of the following criteria:

- there was reported use on at least 10% of the use site and there are no registered alternatives; or
- there was reported use on at least 10% of the use site and alternative active ingredients are registered; however, naled is the preferred active ingredient; or
- maintaining registration was considered key for resistance management and/or plays an important role in integrated pest management (IPM) programs; or
- the use site is of large importance to the economy of Canada.

Non-key uses
Uses of naled were considered to be "non-key uses" either because they did not match the "key use" criteria or because the information available to the PMRA indicated little or no use in Canada.

Non-agricultural uses of naled
Information regarding the extent of non-agricultural use of naled was obtained from 2001 sales data from the registrant of the EP. These uses were also categorized into "key uses" and "non-key uses" based on the above criteria.

6.2 Evaluation results

6.2.1 Sites with key uses of naled

The following sites were identified as having "key uses" of naled.

Greenhouse-grown cucumbers and tomatoes
In greenhouse-grown cucumbers and tomatoes, naled is used for post harvest clean-up as part of greenhouse IPM programs. Producers state that naled is effective and does not leave residues harmful to predators and parasites of greenhouse pests.

The sites that are no longer supported by the registrant were not identified as having any key uses of naled.

6.2.2 Sites with non-key uses of naled

The following sites supported by the registrant were identified as having no "key uses" of naled: alfalfa, clovers, vetch, beans, broccoli, Brussels sprouts, cabbages, cauliflowers, celery, lettuce, lima beans, onions, peas (processing), spinach, potatoes, strawberries, sugar beets, tomatoes (field), greenhouse roses and cut flower crops, nursery ornamentals, corrals, holding pens (dairy cattle, beef cattle, horses, sheep, swine), rangeland, field areas, in and around dairy barns, livestock barns, pig pens, poultry houses, cider mills, wineries, woodlands, livestock pastures, feed lots, and pastures (including dairy cattle).

The food crops that are no longer supported by the registrant (chard, collards, endives, hops, kale and mustard greens) were also identified as having only non-key uses of naled.

7.0 Other assessment considerations

7.1 Toxic Substances Management Policy

During the review of naled, the PMRA has taken into account the federal TSMP[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.

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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.hc-sc.gc.ca/pmra-arla/

- It does not meet the criteria for persistence. Its values for half-life in water (≤ 4 days), soil (≤ 2 days) and sediment (≤ 1 day) are below the TSMP Track 1 cut-off criteria for water (≥ 182 days), soil (≥ 182 days) and sediment (≥ 365 days).

- It is not bioaccumulative. The log K_{ow} was not provided; however, static bioaccumulation studies indicated that naled was not bioaccumulative.

- The TGAI does not contain any by-products or microcontaminants that meet the TSMP Track 1 criteria. Impurities of toxicological concern are not expected to be present in the raw materials nor are they expected to be generated during the manufacturing process.

- The formulated product does not contain any formulants that are known to contain TSMP Track 1 substances.

7.2 Formulant issues

Formulant issues are being addressed through implementation of the PMRA's formulants program (Regulatory Directive DIR2004-01, *Formulants Program*).

- List 1 formulants are subject to removal from products as communicated to registrants of affected products in September 2001.

- Registrants of products containing nonylphenol ethoxylates have been requested to replace nonylphenol ethoxylates with less harmful alternatives.

- Other formulants, including List 2 formulants, formulation preservatives and allergens will be subject to future regulatory action as indicated in the PMRA's formulant policy.

8.0 Proposed regulatory action

The PMRA has determined that the following risks are acceptable provided that the mitigation measures listed in Section 8.1 are implemented and additional data requirements identified in Section 9.0 are provided:

- dietary and drinking water risks;
- risks to workers during mixing, loading and application with ground boom, low-pressure handwand, airblast (mist blower), backpack and by fogging; as well as
- risks to the environment during ground application.

The PMRA has concerns regarding environmental risks posed by aircraft application. The buffer zones calculated for aerial applications were out of range for all proposed uses of naled (buffer zone » 1600 m) and are not considered to be practical. Furthermore, based on available data, worker exposure during mixing, loading and application of large

volumes by high-pressure handwand and by aircraft did not meet the target for inhalation exposure (< 300) even with the use of engineering controls (Appendix II).

Based on the available information, aerial application and high-pressure handwand uses of naled are proposed for phase-out.

8.1 Proposed mitigation measures and label changes

8.1.1 Toxicological information

A) Labels of pesticide products carry statements regarding symptoms of poisoning and treatment, which are especially important for those who may be overexposed when working with the product in a commercial or industrial setting, e.g., mixers/loaders who handle more concentrated forms. Based on the toxicological assessments, the label text of the products containing naled should be expanded and/or standardized, as follows:

Toxicological Information

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

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

NOTE: Product contains a petroleum distillate solvent.

8.1.2 Proposed measures to protect mixer/loader/applicator

The PMRA has determined that the human health risks for naled are acceptable provided that the mitigation measures below are adopted.

For protection when mixing and loading in all agricultural scenarios (except greenhouse and handheld equipment):

- Closed mixing/loading systems are required.

