Proposed Special Review Decision PSRD2019-03

Special Review of Naled and Its Associated End use Product under subsection 17(2) of *Pest Control Products Act*

Consultation Document

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of naled (Canada, 2015) based on the 2012 European Commission regulatory decision to prohibit the use of naled (European Commission, 2012).

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspects of concern that prompted the special review of pest control products containing naled. The aspects of concern for this special review under subsection 17(2) of the *Pest Control Products Act* are relevant to human health (potential occupational and dietary risks) and the environment (potential risks to aquatic and terrestrial species).

In addition, Health Canada in 2017 initiated a special review of naled (Canada, 2017a) pursuant to subsection 17(1) of the *Pest Control Products Act*, based on the toxicology information submitted under section 12 of the *Pest Control Products Act*, following the re-evaluation of naled (Canada, 2004; and Canada, 2006). The aspect of concern identified for the special review under subsection 17(1) of the *Pest Control Products Act* is the potential occupational risk. The outcome of the evaluation of the special review of naled under subsection 17(1) of the *Pest Control Products Act* was published separately (Canada, 2019).

The following sections outline the evaluation of the aspects of concern identified for the special review of naled under subsection 17(2) of the *Pest Control Products Act*.

2.0 Uses of Naled in Canada

Naled (1,2-dibromo-2,2-dichloroethyl dimethyl phosphate) is an organophosphate pesticide used for the control of insects in a wide variety of use areas, including agricultural (food and feed) crops, outdoor ornamentals, greenhouse food crops and ornamentals, in/around structural sites, woodlands, and livestock pastures. It 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. All currently registered pest control products containing naled are considered in this special review (Appendix I).

3.0 Aspects of Concern that Prompted the Special Review

Based on the review of the European Union information (Rotterdam Convention, 2014; European Commission, 2011), the PMRA identified the aspects of concern that prompted the special review of naled under subsection 17(2) of the *Pest Control Products Act* as:

- Human health
    - Potential occupational risk
    - Potential dietary risk
- Environment
    - Potential risks to aquatic and terrestrial organisms

4.0 PMRA Evaluation of the Aspects of Concern that Prompted the Special Review

Following the initiation of the special review, the PMRA requested information related to the aspects of concern from provinces and other relevant federal government departments and agencies in accordance with the subsection 18(2) of the *Pest Control Products Act*. No information was received.

In order to evaluate the aspects of concern for naled, the PMRA considered currently available relevant scientific information, which includes information submitted under section 12 of the *Pest Control Products Act* following the re-evaluation of naled, other toxicology data including the cholinesterase assays, and, use information submitted subsequently, as well as information considered for the re-evaluation of naled (Canada, 2004; and Canada, 2006), and information from the European Union.

4.1 Potential Occupational Risks

Based on the current use pattern of naled, there is a potential for exposure for workers mixing, loading, and applying the pest control product containing naled and for workers entering treated sites to conduct postapplication activities involving foliar contact (for example, pruning, thinning, harvesting or scouting).

Risk is estimated by comparing exposure estimates with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

This special review considers dermal and inhalation risks to workers resulting from the use of naled. While no revision was identified for the inhalation reference value, inhalation exposure results in brain cholinesterase inhibition at higher doses and thus, may contribute to the total effect of naled. Consequently, both dermal and inhalation risks to naled were considered for this special review. Further, given that dichlorvos is a transformation product of naled, the co-occurrence of naled and dichlorvos exposure for workers is considered likely. Both of these organophosphates share a common mechanism of toxicity, namely cholinesterase inhibition. Accordingly, toxicological reference values for dichlorvos based on brain cholinesterase inhibition (Canada, 2017b) were considered relevant for the combined risk assessment. Toxicological reference values for use in the human health risk assessment for naled (Canada, 2019) are presented in Appendix II.

4.1.1 Mixers/Loaders/Applicators

Based on the limit of two applications per year and the timing of application for outdoor uses, workers applying naled would generally have a short (<30 days) duration of exposure. Custom applicators may also have intermediate-term (up to several months) exposure for those crops with multiple applications. As greenhouse crops may have treatments year round,

intermediate/long-term duration of exposure may occur; however, since the number of applications is limited to three (including one post-harvest), exposure is likely to be short/intermediate-term.

The PMRA assessed daily exposure for workers exposed to naled during mixing/loading (liquid formulation) and applying naled using different types of application equipment:

- groundboom (farmer and custom scenarios),
- airblast/tractor drawn mistblower/ultra-low volume (ULV),
- aerial,
- handheld (manually pressurized handwand, backpack, mechanically pressurized handgun),
- automated fogger and mistblower,
- greenhouse vapour treatment to cold pipes, and
- handheld mistblower and handheld fogger equipment.

Dermal and inhalation exposure of mixers/loaders/applicators to naled

The PMRA calculated daily exposure using exposure data from the Agricultural Handler Exposure Task Force (AHETF) (for open cab airblast application) and the Pesticide Handlers Exposure Database (PHED) (for the remaining mixing/loading/application scenarios). The derived exposure estimates for mixers/loaders/applicators account for the current conditions of use as outlined in the pest control product labels.

The risk assessment under the current label directions is presented in Appendix III.

For the following identified mixer/loader/applicator scenarios, the best available data were used:

- Fogging/mist blowing applications: Automated (stationary) fogger/mist blower mixing/loading exposure was estimated using PHED mixing/loading exposure data and applicator exposure was considered negligible. No data were available for workers using handheld mistblower or handheld fogger.
- Tractor-drawn mistblower or ULV application for mosquito control: For outdoor scenarios, PHED closed cab airblast and AHETF open cab airblast data were used.
- Handheld sprayer to apply an insecticide to flying insects: PHED data for backpack, manually pressurized handwand, and mechanically pressurized handgun application were used.
- Vapour treatment (application using a squeeze bottle to cold pipes): Since no PHED or other data are available for this scenario, the backpack sprayer data was used.

Additional assumptions used to estimate daily exposure for workers mixing, loading, and applying naled included: label application rates (covering multiple pests), default or refined area treated per day (ATPD) values, and an 80 kg body weight.

Dermal and inhalation risks from exposure to naled were assessed using reference values summarized in Appendix II, Table 1. While dermal and inhalation reference values for naled do not have the same toxicological endpoint, brain cholinesterase inhibition was observed via inhalation at a higher dose ($BMDL_{10}$ of 1.254 µg/L or 0.35 mg/kg bw/day with a target MOE of 300). Therefore, a combined MOE approach was considered appropriate for assessing combined risks resulting from dermal and inhalation exposures to naled.

The risk assessment for mixers/loaders/applicators exposed to naled is presented in Appendix III, Tables 3.1 to 3.5. Risk from dermal exposure of naled was higher than that from inhalation exposure for mixers/loaders/applicators. The calculated dermal, inhalation, and/or combined (dermal plus inhalation) MOEs did not meet the target MOE for all scenarios using the current PPE stated on the label. Based on this, the risks to all mixers/loaders/applicators from dermal and inhalation exposure to naled are not considered to be acceptable under current conditions of use.

Risks to mixers/loaders/applicators using handheld mistblower or fogger were not assessed due to the lack of exposure data for these types of application equipment. Considering that exposure is anticipated to be significant due to the characteristics of the spray, the risk to mixers/loaders applicators using this type of equipment is not considered to be acceptable.

Inhalation exposure to naled and dichlorvos during application

Naled is considered to be volatile; therefore, the use of AHETF and PHED data, which is based on generic exposures to non-volatile pesticides, may lead to the underestimation of inhalation exposure of naled to mixers/loaders/applicators. Furthermore, studies have shown that dichlorvos, a degradate of naled, and also a volatile substance, is detected in the air during application resulting in potential inhalation exposure to both naled and dichlorvos. Therefore, the PMRA conducted a supplemental exposure and risk assessment for mixers/loaders/applicators exposed via inhalation to both naled and dichlorvos during outdoor applications using the inhalation reference values for the combined assessments of naled and dichlorvos (Appendix II).

There are no chemical-specific data on file to determine the inhalation exposure to naled and dichlorvos during application. Therefore, the PMRA considered published scientific studies, in which air concentrations during and after naled application were measured; however, there were no studies directly measuring inhalation exposure to workers. The most suitable studies were conducted in California in vineyards and orange groves (CalEPA 1993, 1995). Both studies measured air concentrations of naled and dichlorvos from the field edge during airblast application and up to approximately one hour after application was completed. These data are not a true representation of applicator exposure since the samples are taken from the field's edge and not in the field itself, and thus, are likely an underestimate of air concentration closer to the application sites. However, in the absence of better data, the field edge concentration data were used to estimate inhalation exposure to naled and dichlorvos during outdoor application.

The maximum air concentration of naled and the concurrent concentration of dichlorvos (6.3 $\mu g/m^3$ and 0.508 $\mu g/m^3$ respectively) from the 1995 Cal EPA study were used in the risk assessment. Exposures were adjusted to account for a standard working day. This is likely an overestimate of exposure since mixing, loading, and applying activities may not necessarily require a full working day.

As the inhalation route of exposure for naled and dichlorvos (resulting from the use of naled) have the same toxicological endpoint for the combined assessment, but different points of departure (Appendix II), an aggregate risk index (ARI) was calculated. ARIs greater than or equal to 1 do not require risk mitigation. If the ARI is less than 1, it does not necessarily mean that exposure will result in adverse effects. However, ARIs less than 1 require measures to mitigate (reduce) risk. For the individual inhalation exposures to naled and dichlorvos, as well as for the combined inhalation exposure to both chemicals, the calculated MOEs for outdoor workers mixers/loaders/applicators are greater than the target MOE and the ARI, indicating no concerns for inhalation exposure to naled and dichlorvos (Appendix III, Table 3.6). On this basis, the potential risks to applicators from inhalation exposure to naled and dichlorvos is considered to be acceptable.

Combined dermal and inhalation exposure to naled and dichlorvos

Since exposure to both naled and dichlorvos from inhalation and dermal sources contribute to a common toxicological effect (brain cholinesterase inhibition), the contribution from all sources should be combined for workers. Given that combined (dermal plus inhalation) risks for mixers/loaders/applicators from exposure to naled alone are not considered to be acceptable (Appendix III, Tables 3.1 to 3.6), a combined risk assessment for workers from exposure to both naled and dichlorvos was not conducted at this time.