Although calculated MOEs exceed target MOEs for mixer/loader exposure for low hectarage airblast and groundboom scenarios, closed mixing/loading systems are still warranted for all ground application for the following reason: naled is highly acutely toxic by both the oral and dermal routes of exposure and is severely irritating to both skin and eyes. Any incidents in handling this highly toxic chemical could result in serious injury to the handler.

For protection when mixing and loading with open systems (greenhouse and handheld equipment):

- Workers must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, a respirator, chemical-resistant gloves and eye protection.

For protection when applying using ground equipment (ground boom, airblast or mist blower):

- Workers must use a closed cab when applying to areas larger than 30 ha in one day.
- Workers must wear cotton coveralls over a long-sleeved shirt and long pants, a respirator, chemical-resistant gloves and eye protection when applying to areas smaller than 30 ha per day.

For protection when applying using hand held equipment:

- Workers must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, a respirator, chemical-resistant gloves and eye protection
- Workers must not handle more than 1000 L per day.

Aerial application:

- Not considered because of environmental concerns.

For protection of workers conducting re-entry activities

- A 48-hour REI is required for all greenhouse and outdoor crops. To mitigate exposure for greenhouse workers, a maximum of one application can be applied per crop, and it must be applied post-harvest. In addition, greenhouses must be well ventilated before workers re-enter a treated area.

8.1.3 Label statements to protect mixer/loader/applicator

Under the "Precautions" section of the label, the following label statements are required.

Engineering controls:

Mixers and loaders supporting ground applications (groundboom or mist blower) must use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. In addition, mixers and loaders must wear the PPE specified below and have immediately available for use in case of an emergency, such as a broken package or spill, the PPE specified in the PPE section of this labelling for handlers engaged in those activities for which use of an engineering control is not possible.

Applicators using motorized ground equipment to treat an area larger than 30 hectares per day must use an enclosed cab with a nonporous barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. The cab must either have a properly functioning ventilation system that is used and maintained according to the manufacturer's written operating instructions or the occupant must wear a respirator as specified in the PPE below. The applicator must have immediately available for use in case of an emergency, such as a broken package or spill, the PPE specified in the PPE section of this labelling for handlers engaged in those activities for which use of an engineering control is not possible.

Personal protective equipment (PPE):

Mixers, loaders, applicators and other handlers using engineering controls must wear the following PPE:

- a long-sleeved shirt and long pants,
- socks and shoes,
- chemical-resistant gloves when mixing or loading, and
- eye protection.

Mixers, loaders, applicators and other handlers using handheld equipment to apply naled in greenhouses or engaged in other handler activities for which use of an engineering control is not possible (such as cleaning up a spill or leak and cleaning or repairing contaminated equipment) must wear the following PPE:

- chemical-resistant coveralls,
- a long-sleeved shirt and long pants,
- chemical-resistant gloves,
- chemical-resistant footwear plus socks,
- chemical-resistant headgear for overhead exposure,
- a NIOSH approved respirator, and
- eye protection.

Applicators using open-cab ground equipment (groundboom and mist blower) for areas smaller than 30 ha must wear the following PPE:

- cotton coveralls,
- a long-sleeved shirt and long pants,
- chemical-resistant gloves,
- socks and shoes,
- a NIOSH approved respirator, and
- eye protection.

Do not apply by high-pressure handwand.

Restricted Entry Interval (REI):

- Do not enter or allow worker entry into treated areas (indoor or outdoor) for 48 hours following application.
- Greenhouses must be thoroughly ventilated prior to re-entry.

8.1.4 Proposed regulatory actions relating to environment

Canadian EP labels should be amended to include the following statements.

Ground application
Overspray or drift to sensitive habitats should be avoided. A buffer zone specified in the tables below is required between the downwind point of direct application and the closest edge of sensitive aquatic habitats including lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs or wetlands. Do not contaminate these habitats when cleaning and rinsing spray equipment or containers.

Do not apply during periods of dead calm or when winds are gusty.

When a tank mixture is used, consult the label of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Aerial application
Do not apply by air.

Table 8.1.4 Summary of buffer zones for application of naled

Method of application	Buffer zone (metres) required for the protection of aquatic habitat with water depth of:		
	< 1 metres	1–3 metres	> 3 metres
Field sprayer	70	55	45
Airblast (early season)	65	50	45
Airblast (late season)	55	45	35
Aerial	» 1600	» 1600	» 1600

8.2 Definition of the residue of concern

Division 15, Table II of the Food and Drug Regulations currently defines naled (1,2-dibromo-2,2-dichloroethyl dimethyl phosphate) as a residue of concern. It is recommended that the residue of concern be defined as the sum of parent naled and its metabolite dichlorvos (0,0-dimethyl-2,2 dichlorovinyl phosphate) expressed as naled equivalents. Dichlorvos is also registered as a pest control product. The Food and Drug Regulations lists the MRLs for dichlorvos separately. These MRLs will be reconsidered as part of the re-evaluation of dichlorvos.

8.3 Maximum residue limits for naled in food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian MRLs and 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 are required to support Canadian food-use registrations. In addition, the PMRA requires residue data (MOR trials) that are representative of use conditions in exporting countries, in the same manner that representative residue data to support domestic use of the pesticide are required. The PMRA requires these data to determine whether the requested MRLs are needed and to ensure that the MRLs would not result in unacceptable health risks.

After the revocation of an MRL, or where there is no specified MRL, the general MRL of 0.1 ppm, as specified in subsection B.15.002(1) of the Food and Drug Regulations, applies for enforcement purposes. Changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

As indicated in Table 8.3, the Food and Drug Regulations specifies MRLs for naled residues in beans, broccoli, Brussels sprouts, cabbages, cauliflowers, chard, cucumbers, lettuce, spinach, strawberries, peas and tomatoes for commodities approved for treatment in Canada; and citrus fruit, eggplant, melons, peppers, pumpkins, rice, soybeans, squash and turnip tops for import commodities. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specified MRL (i.e., celery, sugar beets, onions and potatoes), must not exceed the general MRL of 0.1 ppm.

For all commodities specified, residue data were available to indicate the existing MRLs should not be exceeded if naled is used according to good agricultural practice (GAP), as described by the current product labels. However, in most cases, the existing residue data are dated and do not fully satisfy the requirements as described in Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*. The registrant is asked to provide confirmation that residue field trial data for all commodities meet contemporary standards by submitting the appropriate data and/or American Data Evaluation Reports (DERs).

As the registrant indicated an intent to phase out the use of naled on chard, the PMRA will update the Food and Drug Regulations to remove the MRL of 3 ppm for this commodity once treated chard has cleared the channels of trade. After that time, the general MRL of 0.1 ppm will apply for enforcement purposes with respect to residues of naled in chard.

Parties interested in supporting an MRL for naled should contact the PMRA during the comment period of this document to discuss submitting appropriate data.

Table 8.3 MRLs for naled on commodities approved for treatment in Canada and import commodities with specified MRLs

Commodity	MRL (ppm)
Chard[x]	3
Citrus fruits*, spinach, turnip tops*	3
Brussels sprouts, broccoli, cabbages, cauliflowers, lettuce, strawberries	1
Beans, cucumbers, eggplants*, melons*, peas, peppers*, pumpkins*, rice*, soybeans*, squash*, tomatoes	0.5
celery, sugar beets, onions, potatoes	0.1**

[x] Future amendments are proposed that would remove the maximum residue limit of 3 ppm for chard.

* MRL for import purposes; use not registered in Canada

** General MRL, Food and Drug Regulations, B15.002(1)

9.0 Additional data requirements

9.1 Data requirements relating to chemistry

The label guarantee must be revised at the next printing to reflect a nominal guarantee.

9.2 Data requirements relating to toxicology

The following confirmatory data is required to support the continued registration of naled and any expansion of naled use:

- Developmental neurotoxicity study (DACO 4.5.14)

9.3 Data requirements relating to food residue exposure

a) The following confirmatory data are required to support the continued registration of naled or any expansion of naled use:

- Available residue data (DACO 7.4.1), freezer storage stability studies (DACO 7.3) and the respective USEPA DERs applicable to the re-evaluation of Canadian MRLs.

b) Although not critical to the determination of risk in the current re-evaluation, the following data gaps were identified and must be filled:

- Confirmation that residue field trial data (DACO 7.4) for all commodities meet contemporary standards, as per PMRA Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*.

9.4 Data requirements relating to environmental risk

The following studies were identified as data gaps. These data are not required at this time, but should be fulfilled before the next re-evaluation.

- Aerobic aquatic biotransformation (DACO 8.2.3.5.2)
- Anaerobic sediment/water biotransformation (DACO 8.2.3.5.6)
- Canadian terrestrial field dissipation studies (DACO 8.3.2.1)
- Earthworm toxicity study (DACO 9.2.3)

For expansion of uses of naled, the data requirements will be revisited and additional data gaps may be identified at that time.

10.0 Re-evaluation conclusions

By the way of this document, the Agency is soliciting comments from interested parties on the proposed regulatory decision for naled. The PMRA will accept written comments up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

List of Abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
ARS	Agricultural Research Services
atm	atmospheres
bw	body weight
DACO	Data Code
DER	Data Evaluation Reports
DFR	dislodgeable foliar residue
DWLOC	drinking water level of comparison
EC	engineering control
EC_{50}	effective concentration to 50%
EEC	estimated environmental concentration
EP	end-use product
EXAMS	Exposure Analysis Modeling System
g	gram(s)
h	hour(s)
ha	hectare(s)
IPM	integrated pest management
kg	kilogram(s)
K_{ow}	*n*-octanol-water partition coefficient
L	litre(s)
LC_{50}	median lethal concentration to 50%
LD_{50}	median lethal dose to 50%
LEACHM	Leaching Estimation and Chemistry Model
LOAEL	lowest observed adverse effect level
m	metre(s)
mg	milligram
MOE	margin of exposure
MOR	magnitude of residue
MRL	maximum residue limit
N/A	not available
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OP	organophosphate
PACR	Proposed Acceptability for Continuing Registration
PCP	pest control product
PHED	Pesticide Handlers' Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRZM	Pesticide Root Zone Model
REI	restricted entry interval
RQ	risk quotient [EEC/NOEC]

SF	safety factor
SRL	safe residue limit
TC	transfer coefficient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
WP	wettable powder
µg	microgram(s)