4.1.2 Postapplication Workers

The postapplication occupational risk assessment considers dermal and inhalation exposures to workers who enter treated sites to conduct postapplication activities involving foliar contact, such as outdoor and greenhouse crops. The postapplication assessment considers exposure to naled as well as dichlorvos resulting from the use of naled (when data are available).

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before workers can enter after application to perform tasks involving hand labour. An REI is the duration of time that must elapse in order to allow residues to decline to a level where there are no risks of concern for postapplication worker activities.

Dermal exposure for postapplication workers was estimated using updated activity-specific transfer coefficients (TCs) and dislodgeable foliar residues (DFRs).

Dislodgeable Foliar Residues (DFRs)

For outdoor crops, dermal exposure of postapplication workers to naled and dichlorvos is estimated using chemical-specific DFRs (Canada, 2004). The studies measured the dissipation of naled and its primary metabolite, dichlorvos, after two applications of 2.1 kg a.i./ha (as Dibrom 8 Emulsive) to cotton plants, broccoli, and orange trees. Each study was conducted at two American sites. The broccoli study also included an Ontario site. All three studies were evaluated to get a general understanding of the foliar dissipation of naled and dichlorvos in the field. In the studies, naled and dichlorvos DFRs declined rapidly and were below the limit of quantification after 72 hours with the exception of citrus in California.

The broccoli DFR results for Ontario were considered the most appropriate for assessing postapplication exposure to naled and dichlorvos. The chemical-specific DFRs were used on the following outdoor ground crops:

- Alfalfa, clover, and vetch,
- Peas, beans, and lima beans,
- Broccoli, Brussels sprouts, cabbage, and cauliflower,
- Outdoor lettuce,
- Onion,
- Potato,
- Strawberry,
- Tomato,
- Sugar beets,
- Outdoor ornamentals, and
- Woodlands.

Although broccoli may not be representative of some of the crops listed above, it is expected that because it is a waxy foliage crop it will not underestimate risk for crops with smooth or hairy foliage. In addition, the study was conducted in Ontario, which is representative of some of the geographic and climatic conditions of the naled use pattern. This is consistent with the approach that was taken in the previous naled re-evaluation (Canada, 2004 and Canada, 2006).

For indoor crops, there are no chemical-specific DFR studies available. Therefore, exposure was estimated using default DFRs that were calculated assuming 25% deposition of the application rate, with a 2.3% dissipation rate for greenhouse ornamentals, and no dissipation for greenhouse vegetables.

Transfer Coefficient

A transfer coefficient (TC), usually expressed in units of cm^2 per hour, expresses the relationship between worker dermal exposure and dislodgeable residues. Transfer coefficients are specific to a given crop (and crop stage) and activity combination (for example, hand harvesting broccoli) and reflect standard agricultural work clothing worn by adult workers. Activity-specific TCs from the Agricultural Re-Entry Task Force (ARTF) were used.

4.1.2.1 Outdoor crops

Based on the naled use pattern, there is potential for short- to intermediate-term postapplication exposure (dermal and inhalation) to naled and dichlorvos for workers entering treated fields.

There is potential for postapplication dermal exposure of workers to both naled and dichlorvos. Dermal exposure was estimated using chemical-specific DFRs (see above), standard TC values (ARTF), and assuming an 8-hour workday, 30% dermal absorption for dichlorvos (Canada, 2017b), and an 80-kg worker body weight. Since the dermal reference dose for naled was based on a dermal study, dermal absorption was not needed for naled. The dermal risks were calculated using the short/intermediate-term dermal reference values for naled and dichlorvos (Appendix II). The combined risk from exposure to naled and dichlorvos was estimated using the ARI approach.

The dermal risk assessment for workers performing postapplication activities in outdoor crops is presented in Appendix IV, Table 4.1. Target dermal MOEs and ARIs were met for all crops/sites at the 48-hour REI specified on the current label, with the exception of hand harvesting for brassica leafy vegetables. For this scenario, although the target MOE was not met for dermal exposure to dichlorvos, the risk is considered to be acceptable since the broccoli DFR data had no measurable amount of dichlorvos beyond 48 hours at any location. Therefore, it is recommended that the REI remain at two days for all crops and activities based on dermal exposure.

There is also potential for inhalation exposure to naled and dichlorvos for workers performing postapplication activities in crops treated with naled due to the volatility of naled and dichlorvos. The risk assessment was based on an ARTF study (Lamb et al., 1994) measuring dermal and inhalation exposures to naled and dichlorvos for workers harvesting in grape vineyards after three applications of Dibrom 8 Emulsive. Although grapes are not on the current label, the worker inhalation exposures measured in this study was considered to be representative of workers entering a treated field to conduct standard agricultural activities. Inhalation exposures (on day one) in the study were adjusted for a standard workday and default body weight. The postapplication inhalation assessment for workers exposed to naled and dichlorvos is presented in Appendix IV, Table 4.2. Target inhalation MOEs for naled and dichlorvos were met. However, the combined ARI for exposure to both chemicals is less than one assuming air concentrations measured on day one. Taking into consideration that the current label REI is 48 hours, the combined inhalation risk to both naled and dichlorvos is considered to be acceptable.

4.1.2.2 Outdoor farm areas

Naled can be applied in/around outdoor farm areas such as rangeland, field areas, pastures, feedlots, corrals, and holding pens (dairy and beef cattle present). The postapplication dermal exposure of workers following such applications is expected to be low due to the limited direct contact with naled residues. Since dairy cattle may be present during spraying, some worker exposure is possible.

A 48-hour REI is currently required on the commercial end-use product label and workers are required to wear chemical-resistant gloves if animals are to be handled within 48 hours. Consequently, postapplication dermal risks to workers exposed to naled following applications in/around outdoor farm areas are considered to be acceptable. The inhalation exposure following outdoor farm area applications is considered to be lower than exposure of workers entering treated sites (outdoor crops) to conduct postapplication activities. On this basis, the inhalation risk to workers following outdoor farm areas applications is considered to be acceptable.

4.1.2.3 Indoor sites

Greenhouse crops

Dermal exposure to postapplication workers in greenhouses was estimated using agricultural TCs and default DFR assumptions in the absence of chemical-specific data for greenhouse DFRs. The dermal risks were calculated using the long-term dermal reference values for naled (Appendix II). The postapplication risk assessment for greenhouse workers is presented in Appendix IV, Table 4.3. Target dermal MOEs are not met on the day of application for naled alone and calculated REIs that are required to meet the target MOE are not considered to be agronomically feasible. Consequently, the potential risks to postapplication greenhouse workers exposed to naled residues are not considered to be acceptable under current conditions of use. It should be noted, that in the absence of chemical-specific data, the dermal risk assessment for naled is based on assumptions for typical pesticides, which are considered to be non-volatile. Naled is volatile and compared to typical pesticides, a larger fraction would be expected to volatilize and not be available for dermal exposure from the foliage. Therefore, the assumptions used may not be appropriate and are likely over estimates of dermal exposure. However, there is no information available to refine the current risk assessment for greenhouse workers.

There is also a potential for inhalation exposure to naled and dichlorvos for workers performing postapplication activities in greenhouse crops due to the volatility of these compounds. At this time, greenhouse postapplication air concentration data for naled and dichlorvos are not available. Inhalation risks of concern for all indoor scenarios are expected based on volatility and toxicity of naled and dichlorvos. A worker exposure study (for example, passive dosimetry or biomonitoring), or air concentration study, could be considered for better characterization of greenhouse postapplication inhalation risks.

Other indoor areas

There is a potential for postapplication exposure to workers re-entering indoor areas (poultry houses, pig pens, cider mills, livestock barns and wineries) which have been treated with naled. Postapplication exposure activities may vary from handling livestock, packaging stored items to cleaning activities. Due to the limit of applications to twice per year, exposure is likely to be short-term in duration.

The predominant route of exposure is expected to be inhalation due to the volatility of naled and dichlorvos. Although dermal exposure is possible, contact with potentially contaminated surfaces in structural sites is expected to be minimal; therefore, a quantitative dermal risk assessment was not conducted.

At this time, postapplication air concentration data are not available for indoor application sites. However, inhalation exposure risk is expected to occur based on the volatility of naled and dichlorvos. A worker exposure study (for example passive dosimetry, biomonitoring) or air concentration study is required for the indoor postapplication inhalation risk assessment.

4.1.3 Overall Conclusion for Occupational Risks

Based on the available information, the results of the occupational risk assessment indicate that:

- the risks to mixers/loaders/applicators (outdoor and indoor applications) as well as to postapplication workers indoors are not considered to be acceptable under the current conditions of use.
- the risks to postapplication workers outdoors are considered to be acceptable under current conditions of uses.

Consequently, all uses of naled are proposed to be cancelled based on occupational risks that are not considered to be acceptable. A summary of the occupational risk assessment is presented in Appendix V. Given the proposed cancellation of all uses, no further label amendments are proposed at this time.

No additional scientific data are being requested. However, during the consultation period, the registrants may consider submission of further data and risk management options for naled that could be used to address the uncertainties in the assessment and to refine the risk assessment. These data and information are identified in Section 7.0 of this Proposed Special Review Decision.

4.2 Potential Dietary Risk

The PMRA assessed potential acute and chronic dietary (food and drinking water) risks from exposure to naled residues for this special review. Potential dietary risks from exposure to dichlorvos, a degradate of naled, as well as a plant and animal metabolite of naled, were assessed separately since dichlorvos itself is registered as an organophosphate pesticide (Canada, 2017b). However, since naled readily degrades to dichlorvos in food and water, and because the two active ingredients have the same toxicological effects (that is cholinesterase inhibition), as part of this special review the PMRA estimated a potential combined risk from dietary exposure to both naled and dichlorvos by using the ARI approach. The reference values used in the dietary exposure and risk assessment conducted for this special review are summarized in Appendix II.

The acute and chronic dietary (food plus drinking water) assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™; Version 4.02) program which incorporates food consumption data from the National Health and Nutrition Examination Survey/“What We Eat in America” dietary survey for the years 2005-

2010 available through the Centers for Disease Control and Prevention's National Center for Health Statistics. Dietary exposure 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, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults.

The dietary exposure assessment for naled was conducted using Canadian Food Inspection Agency and United States Pesticide Data Program residue monitoring data for most of the commodities; for a few commodities with no monitoring data, anticipated residues from American field trials or maximum residue level (MRL)/tolerance levels were used. Policies from the PMRA and United States Environmental Protection Agency were used for crop translations when necessary. In addition, the following inputs were incorporated where available: percent crop treated information in Canada and the United States; 100% crop treated for commodities for which no percent crop treated information was available; and available experimental processing factors. DEEM-FCID default processing factors were used when experimental processing factors were not available. No Canadian MRLs are specified for animal commodities. Canadian MRLs for meat, milk, poultry and eggs are not required as feeding of raw agricultural commodities items is not expected to result in measurable residues. Moreover, previously established American tolerances in animal tissues, milk and eggs were revoked. Based on the calculated animal dietary burden, the United States Environmental Protection Agency concluded that there is no reasonable expectation of finite residues in meat, milk, poultry, and eggs resulting from feeding of treated crops. In addition, the contribution of the residues from uses in livestock premises is not expected to be significant. Thus, contribution of residues from animal commodities to human dietary exposure is assumed negligible and was, therefore, not included in the assessment.

Estimated environmental concentrations (EECs) of naled in potential drinking water sources were modelled using the Pesticide in Water Calculator model for both groundwater and surface water. Based on the modelling, naled is not expected to leach into ground water. Acute (90^{th} percentile of yearly peak concentrations) and chronic (90^{th} percentile of yearly average concentrations) EECs of naled resulting from run-off were 0.065 ppm and 0.00025 ppm, respectively. These values are considered to be upper bound concentrations in surface water. For the acute exposure assessment, the entire distribution of the 50-year peak concentrations in surface water was used in the probabilistic dietary exposure assessment. For the chronic assessment, the EEC point estimate was incorporated directly in the dietary (food and drinking water) assessment.

The results of the dietary exposure and risk assessment for naled are presented in Appendix VI, Table 6.1. The acute food-only exposure estimates (at the 99.9^{th} percentile) are at or below 2% of the acute reference dose (ARfD) for the general population and all subpopulations. The acute dietary (food and drinking water) exposure estimates, at the 99.9^{th} percentile, are at approximately 14% of the ARfD for the general population and range from 10% to 37% of the ARfD for all subpopulations and, therefore, risks are considered to be acceptable.

The most exposed subpopulation is infants less than 1 year old. For this subpopulation, the major contributor to the exposure is water, indirect, from all sources, accounting for 94% of the total exposure.

The chronic food-only exposure estimates for naled are at or below approximately 1% of the acceptable daily intake (ADI) for the general population and all subpopulations. The chronic dietary (food and drinking water) exposure estimate for the general population and all subpopulations is at or below 2% of the ADI. Thus, the chronic dietary risk from exposure to naled residues through food and drinking water is considered to be acceptable.

A combined risk from exposure to both naled and dichlorvos was calculated using the ARI approach. The calculated ARIs for combined exposure to dichlorvos and naled are all greater than 1 for both acute and chronic exposures and, therefore, risks are considered to be acceptable. The most exposed subpopulation is infants less than 1 year old for the acute exposure and children 1 to 2 years old for the chronic exposure (Appendix VI, Table 6.2).

4.2.1 Overall Conclusion for the Potential Dietary Risk

Based on the results of the dietary exposure assessment, the PMRA concluded that dietary risks from exposure to naled and combined exposure to naled and dichlorvos are considered to be acceptable.

4.3 Potential Risks to Aquatic and Terrestrial Organisms

The PMRA assessed potential risks to non-target aquatic and terrestrial organisms resulting from application of naled using available information (Canada, 2004; Canada, 2006; Canada, 2017b). As part of the special review, PMRA considered the environmental fate characteristics of naled and toxicity to non-target organisms.

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models, which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (that is, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing

the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

Naled is not expected to persist in soil. Biotransformation is an important route of transformation of naled in aerobic as well as in anaerobic soil; the half-life was less than one day for both systems. The major transformation products in soil include dichlorvos, BDCA (bromodichloro acetaldehyde) and DCAA (dichloroacetic acid). In water, hydrolysis and phototransformation are important routes of transformation of naled. Naled is expected to be rapidly lost from moist soil and water surface as indicated by its Henry's law constant (9.9×10^{-4} atm $\times$ $m^3 \times mole^{-1}$).

Dichlorvos, a transformation product of naled, is not expected to persist in soil or water. For dichlorvos, hydrolysis and biotransformation in soil and water/sediment are considered to be important routes of transformation (Canada, 2017b). Terrestrial and aquatic dissipation studies indicate naled and its transformation product, dichlorvos, are expected to dissipate rapidly in the environment.

4.3.1 Potential Risks to Terrestrial Species

There is a potential for exposure of non-target terrestrial species following the use of naled in a variety of use areas such as outdoor and indoor sites.

In/around structure uses

Exposure to the environment from application of naled in/around structures (for example, greenhouse, animal housing, cider mills, and wineries) is expected to be limited. Following application, volatilisation from surfaces, and subsequent breakdown in air, are also expected to occur, and will minimise any residues left after treatment. Based on the above, the risk to non-target terrestrial species posed by naled following application to in/around structures is considered to be acceptable under current conditions of use.

Outdoor uses

The PMRA assessed the potential risks to non-target terrestrial species following outdoor applications of naled to food and feed crops.

Bees: Naled is highly toxic to honey bees based on the acute contact toxicity study. Based on the acute contact toxicity (LD_{50} = 0.54 kg a.i./ha), the RQs range from 2 to 35 if applied to crops in blossom (Canada, 2004). The extent of the residual hazard varies with application rate, weather conditions, and the formulation of the specific product applied. In order to minimize the potential for bee exposure, updated standard bee caution label statements are proposed to be included on the end-use product labels (Appendix VIII).

Birds: Naled is 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. Chronic toxicity (reproduction) studies conducted on mallard duck and bobwhite quail showed that the mallard was the more sensitive of the two species, with a No Observed Adverse Concentration (NOEC) of 260 mg a.i./kg based on reduction in the number of eggs (Canada, 2004; Canada, 2006).

Birds could be exposed to naled spray drift or through consumption of contaminated food. Potential risks to birds were calculated based on the EECs on various food sources and the most appropriate toxicity endpoint for birds (no observed effect level [NOEL]) = 2.675 mg a.i./kg (Canada, 2004, 2006). The assessment indicated that birds would have to consume contaminated food sources for less than 1 day (0.04–0.7 days) to reach the dose equivalent to the NOEL, and, 0.4–7 days to reach LD_{50}. Based on this, there is potential for acute risks to birds from consumption of food contaminated with naled. The chronic RQ values for birds (0.01 to 0.25) are considered to be acceptable based on the NOEC of 260 mg a.i./kg from the avian reproduction study on the mallard duck (Canada, 2006).

A potential acute risk was identified for birds based on the modelled EECs for a single dietary item. However, it is unlikely that the bird diet will be comprised entirely of a single dietary item. Furthermore, naled is volatile (260 mPa at 20^{o}C), and expected to be rapidly lost from moist surfaces, resulting in lower concentrations of naled on food commodities. Consequently, the actual acute and dietary risks to birds are expected to be lower than the modelled risk estimates. On this basis, the risk to birds is considered to be acceptable under current conditions of use. A standard environmental hazard label statement, *Toxic to birds*, is proposed to be included on the commercial-class product label.

Mammals: Naled is moderately toxic to mammals on an acute basis (LD_{50} = 92 mg a.i./kg). On a chronic basis, a two-generation reproduction study with rats produced parental and offspring NOELs of 90 mg/kg.

Wild mammals could be exposed to naled through consumption of contaminated food (for example, grass, seeds and leafy plants). Potential risks to mammals were calculated based on the EECs on various food sources and using the acute oral endpoint (NOEL = 9.2 mg a.i./kg). Based on this, a potential acute risk to mammals through the consumption of contaminated food was identified. Assessment of chronic (reproduction) toxicity to mammals resulted in RQs ranging from 0.6 to 10.7. A potential acute risk was identified for wild mammals based on the modelled EECs for a single dietary item.

However, as the diet of wild mammals is unlikely to be comprised entirely of a single dietary item and the residues of naled on food commodities are not expected to persist (naled is volatile) in the environment, acute and chronic risks to mammals are considered to be acceptable under current conditions of use.

4.3.2 Potential Risks to Aquatic Organisms

Aquatic organisms can be exposed to naled as a result of spray drift during outdoor applications, as well as to naled and dichlorvos as a result of runoff from treated fields. There is also a potential for exposure following applications in/around structures. Both naled and its transformation product, dichlorvos, are highly toxic to freshwater and estuarine/marine organisms (Appendix VII, Tables 3 and 4).

In/around structures uses

The potential for exposure of aquatic organisms from use of naled in/around structures is expected to be minimal. However, effluent from greenhouses may be a potential route of exposure of naled to aquatic systems. Therefore, to minimize potential exposure from the release of effluent containing residues of naled to aquatic systems through this use, label statements are proposed (stating that effluent containing this active ingredient, from use of naled in greenhouses, should not be discharged into waterbodies) as part of this special review.

Outdoor uses

Spray drift from ground/aerial applications and runoff from the site of application can enter non-target aquatic habitats. At the screening level, the potential risk to non-target aquatic species from direct spray onto a body of water is conducted (Canada, 2004; Canada, 2006). In addition, an assessment of potential risks to aquatic organisms from exposure to naled and its transformation product, dichlorvos, from runoff from treated fields was conducted.

Direct spray
The PMRA calculated surface water EECs assuming a direct spray (100% deposit) of naled onto a body of water. The EEC_{water} of naled, assuming application rates of 0.11-1.9 kg a.i./ha, ranged from 0.073 to 1.27 (15 cm depth of water) and from 0.037 to 0.63 mg a.i./L (30 cm depth of water) (Canada, 2004; Canada, 2006).

Screening level acute RQs for *Daphnia magna,* grass shrimp and lake trout are 120-1750, 38.7-677, and 0.04–-0.07, respectively, and they exceeded the LOC of aquatic organisms. For aquatic plants, the estimated RQs range from 14.4 to 252 (Navicula pelliculosa), and it is above the LOC for aquatic plants. The chronic RQs exceeded the level of concern for aquatic organisms.