Appendix I Toxicology endpoints for health risk assessment for naled

Exposure scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE[c]
Acute dietary	NOAEL = 1.0	Clinical signs of toxicity in first week	28-day oral toxicity—rat	100
	ARfD = 0.01 mg/kg bw			
Chronic dietary	NOAEL = 0.2	Brain cholinesterase inhibition, liver pathology	2-year oral chronic toxicity—rat	100
	ADI = 0.002 mg/kg bw/day			
Short-term[a] dermal	Dermal NOAEL = 10.0	Erythrocyte, brain cholinesterase inhibition	28-day dermal toxicity—rat	100
Intermediate-Term[b] Dermal	Dermal NOAEL = 10.0	Erythrocyte, brain cholinesterase inhibition	28-day dermal toxicity—rat	100
Short-term[a] inhalation	Inhalation LOAEL = 0.065 (= 0.23 µg/L)	Clinical signs, nasal pathology (chronic rhinitis, epithelial dysplasia)	90-day inhalation toxicity—rat	300
Intermediate-term[b] inhalation	Inhalation LOAEL = 0.065 (= 0.23 µg/L)	Clinical signs, nasal pathology (chronic rhinitis, epithelial dysplasia)	90-day inhalation toxicity—rat	300

[a] Duration of exposure is 1 to 7 days.

[b] Duration of exposure is 8 days to 3 months.

[c] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments; MOE refers to desired margin of exposure for occupational or residential assessments.

Appendix II Dermal and inhalation MOEs for mixing/loading and applying naled

Crop	Activity scenario	Application equipment	Application rate (kg a.i./ha)	Area treated per day (ha)	Margins of Exposure					
					Dermal[a]			Inhalation[b]		
					Minimum PPE[e]	Maximum PPE[f]	EC[d]	No respirator	Respirator	EC[d] (no respirator)
USC 4 Forests and Woodlots										
woodland (mosquitoes, gnats, houseflies)	M/L/A	mist blower (airblast)	0.11	16	764	792	6552	349	3494	3747
	M/L/A	mist blower (airblast)	0.28	16	306	317	2621	140	1397	1499
	M/L	aircraft	0.28	400	194	219	336	26	259	376
	A	aircraft	0.28	400	N/A	N/A	659	N/A	N/A	376
USC 5/6 Greenhouse Food Crops/Greenhouse Non-Food Crops										
cut flowers, tomatoes, cucumbers	M/L	fogging[c]	0.06 g a.i./m^3	53550	6593	7427	11402	878	8778	12767
	M/L	fogging[c]	0.12 g a.i./m^3	53550	3298	3715	5703	439	4390	6386
USC 13 Terrestrial Feed Crops										
alfalfa, clovers, vetch	M/L	aircraft	0.95	400	56	63	97	7	75	109
	A	aircraft	0.95	400	N/A	N/A	191	N/A	N/A	109
	M/L/A	ground boom	0.95	80[g]	171	193	307	23	234	352
	M/L	aircraft	1.9	400	28	32	49	4	37	54
	A	aircraft	1.9	400	N/A	N/A	95	N/A	N/A	54
	M/L/A	ground boom	1.9	80[g]	86	96	153	12	117	176
	M/L/A	groundboom	1.9	30[h]	228	257	409	31	312	469
livestock pastures, feed lots (mosquitoes, gnats, houseflies)	M/L	aircraft	0.11	400	485	547	840	65	646	940
	A	aircraft	0.11	400			1647	N/A	N/A	940
	M/L/A	mist blower (airblast)	0.11	16	764	792	6552	349	3494	3747
	M/L	aircraft	0.28	400	194	219	336	26	259	376
	A	aircraft	0.28	400	N/A	N/A	659	N/A	N/A	376
	M/L/A	mist blower (airblast)	0.28	16	306	317	2621	140	1397	1499
rangeland, field areas, pastures (grasshoppers)	M/L	aircraft	0.86	400	62	70	107	8	82	120
	A	aircraft	0.86	400	N/A	N/A	210	N/A	N/A	120
	M/L/A	ground boom	0.86	80[g]	188	212	338	26	257	387

Crop	Activity scenario	Application equipment	Application rate (kg a.i./ha)	Area treated per day (ha)	Margins of Exposure					
					Dermal[a]			Inhalation[b]		
					Minimum PPE[e]	Maximum PPE[f]	EC[d]	No respirator	Respirator	EC[d] (no respirator)
USC 14 Terrestrial Food Crops										
peas, beans, lima beans	M/L/A	ground boom	0.95	80[g]	171	193	307	23	234	352
	M/L	aircraft	0.95	400	56	63	97	7	75	109
	A	aircraft	0.95	400	N/A	N/A	191	N/A	N/A	109
	M/L/A	ground boom	1.9	80[g]	86	96	153	12	117	176
	M/L/A	ground boom	1.9	30[h]	228	257	409	31	312	469
	M/L	aircraft	1.9	400	28	32	49	4	37	54
	A	aircraft	1.9	400	N/A	N/A	95	N/A	N/A	54
cole crops	M/L/A	ground boom	0.95	30	456	513	819	62	624	939
	M/L/A	ground boom	1.9	30	228	257	409	31	312	469
celery, lettuce, spinach	M/L/A	ground boom	0.95	30	456	513	819	62	624	939
	M/L/A	ground boom	1.42	30	305	343	548	42	417	628
onions	M/L/A	ground boom	0.48	30	913	1027	1637	125	1247	1878
potatoes	M/L/A	ground boom	0.95	65	211	237	378	29	288	433
	M/L	aircraft	0.95	400	56	63	97	7	75	109
	A	aircraft	0.95	400	N/A	N/A	191	N/A	N/A	109
strawberries	M/L/A	ground boom	0.95	5	2738	3079	4910	374	3740	5632
tomatoes	M/L/A	ground boom	0.95	30	456	513	818	62	624	939
	M/L	aircraft	0.95	100	225	253	389	30	299	435
	A	aircraft	0.95	100	N/A	N/A	762	N/A	N/A	435
	M/L/A	ground boom	1.73	30	251	283	451	34	343	517
	M/L	aircraft	1.73	100	124	139	214	16	165	239
	A	aircraft	1.73	100	N/A	N/A	419	N/A	N/A	239
sugar beets	M/L/A	ground boom	1.9	80[g]	86	96	153	12	117	176
	M/L/A	ground boom	1.9	30[h]	228	257	409	31	312	469