As the LOC exceeded at the screening level, the potential risks from runoff was further characterized.

Runoff
EECs in water were calculated using the Pesticide in Water calculator model for a 10-ha field adjacent to a 1 ha water body with a depth of 80 cm to represent a permanent water body, or 15 cm to represent a seasonal water body used by amphibians, assuming two applications of 1.9 g a.i./ha at a re-treatment interval of 7 days. The modelling inputs and resulting EECs are summarized in Appendix VII, Tables 1 and 2.

Using the EECs and the most sensitive acute endpoints for naled, the acute RQs were 160 for freshwater and estuarine/marine invertebrates, 4 for aquatic plants, and 29 for amphibians (Appendix VII, Table 3). Using the most sensitive acute endpoints for dichlorvos, acute RQs were 12–31 for freshwater organisms, and 656 for amphibians (Appendix VII, Table 4). Based on the above, acute risks to aquatic organisms from runoff of naled and dichlorvos are not considered to be acceptable under current conditions of use. The chronic risks to aquatic organisms from exposure to naled and dichlorvos (Appendix VII, Tables 3 and 4) are considered to be acceptable under current conditions of use

Spray drift
In order to reduce the potential risk from spray drift to non-target aquatic organisms, updated spray buffer zones (up to 35 m and 625 m for ground and aerial applications), are proposed to be included on the commercial-class product label. The risk to aquatic organisms from spray drift is considered to be acceptable with the proposed mitigation measures (buffer zones).

4.3.3 Overall Conclusion for Potential Risks to Terrestrial and Aquatic Organisms

Potential risks to terrestrial organisms are considered to be acceptable for all uses with the following proposed label amendments:

- A standard hazard label statement “Toxic to birds”
- An update to standard precautionary bee statements.

Potential risk to aquatic organisms from indoor applications of naled (in/around structures) is considered to be acceptable with the following proposed mitigation measures:

- A label statement prohibiting the discharge of greenhouse effluents to waterbodies.

Potential risk to aquatic organisms from spray drift of naled (from outdoor application) is considered acceptable with the proposed updated buffer zones.

Potential risk to aquatic organisms from runoff (outdoor applications of naled) is not considered acceptable under current conditions of use. Therefore, all outdoor uses of naled are proposed for cancellation.

The proposed label amendments are summarized in Appendix VIII.

5.0 Incident Reports

The PMRA incident reporting database was searched for incident reports related to the identified aspects of concern for naled. As of 17 May 2017, there was one human incident.

The reported incident occurred in the United States and was classified as major. According to the report, the subject was exposed to a significant quantity of a concentrated naled product when a hose exploded from an airplane tank and the product splashed onto his eyes and face from under a face shield.

The initial symptoms experienced by the subject were tongue swelling and erythema. The subject was hospitalized and aggressively treated for organophosphate toxicosis. The incident was considered related to the reported pesticide exposure.

The circumstances of exposure reported in the incident relate to equipment failure. Therefore, no health concerns were identified in the incident data when the product is used as per the label directions.

There are no incident reports related to the environment in the PMRA incident reporting database.

6.0 Proposed Special Review Decision for Naled

Evaluation of the available relevant scientific information related to the aspects of concern indicated that the potential risk to human health (occupational workers) and to the environment (aquatic organisms) is not considered to be acceptable under the current label directions. Based on this, Health Canada, under the authority of the *Pest Control Products Act*, is proposing to cancel the current registration of pest control products containing naled for sale and use in Canada pursuant to subsection 21(2) of the Pest Control Products Act.

Evaluation of available relevant scientific information related to the aspect of concern, indicates that the potential risk to postapplication workers for outdoor applications of naled is considered to be acceptable under the current conditions of use. However, the occupational risks to workers mixing, loading and applying naled (outdoor and indoor applications), as well as to post application workers in indoor areas are not considered to be acceptable under the current label directions. Potential dietary risk from exposure to naled is considered to be acceptable.

The potential risk to terrestrial organisms (from all uses of naled) and to aquatic organisms (from indoor applications) is considered to be acceptable with additional label updates. However, the potential risk to aquatic organisms from outdoor applications of naled is not considered to be acceptable under the current conditions of use.

This proposed special review decision is a consultation document.[1] The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

7.0 Additional Data that May Help Address Uncertainties and Refine the Assessments

No additional scientific data are being requested. However, during the consultation period, the registrants and other stakeholders may consider submitting the following information that may address uncertainties in the available information database of naled and support refined risk assessment. In addition, stakeholders may consider providing information on risk management options for naled (for example, additional PPE, engineering control).

The evaluation of any additional data would be based on the scientific merit and relevance to the risk assessment. While additional data may reduce uncertainty in the risk assessment, continued registration of any uses would be based on the acceptability of risk assessed using a science-based approach.

Human health:
All studies would need to include consideration of both naled and dichlorvos (degradate of naled). When using biomonitoring studies (DACO 5.5 or 5.7) suitable human pharmacokinetic data is required to adequately characterise the pharmacokinetics in humans.

Greenhouse (non-food crops: roses and cut flowers) (food crops: cucumbers, tomatoes, eggplant, peppers):

1. DACO 5.9 DFR data (greenhouse vegetable and a smooth ornamental crop),
2. DACO 5.10 Ambient air samples and dissipation data following a greenhouse application and continued until the residues are below Limit of Detection (LOD) (breathing zone samples are preferable),
3. DACO 5.6/5.7 Post application passive dosimetry/biological monitoring (this could replace DACO 5.9 and DACO 5.10 above, if both dermal and inhalation exposure are considered),
4. DACO 5.4/5.5 Vapour treatment: Mixing/Loading/Applying (M/L/A) passive dosimetry/biological monitoring (if this application method is required) (include both dermal and inhalation exposure).

Other indoor areas (poultry houses, cider mills, livestock barns, wineries):

1. DACO 5.10 Ambient air samples and dissipation data following an indoor application and continued until the residues are below LOD (breathing zone samples are preferable),

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2. DACO 5.4/5.5 Handheld mistblower MLA passive dosimetry/biological monitoring (if this equipment is required indoors) (include both dermal and inhalation exposure).

Outdoor Crops:

1. DACO 5.4/5.5 Handheld mistblower M/L/A passive dosimetry/biological monitoring (if this equipment is required outdoors) (include both dermal and inhalation exposure)
2. DACO 5.4/5.5 M/L/A passive dosimetry/biological monitoring (for any application scenario that is required but has not been shown to have acceptable risk).

Environment:
Additional environmental fate and toxicity data related to the aspect of concern.

8.0 Next Steps

Before making a special review decision on naled, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on naled. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision, and the PMRA's response to these comments.

Appendix I Registered Products Containing Naled as of 23 January 2019

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
23202	Technical	AMVAC Chemical Corporation	AMVAC Naled Technical	Solution	94.5%
7442	Commercial	Loveland Products Canada Inc.	Dibrom Insecticide	Emulsifiable concentrate	900 g/L

Appendix II Toxicology Endpoints for Use in Human Health Risk Assessment

Table 1 Toxicological Reference Values for Use in the Human Health Risk Assessment for Naled

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[a] or Target MOE
Acute dietary - general population, combined[b] acute	Acute oral cholinesterase in rats	$BMDL_{10}$ = 5.9 mg/kg bw Decreased BChE activity	100
	ARfD = 0.06 mg/kg bw		
Repeated dietary - general population, combined[b] long-term	7-day oral cholinesterase in rats	$BMDL_{10}$ = 0.67 mg/kg bw/day Decreased BChE activity	300
	ADI = 0.002 mg/kg bw/day		
Short- and intermediate-term dermal	28-day dermal in rats	$BMDL_{10}$ = 1.96 mg/kg bw/day Decreased BChE activity	300
Long-term dermal	28-day dermal in rats	$BMDL_{10}$ = 1.96 mg/kg bw/day Decreased BChE activity	1000
Inhalation, all durations	90-day inhalation in rats	LOAEL = 0.065 mg/kg bw/day Clinical signs and nasal pathology	100
Aggregate short-term, Co-exposure[b]	Oral: 7-day oral cholinesterase in rats	$BMDL_{10}$ = 0.67 mg/kg bw/day	100
	Dermal: 28-day dermal in rats	$BMDL_{10}$ = 1.96 mg/kg bw/day	300
	Inhalation: 90-day inhalation in rats	$BMDL_{10}$ = 1.254 µg/L (~0.35 mg/kg bw/day) Common endpoint: Decreased BChE activity	300
Cancer	No evidence of oncogenicity		

[a] CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary assessments; MOE refers to a target MOE for occupational and residential assessments; $BMDL_{10}$ – benchmark dose level for 10% change; BChE- brain cholinesterase; ARfD – acute reference dose; ADI – acceptable daily intake; LOAEL – lowest observed adverse effect level

[b] Co-exposure refers to risk assessments for co-occurrence of naled with dichlorvos

Table 2 Toxicological Reference Values for Use in Health Risk Assessment for Dichlorvos (Canada, 2017b)

Exposure Scenario	Endpoint	Study	CAF[a] or Target MOE
Acute Dietary combined[d] (all populations)	$BMDL_{10}$ = 1.4 mg/kg bw (BChE inhibition)	Two Acute Oral Cholinesterase Inhibition Studies - neonate and young adult Rats	100
	ARfD = 0.014 mg/kg bw		
Chronic Dietary combined[d] (all populations)	$BMDL_{10}$ = 0.011 mg/kg bw (BChE inhibition)	7-day Repeat-dose Oral Cholinesterase Inhibition Study - PND 18 and 48 rats	100
	ADI = 0.0001 mg/kg bw/day		
Dermal[b], all durations	$BMDL_{10}$ = 0.011 mg/kg bw (BChE inhibition)	7-day Repeat-dose Oral Cholinesterase Inhibition Study - PND 18 and 48 rats	100
Inhalation[c], all durations	$BMDL_{10}$ = 0.011 mg/kg bw (BChE inhibition)	7-day Repeat-dose Oral Cholinesterase Inhibition Study - PND 18 and 48 rats	100
Aggregate short-term, co-exposure[d]	Oral, dermal, and inhalation: $BMDL_{10}$ = 0.011 mg/kg bw (BChE inhibition)	7-day Repeat-dose Oral Cholinesterase Inhibition Study - PND 18 and 48 rats	100
Cancer Oral, Dermal and Inhalation	Dichlorvos is an in vitro mutagen and clastogen; however, the overall weight of evidence suggested that it is neither mutagenic nor clastogenic in vivo. The available evidence is insufficient to rule out the possibility that dichlorvos may be carcinogenic. Although a data gap remains in the dichlorvos database with respect to carcinogenicity, there is a large margin (~40,000) between the proposed reference values for repeat-exposure and the lowest dose resulting in tumours in the available dichlorvos studies.		

$BMDL_{10}$ – benchmark dose level for 10% change; BChE – brain cholinesterase; PND – post-natal day

[a] CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary assessments; MOE refers to a target MOE for occupational and residential assessments.

[b] Since an oral NOAEL was selected, a 30% dermal absorption was used for route-to-route extrapolation

[c] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used for route-to-route extrapolation

[d] Co-exposure refers to risk assessments for co-occurrence of naled with dichlorvos

Appendix III Mixer/Loader/Applicator Risk Assessment

Table 3.1 Mixer/Loader/Applicator Exposure and Risk Assessment of Naled by Groundboom Application

Crop	Application Rate (kg a.i./ha)	ATPD (ha/day)[a]	Amount handled per day (kg a.i./day)	Dermal Exposure[b] (mg/kg bw/day)	Inhalation Exposure[c] (mg/kg bw/day)	Dermal MOE[d]	Inhalation MOE[e]	Combined MOE[f]
PPE: Mid-level PPE + open M/L + open cab + respirator [g]								
Broccoli, Brussels sprouts, cabbage, cauliflower	1.9	26	49	3.32×10^{-2}	1.58×10^{-4}	59	410	57
Lettuce	1.425	26	37	2.49×10^{-2}	1.19×10^{-4}	79	550	77
Onion	0.48	26	12.48	8.39×10^{-3}	3.99×10^{-5}	230	1600	227
Strawberries	0.95	26	25	1.66×10^{-2}	7.9×10^{-5}	120	820	115
Tomatoes	1.728	26	45	3.02×10^{-2}	1.44×10^{-4}	65	450	63
PPE: Maximum-level PPE + open M/L + open cab + respirator [g]								
Alfalfa, clover, vetch	1.9	200	380	2.27×10^{-1}	1.22×10^{-3}	9	53	8
Rangeland, field areas, pastures (dairy cattle present)	0.864	360	311	1.86×10^{-1}	9.95×10^{-4}	11	65	10
Peas, beans, lima beans	1.9	200	380	2.27×10^{-1}	1.22×10^{-3}	9	53	8
Potatoes	0.95	360	342	2.05×10^{-1}	1.09×10^{-3}	10	59	9
Sugarbeet	1.9	200	380	2.27×10^{-1}	1.22×10^{-3}	9	53	8

M/L = mixing/loading, ATPD = area treated per day, MOE = margin of exposure, PPE = personal protective equipment

[a] Default ATPD values were used for custom applicators. Farmer values were refined based on the Census of Agriculture (Statistics Canada, 2011) however they were not presented here since the risk for custom applicators is not considered to be acceptable. Label limits workers using maximum rate of 2.2 L end-use product/ha to treat only 200 ha/day.

[b] Dermal exposure (mg/kg bw/day) = (dermal unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[c] Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[d] Based on a short- and intermediate-term $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 for the dermal endpoint

[e] Based on a LOAEL of 0.065 mg/kg bw/day, and a target MOE of 100 for the inhalation endpoint

[f] Combined MOE = 1 / (1/MOE dermal) + (1/MOE inhalation); based on a dermal $BMDL_{10}$ of 1.963 mg/kg bw/day, and a target MOE of 300 and an inhalation $BMDL_{10}$ of 0.35 mg/kg bw/day, and a target MOE of 300

[g] Current PPE on the label states: Maximum-level PPE when applying to areas larger than 30 ha/day, Mid-level PPE if less than 30 ha/day, open mixing/loading plus respirator.

Shaded cells indicate MOEs that are less than the target MOE.

Table 3.2 Mixer/Loader/Applicator Exposure and Risk Assessment of Naled by Aerial Application

Crop	Application Rate (kg a.i./ha)[a]	ATPD (ha/day)[b]	Amount handled per day (kg a.i./day)	Dermal Exposure[c] (mg/kg bw/day)	Inhalation Exposure[d] (mg/kg bw/day)	Dermal MOE[e]	Inhalation MOE[f]	Combined MOE[g]
Aerial with closed M/L (maximum-level PPE + respirator) [h]								
Potatoes	0.950	240	228	2.21×10^{-2}	3.14×10^{-4}	89	210	88
Tomatoes	0.950	200	190	1.84×10^{-2}	2.61×10^{-4}	110	250	106
Corrals, pastures, holding pens, (dairy and beef cattle present)	0.275	222	61	5.91×10^{-3}	8.39×10^{-5}	330	770	329
Alfalfa, clover, vetch	1.900	200	380	3.68×10^{-2}	5.23×10^{-4}	53	120	53
Rangeland, field areas, pastures (dairy cattle present)	0.864	222	192	1.86×10^{-2}	2.64×10^{-4}	110	250	105
Livestock pastures, feed lots, pastures (dairy cattle present)	0.275	222	61	5.91×10^{-3}	8.39×10^{-5}	330	770	329
Peas, beans, lima beans	1.900	200	380	3.68×10^{-2}	5.23×10^{-4}	53	120	53
Aerial applicator. Baseline PPE: single layer, no gloves								
Potatoes	0.950	240	228	2.75×10^{-2}	2.00×10^{-4}	71	330	68
Tomatoes	0.950	200	190	2.29×10^{-2}	1.66×10^{-4}	85	390	82

Crop	Application Rate (kg a.i./ha)[a]	ATPD (ha/day)[b]	Amount handled per day (kg a.i./day)	Dermal Exposure[c] (mg/kg bw/day)	Inhalation Exposure[d] (mg/kg bw/day)	Dermal MOE[e]	Inhalation MOE[f]	Combined MOE[g]
Corrals, pastures, holding pens, (dairy and beef cattle present)	0.275	222	61	7.37×10^{-3}	5.34×10^{-5}	266	1200	256
Alfalfa, clover, vetch	1.900	200	380	4.59×10^{-2}	3.33×10^{-4}	43	200	41
Rangeland, field areas, pastures (dairy cattle present)	0.864	222	192	2.32×10^{-2}	1.68×10^{-4}	85	390	81
Livestock pastures, feed lots, pastures (dairy cattle present)	0.275	222	61	7.37×10^{-3}	5.34×10^{-5}	266	1200	256
Peas, beans, lima beans	1.900	200	380	4.59×10^{-2}	3.33×10^{-4}	43	200	41

M/L = mixing/loading, ATPD = area treated per day, MOE = margin of exposure, PPE = personal protective equipment

[a] Some crops have application rates that vary; this may depend on the insect targeted. The maximum rate is presented here.

[b] ATPD values were mostly refined. The label limits workers using maximum rate of 1.9 kg a.i./ha to treat only 200 ha/day.

[c] Dermal exposure (mg/kg bw/day) = (dermal unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[d] Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[e] Based on a short- and intermediate-term $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 for the dermal endpoint

[f] Based on a LOAEL of 0.065 mg/kg bw/day, and a target MOE of 100 for the inhalation endpoint

[g] Combined MOE = 1 / (1/MOE dermal) + (1/MOE inhalation); based on a dermal $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 and an inhalation $BMDL_{10}$ of 0.35 mg/kg bw/day, and a target MOE of 300

[h] Label states "The field crew and the mixer/loaders must wear chemical resistant gloves, coveralls and goggles or face shield during mixing/loading, cleanup and repair. Follow the more stringent label precautions in cases where the operator precautions exceed the label recommendations on the existing ground boom label." also "All applications must use closed mixing/loading systems". Therefore, the PPE for groundboom was applied here.

Shaded cells indicate MOEs that are less than the target MOE.

Table 3.3 Mixer/Loader/Applicator Exposure and Risk Assessment of Naled by Handheld Application

Equipment	Crop	Application Rate (kg a.i./L)[a]	ATPD (L/day)[b]	Amount handled per day (kg a.i./day)	Dermal Exposure[c] (mg/kg bw/day)	Inhalation Exposure[d] (mg/kg bw/day)	Dermal MOE[e]	Inhalation MOE[f]	Combined MOE[g]
PPE: Mid-level PPE									
MPHW	Strawberries	0.0095	150	1.4	1.31×10^{-2}	8.05×10^{-4}	150	81	110
	In and around dairy barns, livestock barns, pig pens, poultry houses	0.0026	150	0.4	2.58×10^{-3}	2.20×10^{-4}	550	290	407
	Cider mills, wineries	0.0052	150	0.8	7.17×10^{-3}	4.41×10^{-4}	270	150	200
	Outdoor ornamentals	0.00108	150	0.2	1.49×10^{-3}	9.15×10^{-5}	1300	710	980
Backpack	Strawberries	0.0095	150	1.4	4.63×10^{-2}	1.11×10^{-3}	42	59	37
	In and around dairy barns, livestock barns, pig pens, poultry houses	0.0026	150	0.4	1.27×10^{-2}	3.03×10^{-4}	150	210	140
	Cider mills, wineries	0.0052	150	0.8	2.53×10^{-2}	6.05×10^{-4}	80	110	70
	Outdoor ornamentals	0.00108	150	0.2	5.26×10^{-3}	1.26×10^{-4}	370	520	330
PPE: Maximum-level PPE + respirator									
MPHG	Strawberries	0.0095	1000	9.5	2.17×10^{-1}	1.79×10^{-3}	10	36	9

Equipment	Crop	Application Rate (kg a.i./L)[a]	ATPD (L/day)[b]	Amount handled per day (kg a.i./day)	Dermal Exposure[c] (mg/kg bw/day)	Inhalation Exposure[d] (mg/kg bw/day)	Dermal MOE[e]	Inhalation MOE[f]	Combined MOE[g]
PPE: Mid-level PPE									
	In and around dairy barns, livestock barns, pig pens, poultry houses	0.0026	1000	2.6	5.94×10^{-2}	4.91×10^{-4}	30	130	32
	Cider mills, wineries	0.0052	1000	5.2	1.19×10^{-1}	9.82×10^{-4}	20	66	16
	Outdoor ornamentals	0.00108	1000	1.1	2.47×10^{-2}	2.04×10^{-4}	80	320	76

ATPD = area treated per day, MOE = margin of exposure, MPHW = manually pressurized hand wand, MPHG = mechanically pressurized hand gun, PPE = personal protective equipment

[a] Application rates in kg a.i./L were calculated: application rate (kg a.i/ha) / spay volume (100 – 300 L/ha as stated on the label).