Crop	Activity scenario	Application equipment	Application rate (kg a.i./ha)	Area treated per day (ha)	Margins of Exposure					
					Dermal[a]			Inhalation[b]		
					Minimum PPE[e]	Maximum PPE[f]	EC[d]	No respirator	Respirator	EC[d] (no respirator)
USC 20 Structural										
In and around dairy barns, livestock barns, pig pens, poultry houses, cider mills, wineries (mosquitoes, gnats, houseflies, fruitflies)	M/L/A	low-pressure handwand	2.6 g a.i./L	150 L	2449	2596	N/A	259	2589	N/A
	M/L/A	high-pressure handwand	2.6 g a.i./L	3750 L	29	39	N/A	3	31	N/A
	M/L/A	backpack	2.6 g a.i./L	150 L	693	888	N/A	188	1884	N/A
corrals, adjacent pastures, holding pens (mosquitoes, houseflies)	M/L	aircraft	0.11	400	485	547	840	65	646	940
	A	aircraft	0.11	400	N/A	N/A	1647	N/A	N/A	940
	M/L	aircraft	0.28	400	194	219	336	26	259	376
	A	aircraft	0.28	400	N/A	N/A	659	N/A	N/A	376
USC 27 Ornamentals Outdoor										
outdoor ornamentals	M/L/A	low-pressure handwand	1.08 g a.i./L	150L	5877	6230	N/A	621	6214	N/A
	M/L/A	high-pressure handwand	1.08 g a.i./L	3750 L	70	95	N/A	7	74	N/A
	M/L/A	backpack	1.08 g a.i./L	150L	1664	2131	N/A	452	4523	N/A
	M/L/A	ground boom	2.16	30	201	226	360	27	274	413

[a] Dermal MOE = dermal NOEL/dermal exposure. The dermal NOEL is 10 mg/kg bw/day. The target dermal MOE is 100.

[b] Inhalation MOE = inhalation NOEL/inhalation exposure. The inhalation NOEL is 0.065 mg/kg bw/day. The target inhalation MOE is 300.

[c] Exposure estimates are for mixing/loading only. The PHED does not contain application data for applying by fogging.

[d] EC (engineering controls) = closed mixing, closed cab and baseline PPE (a long-sleeved shirt, long pants, no gloves) except for airblast application that, for applicators, included chemical-resistant gloves because data regarding application with closed cab and no gloves were not available. EC is not available for low-pressure handwand, high-pressure handwand or backpack application methods.

[e] Minimum PPE = coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, with and without a respirator.

[f] Maximum PPE = chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, with and without a respirator.

[g] Area treated per day: upper range for large hectarage crops.

[h] Area treated per day: typical area treated per day for field crops.

N/A = not available M/L/A = mixer/loader/applicator

Appendix III Postapplication exposure estimates, safe residue limits (SRLs) and restricted entry intervals (REIs)

Table 1 Proposed REIs based on postapplication exposure to naled

Crop	Activity	Transfer coefficient (cm^2/hr)[a]	Maximum application rate[b] (kg a.i./ha)	SRL[c, d]	Day 0 DFR Value[e]	Proposed REI[f] (days)
Berry, Low						
strawberries	hand harvest, pinching, pruning, training	1500	0.95	0.583	0.055	0
	irrigating, weeding, scouting, mulching	400	0.95	2.187	0.055	0
Field/row crop low, medium						
beans, peas, lima beans	hand harvesting	2500	1.90	0.35	0.109	0
	irrigating, scouting	1500	1.90	0.583	0.109	0
	hand weeding, thinning	100	1.90	8.75	0.109	0
sugar beets	irrigating, scouting	1500	1.90	0.583	0.109	0
	thinning, hand weeding	100	1.90	8.75	0.109	0
Vegetable, root						
onions, dry	irrigating, scouting, thinning, hand weeding	300	0.48	2.917	0.028	0
	mechanical weeding, mechanical harvesting	300	0.48	2.917	0.028	0
	hand harvesting	out of scope	0.48	N/A		N/A
potatoes	irrigation, scouting	1500	0.95	0.583	0.055	0
	hand weeding	300	0.95	2.9167	0.055	0
	hand harvesting	out of scope	0.95			
Vegetables, fruiting						
tomatoes	transplanting	out of scope	1.73	N/A		N/A
	hand harvest, pruning, staking, thinning, training, tying	1000	1.73	0.875	0.099	0
	irrigation, scouting	700	1.73	1.25	0.099	0
	hand weeding	500	1.73	1.75	0.099	0
Vegetables, head and stem, *Brassica*						
broccoli, cabbages, cauliflowers, Brussels sprouts	hand harvest, irrigation, pruning, topping, thinning, tying	5000	1.90	0.175	0.109	0
	scouting	4000	1.90	0.219	0.109	0
	hand weeding	2000	1.90	0.437	0.109	0
	mechanical harvesting	special concern	1.90	N/A	0.109	N/A