[b] Default value of 150 L/day was used for MPHW and backpack. A maximum value of 1000 L/day was used for MPHG as stated on the label.

[c] Dermal exposure (mg/kg bw/day) = (dermal unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[d] Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[e] Based on a short- and intermediate-term $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 for the dermal endpoint

[f] Based on a LOAEL of 0.065 mg/kg bw/day, and a target MOE of 100 for the inhalation endpoint

[g] Combined MOE = 1 / (1/MOE dermal) + (1/MOE inhalation); based on a dermal $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 and an inhalation $BMDL_{10}$ of 0.35 mg/kg bw/day, and a target MOE of 300

Shaded cells indicate MOEs that are less than the target MOE.

Table 3.4 Mixer/Loader/Applicator Exposure and Risk Assessment of Naled by Airblast/Tractor Drawn Mistblower/ULV[a] Application

Site	Application Rate (kg a.i./ha)	ATPD (ha/day)[b]	Amount handled per day (kg a.i./day)	Dermal Exposure[c] (mg/kg bw/day)	Inhalation Exposure[d] (mg/kg bw/day)	Dermal MOE[e]	Inhalation MOE[f]	Combined MOE[g]
PPE: mid-level PPE								
Airblast: Livestock pastures, feed lots, pastures (dairy cattle present)	0.275	20	5.5	2.36×10^{-1}	7.34×10^{-4}	8	89	8
ULV: Livestock pastures, feed lots, pastures (dairy cattle present)	0.275	1200	330	1.42×10^{-1}	4.41×10^{-2}	0	1	0
Airblast: Woodland	0.275	20	5.5	2.36×10^{-1}	7.34×10^{-4}	8	89	8
ULV: Woodland	0.275	500	137.5	5.90×10^{-0}	1.84×10^{-2}	0	4	0
Outdoor ornamentals	0.324	20	6.5	2.78×10^{-1}	8.65×10^{-4}	7	75	7

M/L = mixing/loading, A = apply, ATPD = area treated per day, MOE = margin of exposure, PPE = personal protective equipment,

[a] When the label states mistblower, PHED and/or AHETF airblast data is used. There is no data for handheld mistblower.

[b] Specific ATPD values were not available. The default ATPD for airblast applications was used for tractor drawn mistblower/airblast. Where the target pest is adult mosquitos, ULV treatment was included with an ATPD of 1200 ha/day. Label limitation to woodlands = maximum of 500 ha.

[c] Dermal exposure (mg/kg bw/day) = (dermal unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[d] Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[e] Based on a short- and intermediate-term $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 for the dermal endpoint

[f] Based on a LOAEL of 0.065 mg/kg bw/day, and a target MOE of 100 for the inhalation endpoint

[g] Combined MOE = 1 / (1/MOE dermal) + (1/MOE inhalation); based on a dermal $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 and an inhalation $BMDL_{10}$ of 0.35 mg/kg bw/day, and a target MOE of 300

Shaded cells indicate MOEs that are less than the target MOE.

Table 3.5 Mixer/Loader/Applicator Exposure and Risk Assessment of Naled by Fogger and Vapour Application

Site	Application Rate	ATPD[a]	Amount handled per day (kg a.i./day)	Dermal Exposure[b] (mg/kg bw/day)	Inhalation Exposure[c] (mg/kg bw/day)	Dermal MOE[d]	Inhalation MOE[e]	Combined MOE[f]
PPE: Maximum-level PPE + respirator for all equipment								
Indoor areas (poultry houses, pig pens, cider mills, livestock barns, wineries) – fogger/mistblower (**automated**)[gh]	0.119 kg a.i. /ha	0.022 ha	0.0026	9.53×10^{-7}	5.24×10^{-9}	2.10×10^{6}	1.20×10^{7}	2.00×10^{6}
Indoor areas (poultry houses, pig pens, cider mills, livestock barns, wineries) – fogger/mistblower (handheld)	There is no data available to assess this use.							
Greenhouse (food and non-food) – fogger (**automated**) [hi]	0.00012 kg a.i. /m^2	28000 m^2	3.36	1.22×10^{-3}	6.72×10^{-6}	1600	9700	1556
Greenhouse –vapour treatment [j]	0.000086 kg a.i. /m^3	50000 m^3	4.3	1.09×10^{-1}	2.10×10^{-4}	18	310	18

ATPD = area treated per day, MOE = margin of exposure, PPE= personal protective equipment, CR= chemical resistant

[a] Indoor space spray and greenhouse vapour treatment area treated per day is based on data-call in information for dichlorvos (PMRA, 2016b). Greenhouse fogger area treated per day is based on the Census of Agriculture (Statistics Canada, 2011) for greenhouse vegetables.

[b] Dermal exposure (mg/kg bw/day) = (dermal unit exposure × ATPD × maximum application rate)/body weight (80 kg)

[c] Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/body weight (80 kg). 90% protection factor was used for the respirator to calculate inhalation exposure for the vapour treatment.

[d] Based on a short- and intermediate-term $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 for the dermal endpoint

[e] Based on a LOAEL of 0.065 mg/kg bw/day, and a target MOE of 100 for the inhalation endpoint

[f] Combined MOE = 1 / (1/MOE dermal) + (1/MOE inhalation); based on a dermal $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300 and an inhalation $BMDL_{10}$ of 0.35 mg/kg bw/day, and a target MOE of 300

[g] The application rate for indoor areas was based on: application rate (0.0026 kg a.i./L) × spray volume (45.8 L/ha).The label does not specify fogger or mistblower application equipment for this site, however space spray could be interpreted many ways. Since the PMRA received a confirmation that fogger was being used in a poultry house, this scenario was expanded to include additional application equipment. The spray volume was based on the pest treated to obtain similar coverage as from airblast. Automated fogger was assessed as mixing/loading exposure only. Although this use was assessed for potential human exposure, it is not necessarily a viable option.

[h] Greenhouse fogger assessed as stationary (mixing/loading exposure only) as per label instructions.

[i] Greenhouse crops refer to cucumbers, tomatoes, eggplant, pepper, and roses and cut flowers

[j] Vapour application assessed using backpack data from PHED.

Shaded cells indicate MOEs that are less than the target MOE.

Table 3.6 Applicator Outdoor Supplemental Inhalation Exposure and Risk Assessment

	Air Concentration[a] ($\mu g/m^3$)	Inhalation Exposure[b] (mg/kg bw/day)	MOE[c]	MOE [d] for ARI	ARI (naled and dichlorvos) [e]
Naled	6.30	0.000630	103	556	1.00
Dichlorvos	0.508	0.0000508	217	217	

MOE= margin of exposure, ARI = aggregate risk index

[a] Maximum air concentration value for naled and concurrent dichlorvos sample from Cal EPA, 1995

[b] Inhalation exposure = air concentration × inhalation rate × exposure time/body weight (80 kg)

[c] Based on a LOAEL of 0.065 mg/kg bw/day and a target MOE of 100 for naled and a $BMDL_{10}$ of 0.011 mg/kg bw/day and a target MOE of 100 for dichlorvos

[d] Based on a $BMDL_{10}$ of 0.35 mg/kg bw/day and a target MOE of 300 for naled and a $BMDL_{10}$ of 0.011 mg/kg bw/day and a target MOE of 100 for dichlorvos both based on a common endpoint of decreased BChE activity (Canada, 2017b)

[e] ARI = $1/((\text{target } MOE_{NAL}/MOE_{NAL}) + (\text{target } MOE_{DVP}/MOE_{DVP}))$; NAL – naled, DVP – dichlorvos

Appendix IV Postapplication Worker Risk Assessment

Table 4.1 Postapplication Dermal Exposure and Risk Assessment for Outdoor Applications of Naled (48hrs after application)

Crop	Activity	TC (cm^2/hr)[b]	Application Rate (kg a.i./ha)	Naled DFR ($\mu g/cm^2$)[c]	Naled Dermal Exposure (mg/kg/day)[d]	Naled Dermal MOE[e]	Dichlorvos DFR ($\mu g/cm^2$)[c]	Dichlorvos Dermal Exposure (mg/kg/day)[d]	Dichlorvos Dermal MOE[f]	ARI (naled and dichlorvos)[g]
Outdoor ornamentals	Cut flowers	4000	0.019	0.0002	8.02×10^{-5}	24000	0.0001	1.67×10^{-5}	660	6
	Irrigation (hand-set)	1750	0.019	0.0002	3.51×10^{-5}	30000	0.0001	7.29×10^{-6}	1500	13
	All other activities	230	0.019	0.0002	4.61×10^{-6}	230000	0.0001	9.58×10^{-7}	11000	96
Onion	Weeding, hand	4400	0.48	0.0003	1.31×10^{-4}	8100	0.0002	2.71×10^{-5}	410	4
	Irrigation (hand set)	1750	0.48	0.0003	5.20×10^{-5}	20000	0.0002	1.08×10^{-5}	1000	9
	Scouting, plant thinning	1300	0.48	0.0003	3.86×10^{-5}	28000	0.0002	8.02×10^{-6}	1400	12
Potato	Irrigation (hand set)	1750	0.95	0.0006	1.03×10^{-4}	10000	0.0004	2.14×10^{-5}	510	4
	Roguing	1100	0.95	0.0006	6.47×10^{-5}	16000	0.0004	1.34×10^{-5}	820	7
	Scouting	210	0.95	0.0006	1.24×10^{-5}	86000	0.0004	2.56×10^{-6}	4300	37
	Hand weeding	70	0.95	0.0006	4.12×10^{-6}	260000	0.0004	8.55×10^{-7}	13000	113
Strawberry	Harvesting, hand	1100	0.95	0.0006	6.47×10^{-5}	16000	0.0004	1.34×10^{-5}	820	7
	Transplanting	230	0.95	0.0006	1.35×10^{-5}	79000	0.0004	2.81×10^{-6}	3900	34
	Scouting	210	0.95	0.0006	1.24×10^{-5}	86000	0.0004	2.56×10^{-6}	4300	37
	Weeding, canopy management	70	0.95	0.0006	4.12×10^{-6}	260000	0.0004	8.55×10^{-7}	13000	113
Lettuce	Irrigation (hand set)	1750	1.425	0.0009	1.54×10^{-4}	13000	0.0006	3.24×10^{-5}	340	3
	Harvesting, hand	1100	1.425	0.0009	9.70×10^{-5}	20000	0.0006	2.04×10^{-5}	540	5
	Transplanting	230	1.425	0.0009	2.03×10^{-5}	97000	0.0006	4.26×10^{-6}	2600	24
	Scouting	210	1.425	0.0009	1.85×10^{-5}	110000	0.0006	3.89×10^{-6}	2800	27
	Thinning, weeding, hand	70	1.425	0.0009	6.18×10^{-6}	320000	0.0006	1.30×10^{-6}	8500	80
Tomato	Irrigation (hand set)	1750	1.728	0.0011	1.87×10^{-4}	5700	0.0007	3.89×10^{-5}	280	2
	Harvesting, tying,	1100	1.728	0.0011	1.18×10^{-4}	9000	0.0007	2.44×10^{-5}	450	4