Crop	Activity	Transfer coefficient (cm^2/hr)[a]	Maximum application rate[b] (kg a.i./ha)	SRL[c, d]	Day 0 DFR Value[e]	Proposed REI[f] (days)
Vegetables, leafy						
celery, lettuce, spinach	hand harvest, hand pruning, thinning	2500	1.42	0.35	0.082	0
	irrigation, scouting	1500	1.42	0.583	0.082	0
	hand weeding	500	1.42	1.75	0.082	0
Outdoor ornamentals						
ornamentals	hand harvest, pinching, pruning, thinning	7000	2.16	0.125	0.124	0
	irrigation, scouting	4000	2.16	0.219	0.124	0
	weeding	2500	2.16	0.35	0.124	0
Indoor crops (Greenhouse tomatoes, cucumbers, roses and cut flowers)—insufficient data						

[a] Transfer coefficients are published in *Science Advisory Council for Exposure Agricultural Transfer Coefficient* (USEPA 2000).

[b] Maximum label rate

[c] SRL = (NOAEL × bw / dermal absorption) / (TC × exposure time (hr) × SF)

[d] Based on the short- and intermediate-term NOAEL of 10 mg/kg bw/day.

[e] DFR data from a broccoli study in Ontario is used for all crops.

[f] REI is the day when the DFR value is less than or equal to the SRL.

Table 2 Proposed REIs based on postapplication exposure to dichlorvos as a result of naled application

Crop	Activity	Transfer coefficient (cm^2/hr)[a]	Maximum application rate[b] (kg a.i./ha)	SRL[c, d, e]	REI DFR value (ug/cm^2)	Proposed REI[f] (days)
Berry, Low						
strawberries	hand harvest, pinching, pruning, training	1500	0.95	0.001	0.0004	1
	irrigating, weeding, scouting, mulching	400	0.95	0.0036	0.0004	1
Field/row crop low, medium						
beans, peas, lima beans	hand harvesting	2500	1.90	0.0006	0	2
	irrigating, scouting	1500	1.90	0.001	0.0008	1
	hand weeding, thinning	100	1.90	0.0146	0.0008	1
sugar beets	irrigating, scouting	1500	1.90	0.001	0.0008	1
	thinning, hand weeding	100	1.90	0.0146	0.0008	1
Vegetable, root						
onions, dry	irrigating, scouting, thinning, hand weeding	300	0.48	0.0049	0.0002	1
	mechanical weeding, mechanical harvesting	300	0.48	0.0049	0.0002	1
	hand harvesting	out of scope	0.48	N/A		
potatoes	irrigation, scouting	1500	0.95	0.001	0.0002	1
	hand weeding	300	0.95	0.0049	0.0002	1
Vegetables, fruiting						
tomatoes	transplanting	out of scope	1.73	N/A		
	hand harvest, pruning, staking, thinning, training, tying	1000	1.73	0.0015	0.0007	1
	irrigation, scouting	700	1.73	0.0021	0.0007	1
	hand weeding	500	1.73	0.0029	0.0007	1
Vegetables, head and stem, *Brassica*						
broccoli, cabbages, cauliflowers, Brussels sprouts	hand harvest, irrigation, pruning, topping, thinning, tying	5000	1.90	0.0003	0	2
	scouting	4000	1.90	0.0004	0	2
	hand weeding	2000	1.90	0.0007	0	2
	mechanical harvesting	special concern	1.90	N/A		

Crop	Activity	Transfer coefficient (cm^2/hr)[a]	Maximum application rate[b] (kg a.i./ha)	SRL[c, d, e]	REI DFR value (ug/cm^2)	Proposed REI[f] (days)
Vegetables, leafy						
celery, lettuce, spinach	hand harvest, hand pruning, thinning	2500	1.42	0.0006	0.0006	1
	irrigation, scouting	1500	1.42	0.001	0.0006	1
	hand weeding	500	1.42	0.0029	0.0006	1
Outdoor ornamentals						
ornamentals	hand harvest, pinching, pruning, thinning	7000	2.16	0.0002	0	2
	irrigation, scouting	4000	2.16	0.0004	0	2
	weeding	2500	2.16	0.0006	0	2

[a] Transfer coefficients are published in *Science Advisory Council for Exposure Agricultural Transfer Coefficient* (USEPA 2000).

[b] Maximum label rate

[c] SRL = (NOAEL × bw / dermal absorption) / (TC × exposure time × SF)

[c] Based on the short-, intermediate- and long-term NOAEL of 0.05 mg/kg bw/day.

[e] DFR data from a broccoli study in Ontario is used for all crops.

[f] REI is the day when the DFR value is less than or equal to the SRL.

Appendix IV Use standard for commercial class products containing naled

(Note: The information in this appendix summarizes the acceptable uses, limitations and minimum PPE for the commercial class products containing naled resulting from this re-evaluation. This use standard 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 this use standard.)

COMMON NAME: Naled

CHEMICAL NAME: 1,2-Dibromo-2,2-dichloroethyl dimethyl phosphate

FORMULATION TYPES: Emulsifiable concentrate

SITE CATEGORIES:

4	Forests and Woodlots
5	Greenhouse Food Crops
6	Greenhouse Non-Food Crops
13	Terrestrial Feed Crops
14	Terrestrial Food Crops
20	Structural
27	Ornamentals Outdoor

GENERAL LIMITATIONS:

Do not handle more than 1000 L per day when using hand held equipment

TOXICOLOGICAL INFORMATION:

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

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

"NOTE: Product contains a petroleum distillate solvent."

PRECAUTIONARY STATEMENTS:

PROTECTIVE CLOTHING AND EQUIPMENT:

Engineering controls:
Mixers and loaders supporting ground applications (groundboom or mist blower) must use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. In addition, mixers and loaders must wear the PPE specified below and have immediately available for use in case of an emergency, such as a broken package or spill, the PPE specified in the PPE section of this labelling for handlers engaged in those activities for which use of an engineering control is not possible.

Applicators using motorized ground equipment to treat an area larger than 30 hectares per day must use an enclosed cab with a nonporous barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. The cab must either have a properly functioning ventilation system that is used and maintained according to the manufacturer's written operating instructions or the occupant must wear a respirator as specified in the PPE below. The applicator must have immediately available for use in case of an emergency, such as a broken package or spill, the PPE specified in the PPE section of this labelling for handlers engaged in those activities for which use of an engineering control is not possible.

Personal protective equipment (PPE):

Mixers, loaders, applicators and other handlers using engineering controls must wear:

- a long-sleeved shirt and long pants,
- socks and shoes, and
- chemical-resistant gloves when mixing or loading.

Mixers, loaders, applicators and other handlers using handheld equipment to apply naled in greenhouses or engaged in other handler activities for which use of an engineering control is not possible (such as cleaning up a spill or leak and cleaning or repairing contaminated equipment) must wear the following PPE:

- chemical-resistant coveralls,
- long-sleeved shirt and long pants,
- chemical-resistant gloves,
- chemical-resistant footwear plus socks,

- chemical-resistant headgear for overhead exposure,
- a NIOSH approved respirator, and
- eye protection.

Applicators using open-cab ground equipment (groundboom and mist blower) for areas smaller than 30 ha must wear:

- cotton coveralls,
- a long-sleeved shirt and long pants,
- chemical-resistant gloves,
- socks and shoes,
- a NIOSH approved respirator, and
- eye protection.

RESTRICTED ENTRY INTERVAL (REI):

Workers who conduct re-entry activities must adhere to the following.

- Do not enter or allow worker to enter into treated areas during the REI of 48 hours.
- Greenhouses must be thoroughly ventilated prior to re-entry.

ENVIRONMENTAL HAZARDS:

Naled is toxic to bees exposed to direct treatment. Do not apply when bees are present in the area to be treated.

Toxic to fish and other aquatic organisms. Do not contaminate any body of water by direct application, cleaning of equipment or disposal of wastes and containers.

BUFFER ZONE INFORMATION:

Groundboom application:
Avoid overspray or drift to sensitive aquatic habitats. An appropriate buffer zone from Table 1 is required between the downwind point of direct application and the closest edge of sensitive aquatic habitats including sloughs, coulees, ponds, prairie potholes, lakes, rivers, streams, reservoirs and wetlands that are situated on the periphery of the treated area. Do not contaminate any of these habitats when cleaning and rinsing spray equipment or containers.

Do not apply during periods of dead calm or when winds are gusty.

Buffer zones for ground applications are dependent on the application rate specific to the crop and the depth of the aquatic ecosystem to be protected. It is the applicator’s responsibility to determine the maximum depth of the aquatic ecosystem.

When a tank mixture is used, consult the label of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Aerial application:
Aerial application of naled is not allowed.

Buffer zones (in metres) for the protection of aquatic habitats of various water depths for ground application of naled

Method of application	Ground buffer zone (metres)		
	water depth < 1 metre	water depth 1–3 metres	water depth > 3 metres
Field sprayer	70	55	45
Airblast (early season)	65	50	45
Airblast (late season)	55	45	35

ACCEPTABLE COMMERCIAL USES FOR NALED:

General	EMULSIFIABLE CONCENTRATE **UNLESS OTHERWISE STATED USE THE FOLLOWING INSTRUCTIONS AND LIMITATIONS** **Use Directions:** Dilute with water to 100–300 L/ha unless otherwise stated. Begin application at first sign of insects. On all sites apply as a contact spray or thorough cover spray. **Limitations:** Maximum 2 applications per season. Do not apply by air. Do not apply to food or forage crops within 4 days of harvest or grazing, unless otherwise specified. Do not apply when temperature is over 32˚C. Do not re-enter treated sites for 48 hours.