Crop	Activity	TC (cm^2/hr)[b]	Application Rate (kg a.i./ha)	Naled DFR ($\mu g/cm^2$)[c]	Naled Dermal Exposure (mg/kg/day)[d]	Naled Dermal MOE[e]	Dichlorvos DFR ($\mu g/cm^2$)[c]	Dichlorvos Dermal Exposure (mg/kg/day)[d]	Dichlorvos Dermal MOE[f]	ARI (naled and dichlorvos)[g]
	training (hand)									
	Transplanting	230	1.728	0.0011	2.46×10^{-5}	43000	0.0007	5.11×10^{-6}	2200	19
	Scouting	210	1.728	0.0011	2.25×10^{-5}	47000	0.0007	4.66×10^{-6}	2400	21
	Pruning, weeding (hand)	70	1.728	0.0011	7.49×10^{-6}	140000	0.0007	1.55×10^{-6}	7100	62
Alfalfa, vetch, clover, beans (dry), lima beans, peas (processing)[a]	Irrigation (hand set)	1750	1.90	0.0012	2.06×10^{-4}	5200	0.0008	4.27×10^{-5}	260	2
	Scouting	1100	1.90	0.0012	1.29×10^{-4}	8200	0.0008	2.69×10^{-5}	410	4
Brassica leafy vegetables (Broccoli, Brussels sprouts, cabbage, cauliflower)	Harvesting (hand)	5150	1.90	0.0012	6.06×10^{-4}	1800	0.0008	1.26×10^{-4}	87	0.8
	Weeding (hand)	4400	1.90	0.0012	5.18×10^{-4}	2100	0.0008	1.07×10^{-4}	100	0.9
	Scouting	4000	1.90	0.0012	4.70×10^{-4}	2300	0.0008	9.77×10^{-5}	110	0.96
	Irrigation (hand set)	1750	1.90	0.0012	2.06×10^{-4}	9500	0.0008	4.27×10^{-5}	260	2
	Cabbage: scouting, hand harvesting, mechanically assisted harvesting	1300	1.90	0.0012	1.53×10^{-4}	13000	0.0008	3.18×10^{-5}	350	3
	Transplanting	230	1.90	0.0012	2.71×10^{-5}	39000	0.0008	5.62×10^{-6}	2000	17
Sugar beet	Harvesting (hand)	1100	1.90	0.0012	1.29×10^{-4}	15000	0.0008	2.69×10^{-5}	410	4
	Scouting	210	1.90	0.0012	2.47×10^{-5}	79000	0.0008	5.13×10^{-6}	2100	18
	Weeding, thinning	70	1.90	0.0012	8.23×10^{-6}	240000	0.0008	1.71×10^{-6}	6400	56
Woodlands [h]	Irrigation (hand set)	1750	0.275	0.0002	2.98×10^{-5}	66000	0.00000024	1.27×10^{-8}	860000	215
	Harvesting (Christmas trees)	1400	0.275	0.0002	2.38×10^{-5}	82000	0.00000024	1.02×10^{-8}	1000000	267
	Scouting, shaping, hand pruning	580	0.275	0.0002	9.87×10^{-6}	200000	0.00000024	4.22×10^{-9}	2600000	650
	Transplanting	230	0.275	0.0002	3.92×10^{-6}	500000	0.00000024	1.67×10^{-9}	6600000	1626
	Grading, tagging, weeding	100	0.275	0.0002	1.70×10^{-6}	1200000	0.00000024	7.27×10^{-10}	150000000	3896

TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = margin of exposure, ARI = Aggregate Risk Index

[a] Forage crop TCs were used a surrogate for vetch and clover TCs

[b] The TC values are from the ARTF. The TC value for maximum foliage density was considered as a worst-case scenario for the risk assessment.
[c] The DFR values are based on a broccoli study (Canada, 2004) following a 48-hour REI.
[d] Dermal exposure (mg/kg bw/day) = DFR (µg/cm²) × TC (cm²/hr) × work duration (8 hr) /body weight (80kg)
[e] Based on a short- and intermediate-term $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 300
[f] Based on a short- and intermediate-term $BMDL_{10}$ of 0.011 mg/kg bw/day, and a target MOE of 100. A dermal absorption value of 30% was used (Canada, 2017b)
[g] ARI = 1 / (Target MOE_{NAL} / MOE_{NAL}) + / (Target MOE_{DVP} / MOE_{DVP})
[h] Woodlands may include Christmas tree plantations and tree nurseries.

Table 4.2 Postapplication Outdoor Inhalation Worker Exposure and Risk Assessment

Chemical	Exposure (µg/4hr)[a]	Exposure (µg/hr)	Duration (hr/day)	Body weight (kg)	Exposure (mg/kg/day)[b]	Inhalation MOE[c,d]	Inhalation MOE for ARI[e] (↓BChE)	ARI (Naled and Dichlorvos)[f]
Naled	9.77	2.44	8	80	0.000244	266	1430	0.9
Dichlorvos	2.32	0.58	8	80	0.00058	190	190	

MOE= margin of exposure; ARI = Aggregate Risk Index
[a] Inhalation exposure to naled and dichlorvos as determined in Lamb et al, 1994
[b] Inhalation exposure (mg/kg/day) = [exposure (µg/hr) × duration (hr/day)]/body weight (kg)
[c] Naled is based on an all duration-term LOAEL of 0.065 mg/kg bw/day, and a target MOE of 100
[d] Dichlorvos is based on an all duration-term $BMDL_{10}$ of 0.011 mg/kg bw/day, and a target MOE of 100
[e] Based on a $BMDL_{10}$ of 0.35 mg/kg bw/day and a target MOE of 300 for naled and a $BMDL_{10}$ of 0.011 mg/kg bw/day and a target MOE of 100 for dichlorvos both based on a common endpoint of decreased BChE activity (Canada, 2017b)
[f] ARI = 1 / (Target MOE_{NAL} / MOE_{NAL}) + / (Target MOE_{DVP} / MOE_{DVP})

Table 4.3 Postapplication Dermal Exposure and Risk Assessment for Greenhouse Crops

Crop (Application Type)	Activity	Application Rate[a]	TC (cm^2/hr)[b]	Naled DFR_0 ($\mu g/cm^2$)[c]	Dermal MOE[d,e] (Target = 1000)	REI required to meet target MOE
Roses and cut flowers (Fog)	Harvesting (hand), pruning, disbudding	0.121 g a.i./m^2	4000	5.60	1	303
	All other activities		230		15	180
Roses and cut flowers (Vapour Treatment)	Harvesting (hand), pruning, disbudding	0.01728 g a.i./m^2	4000	0.80	6	219
	All other activities		230		107	97
Cucumber, tomato, eggplant, pepper (Fog)	All activities	0.121 g a.i./m^2	1400	6.05	16	NA [f]
Eggplant, pepper (Vapour Treatment)	All activities	0.01728 g a.i./m^2	1400	0.86	2	NA [f]

TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = margin of exposure, NA = not applicable

[a] Fogging rate was provided as g a.i./m^2. Vapour treatment rate was provided in g a.i./m^3 which was converted to g a.i./m^2 by dividing by the typical greenhouse height of 5 m.

[b] The TC values are from the ARTF

[c] DFR_0 is the expected DFR on the day of application. The DFR values are defaults

[d] Dermal exposure (mg/kg bw/day) = DFR ($\mu g/cm^2$) × TC (cm^2/hr) × work duration (8 hr) /body weight (80kg)

[e] Based on a long term $BMDL_{10}$ of 1.96 mg/kg bw/day, and a target MOE of 1000

[f] Given the data on hand it is not possible to extrapolate beyond the day of application

Shaded cells indicate MOEs that are less than the target MOE.