Site(s)	Pest(s)	Rate (g a.i.)	Application instructions and limitations
broccoli, Brussels sprouts, cabbages, cauliflowers	imported cabbageworms, diamond back moth caterpillars, aphids	950/ha	Ground spray application only.
	cabbage loopers	950–1900/ha	
beans (dry), lima beans, peas (processing)	alfalfa loopers, aphids, red spider mites	950–1900/ha	
alfalfa, clovers, vetch	aphids, leafhoppers, loopers, lygus bugs	950–1900/ha	
celery, lettuce, spinach	looper caterpillars, aphids	950–1425/ha	
onions (bulb or seed only)	thrips, onion maggots (supplemental spray)	475/ha	

General	EMULSIFIABLE CONCENTRATE **UNLESS OTHERWISE STATED USE THE FOLLOWING INSTRUCTIONS AND LIMITATIONS** **Use Directions:** Dilute with water to 100–300 L/ha unless otherwise stated. Begin application at first sign of insects. On all sites apply as a contact spray or thorough cover spray. **Limitations:** Maximum 2 applications per season. Do not apply by air. Do not apply to food or forage crops within 4 days of harvest or grazing, unless otherwise specified. Do not apply when temperature is over 32˚C. Do not re-enter treated sites for 48 hours.

Site(s)	Pest(s)	Rate (g a.i.)	Application instructions and limitations
potatoes	Colorado potato beetles, leafhoppers, flea beetles	950/ha	
strawberries	red spider mites, aphids, spittlebugs		
sugar beets	red spider mites, leafhoppers	1900/ha	Do not apply to food or forage crops within 5 days of harvest or grazing.
tomatoes (field)	fruitflies (*Drosophila* spp)	950/ha	Use 400 L of water/ ha minimum. Make first application at 5–7 days before first picking and reapply once 5–7 days later if necessary.
	tomato fruit worms, hornworms, leafminers	864/1000 L of water	Spray plants thoroughly. Use up to 2000 L diluted spray/ha.
range land, field areas, pastures	young grasshoppers	475–734/ha	Ground spray application only.
	adult grasshoppers	605–864/ha	
livestock pastures, feedlots	mosquitoes, gnats, houseflies	110–275/ha	**Mist blower application:** Calibrate equipment (rate of travel and output) to apply 0.11–0.28 kg a.i./ha. Make applications during peak of infestation. Application may be made up to the day of harvest.
tomatoes, cucumbers, roses, cut flowers (greenhouse)	whiteflies, spider mites, aphids, leafrollers, mealybugs	6–12/100m^3	**Fogging:** Apply with stationery (automated) fogging equipment ONLY. All workers must vacate the premises during fogging operation. Maximum one application as a post harvest clean up. Thoroughly ventilate premises before re-entering. Do not apply within 2 days of harvest.
In and around dairy barns, livestock barns, pig pens, poultry houses, cider mills, wineries	houseflies, lesser houseflies, mosquitoes, gnats, fruitflies (*Drosophila* species)	2.6/L of solution	**Space spray:** Direct spray throughout fly infested area. In dairy barns, livestock barns and pig pens spray around and above animals but not directly at animals. Do not use in milk processing rooms. Do not use inside dwellings. Do not use in poultry houses when birds are present. Do not apply to birds or contaminate eggs with spray. Application may be made up to the day of harvest.
cider mills, wineries	fruitflies (*Drosophila* species)	5.2/L of solution	**Course spray:** Apply as a coarse spray to walls, floors, doorways, windows, refuse and cull piles where insects congregate. Do not apply to cull fruit or refuse piles to be fed to livestock. Avoid contamination of feeds, foodstuffs, and food processing machinery. Do not apply when plants are in operation or when foods are present or exposed. Do not spray surfaces which will come into contact with foods. Cover food containers during spraying periods.

General	EMULSIFIABLE CONCENTRATE **UNLESS OTHERWISE STATED USE THE FOLLOWING INSTRUCTIONS AND LIMITATIONS** **Use Directions:** Dilute with water to 100–300 L/ha unless otherwise stated. Begin application at first sign of insects. On all sites apply as a contact spray or thorough cover spray. **Limitations:** Maximum 2 applications per season. Do not apply by air. Do not apply to food or forage crops within 4 days of harvest or grazing, unless otherwise specified. Do not apply when temperature is over 32˚C. Do not re-enter treated sites for 48 hours.

Site(s)	Pest(s)	Rate (g a.i.)	Application instructions and limitations
outdoor ornamentals: roses, dahlias, chrysanthemums, Canterbury bells, arborvitae, pittosporum, snowballs, Chinese magnolias, aucuba, zinnia, stocks, azaleas, willow, privet	aphids, leafhoppers, red spider mites, tent caterpillars, birch and holly leafminers, willow leaf beetles	1080/1000 L of water	Thorough spray coverage and contact of insects is necessary.
woodland	mosquitoes, gnats, houseflies	110–275/ha	**Mist blower application:** For areas less than 500 ha only. Calibrate equipment (rate of travel and output) to apply 110–275 g a.i./ha. Make applications during peak of infestation. Equipment used for spraying should not be washed in the vicinity of lakes or streams. Application may be made up to the day of harvest.