Appendix V Occupational Risk Assessment Summary

Scenario	Mixer/Loader/Applicator	Postapplication
Groundboom	Risks are not acceptable for all scenarios (alfalfa, clover, vetch, peas, beans, lima beans, broccoli, Brussels sprouts, cabbage, cauliflower, lettuce, onion, potatoes, strawberries, tomatoes, sugar beet, rangeland, field areas, and pastures)	Risks are acceptable following the 48 hour REI.
Aerial	Risks are not acceptable for all scenarios (potatoes, tomatoes, alfalfa, clover, vetch, peas, beans, lima beans, corrals, pastures, holding pens, rangeland, field areas and feed lots)	Risks are acceptable following the 48 hour REI.
Mistblower (airblast)	Risks are not acceptable for all outdoor areas (livestock pastures, feed lots, dairy pastures, woodland, ornamentals)	Risks are acceptable following the 48 hour REI.
Mistblower (tractor-drawn ULV)	Risks are not acceptable for all outdoor areas (livestock pastures, feed lots, dairy pastures, and woodland)	Risks are acceptable following the 48 hour REI.
Mistblower (Handheld) Indoor/Outdoor	No data to assess.	Risks are acceptable following the 48 hour REI outdoors. No data to assess inhalation exposure in indoor scenarios.
Handheld Sprayer (Outdoor)	Risks are not acceptable for all scenarios (strawberries, ornamentals, around dairy barns, pig pens)	Risks are acceptable following the 48 hour REI.
Handheld Sprayer (Indoor)	Risks are not acceptable for all scenarios (in and around dairy bans, livestock barns, pig pens, and poultry houses)	No data to assess inhalation exposure in indoor scenarios. Dermal risk is not acceptable for all greenhouse workers.
Fogger (Automated) Indoor	Risks are acceptable with use of automated stationary fogger.	
Fogger (Handheld) Indoor/Outdoor	No data to assess.	
Vapour treatment Greenhouse	Risks are not acceptable for all crops (cucumbers, tomatoes, eggplant, pepper, roses and cut flowers)	

Appendix VI Dietary Exposure and Risk Assessments

Table 6.1 Dietary Exposure and Risks from Naled

Subpopulation	Refined							
	Acute Dietary (99.9th percentile)[1]				Chronic Dietary[2]			
	Food Only		Food + Drinking Water		Food Only		Food + Drinking Water	
	Exposure (mg/kg/day)	%ARfD	Exposure (mg/kg/day)	%ARfD	Exposure (mg/kg/day)	%ADI	Exposure (mg/kg/day)	%ADI
General Population	0.000613	1.02	0.008309	13.85	0.000011	0.5	0.000015	0.7
All Infants (<1 year old)	**0.001064**	**1.77**	**0.022026**	**36.71**	**0.000016**	**0.8**	**0.000033**	**1.6**
Children 1–2 years old	0.000914	1.52	0.010471	17.45	**0.000027**	**1.3**	**0.000032**	**1.6**
Children 3–5 years old	0.000663	1.11	0.008249	13.75	0.000024	1.2	0.000029	1.4
Children 6–12 years old	0.000366	0.61	0.006968	11.61	0.000013	0.7	0.000017	0.8
Youth 13–19 years old	0.000612	1.02	0.006092	10.15	0.000009	0.4	0.000012	0.6
Adults 20–49 years old	0.000556	0.93	0.006847	11.41	0.000010	0.5	0.000014	0.7
Adults 50–99 years old	0.000263	0.44	0.006005	10.01	0.000008	0.4	0.000011	0.6
Females 13–49 years old	0.000283	0.47	0.006711	11.19	0.000008	0.4	0.000012	0.6

[1]Acute Reference Dose (ARfD) of 0.06 mg/kg bw applies to the general population and all population subgroups;

[2]Acceptable Daily Intake (ADI) of 0.002 mg/kg bw/day applies to the general population and all population subgroups.

Table 6.2 Combined Dietary Exposure and Risk from Naled and Dichlorvos

Subpopulation	Refined	
	Acute Dietary (99.9th percentile)	Chronic Dietary
	Food + Drinking Water	Food + Drinking Water
General Population	6	10
All Infants (<1 year old)	**2**	10
Children 1–2 years old	5	**4**
Children 3–5 years old	6	5
Children 6–12 years old	7	8
Youth 13–19 years old	9	13
Adults 20–49 years old	8	11
Adults 50–99 years old	8	11
Females 13-49 years old	8	12

[1]ARI = 1 / (% $RfD_{dichlorvos}$ + % RfD_{naled})

Appendix VII Runoff Risk Assessment

Table 1 Major Fate Inputs for the Ecological Modelling

Fate Parameter	Naled	Dichlorvos
K_d (L/kg)	1.6	0.3
Water half-life (day) at 25°C	Stable	0.42
Sediment half-life(day) at 25°C	Stable	23.5
Photolysis half-life	Stable	Stable
Hydrolysis half-life (day) at pH 7	0.64	5.19
Soil half-life (day) at 25°C	1	19.3

Table 2 Estimated Environmental Concentrations (EECs) for Naled and Dichlorvos from Runoff

Compound	Water depth	EEC (µg a.i./L)	
		Peak	Yearly
Naled	80 cm	48	0.11
	15 cm	254	0.35
Dichlorvos	80 cm	2.2	0.009
	15 cm	12	0.050

Table 3 Risk Assessment for Aquatic Species Exposed to Naled Following Runoff

Organism	Most sensitive endpoint			EEC (µg a.i./L)	RQ
	Species	Exposure	Endpoint		
Amphibian (surrogate)	Lake trout	Acute	1/10 of 96-hr LC_{50} of 87 µg a.i./L = 8.7 µg a.i./L	254	**29**
	Fathead minnow, early life-stage	Chronic	NOEC 6.9 µg/L	0.35	0.05
Freshwater invertebrates	SSD	Acute	HC_5= 0.3 µg/L	48	**160**
	Waterflea (*Daphnia magna*)	Chronic	NOEC=0.098 µg/L	0.11	1

Organism	Most sensitive endpoint			EEC (µg a.i./L)	RQ
	Species	Exposure	Endpoint		
Freshwater fish	Lake trout	Acute	96-hr LC_{50} = 87 µg a.i./L	48	0.55
	Fathead minnow, early life-stage	Chronic	NOEC 6.9 µg/L	0.11	0.02
Estuarine/marine invertebrates	SSD	Acute	HC5= 0.3 µg/L	48	**160**
	Mysid shrimp (*Mysidopsis bahia*)	Chronic	NOEC=0.33 µg/L	0.11	0.33
Estuarine/marine fish	Sheepshead minnow	Acute	96-hr LC_{50}= 1200 µg/L	48	0.04
	Sheepshead minnow, early life stage	Chronic	NOEC=40 µmg/L	0.11	0.003
Aquatic vascular plants	*Navicula pelliculosa*	Acute	5-day EC_{50}= 12 µg/L	48	**4**

SSD - species sensitivity distribution; HC_5 - hazardous concentration to 5% of species; EC_{50} – effective concentration to 50%; LC_{50} - median lethal concentration to 50%; NOEC – no observed effect concentration

Table 4 Risk Assessment for Aquatic Species Exposed to Dichlorvos Following Runoff

Organism	Most sensitive endpoint (information source)			EEC (µg a.i./L)	RQ
	Species	Exposure	Endpoint		
Amphibian (surrogate)	Lake trout (*Salvelinus namaycush*)	Acute	1/10 96-hr LC_{50} of 0.183 µg/L = 0.0183 µg/L	12	**656**
	Rainbow trout *(Oncorhynchus mykiss)*	Chronic	NOAEC=5.2 µg/L	0.05	0.01
Freshwater invertebrates	Waterflea (*Daphnia pulex*)	Acute	48-hr EC_{50}= 0.07 µg/L	2.2	**31**
	Waterflea (*Daphnia magna*)	Chronic	NOEC=0.0058 µg/L	0.009	0.15
Freshwater fish	Lake trout (*Salvelinus namaycush*)	Acute	96-hr LC_{50} = 0.183 µg a.i./L	2.2	**12**
	Rainbow trout *(Oncorhynchus mykiss)*	Chronic	NOAEC=5.2 µg/L	0.009	0.002
Estuarine/marine invertebrates	Sand shrimp (*Crangon septemspinosa*)	Acute	96-hr LC_{50} = 4 µg/L	2.2	0.55
	Mysid (*Americamysis bahia*)	Chronic	NOAEC=1.48 µg/L	0.009	0.006

Estuarine/marine fish	Herring (*Clupea harengus*)	Acute	96-hr LC_{50} to larvae = 122 µg/L	2.2	0.02
	Sheepshead minnow (*Cyprinodon variegatus*)	Chronic	NOAEC = 960 µg/L	0.009	0.00001

EC_{50} – effective concentration to 50%; LC_{50} - median lethal concentration to 50%; NOAEC – no observed adverse effect concentration

Appendix VIII Proposed Label Amendments for Products Containing Naled

The label amendments proposed below do not include all label requirements for individual products, such as disposal statements, and precautionary statements. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

Add to ENVIRONMENTAL PRECAUTIONS [for Registration No. 7442]

Toxic to birds

Replace the existing statement under ENVIRONMENTAL PRECAUTIONS [for Registration No. 7442]:

May be toxic to bees; avoid application during periods of bee activity.

With the following:

Greenhouse use:
Toxic to bees and other beneficial insects. May harm bees and other beneficial insects, including those used in greenhouse production. Do not apply when bees or other beneficial insects are foraging in the treatment area.

Outdoor use:
TOXIC to bees. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site. Avoid application during the crop/ target plant blooming period. If applications must be made during the crop/target plant blooming period, restrict applications to the evening when most bees are not foraging. Avoid applications when bees are foraging in the treatment area in ground cover containing blooming weeds. To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying – Best Management Practices" on the Health Canada website (www.canada.ca/pollinators).

Add to DIRECTIONS FOR USE [for Registration No. 7442]

To protect pollinators, follow the instructions regarding bees in the Environmental Precautions section.

DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Boom height must be 60 cm or less above the crop or ground.

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

Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Reduce drift caused by turbulent wingtip vortices. Nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan.

Buffer zones:

Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

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

Method of application	Crop	Buffer Zones (metres) Required for the Protection of Aquatic Habitat of Depths:	
		Less than 1 m	Greater than 1 m
Field sprayer	Livestock pastures, feedlots, pastures (dairy cattle present)	4	2
	Outdoor ornamentals	5	2
	Onion	5	3
	Rangeland, field areas and pastures, strawberries, potatoes	10	5
	Lettuce	15	10
	Broccoli, Brussels sprouts, cabbage, cauliflower, beans, lima beans, peas, alfalfa, clover, vetch, sugar beets, tomatoes	20	10

Airblast	Woodland, livestock pastures, feedlots, pastures (dairy cattle present)	Early growth stage	35	25
		Late growth stage	25	15
	Outdoor ornamentals	Early growth stage	35	30
		Late growth stage	25	20
Aerial	Tomatoes, potatoes	Fixed wing	275	175
		Rotary wing	175	100
	Beans, lima beans, peas, alfalfa, clover, vetch	Fixed wing	275	175
		Rotary wing	200	125
	Livestock pastures, pastures (dairy cattle present), corrals, feedlots, holding pens	Fixed wing	350	175
		Rotary wing	150	75
	Rangeland	Fixed wing	625	425
		Rotary wing	375	200

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.

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