Proposed Re-evaluation Decision PRVD2018-01

Ethephon and Its Associated End-use Products

Consultation Document

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Proposed Re-evaluation Decision

Under the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Ethephon is a plant growth regulator intended to promote fruit ripening, abscission, flower induction, and an increase in lateral branching through the release of ethylene gas, a natural plant hormone. Ethephon is applied as a broadcast foliar spray via ground, aerial, or backpack sprayer equipment and is used in a variety of crops including cereals, apples, sweet and sour cherries, blueberries, field tomatoes and tobacco, as well as in potted greenhouse ornamentals. It is registered for commercial use only.

This document presents the proposed regulatory decision for the re-evaluation of ethephon including proposed risk mitigation measures to further protect human health and the environment, as well as the science evaluation on which the proposed decision was based. All products containing ethephon registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public, including manufacturers and stakeholders, may submit written comments and additional information to the PMRA. The final re-evaluation decision will be published taking into consideration the comments and information received.

Outcome of Science Evaluation

Ethephon is especially of value for field tomatoes intended for processing, as it promotes uniform ripening thus facilitating the mechanical harvest. It is also of value for greenhouse ornamentals, as it promotes lateral branching, which is desirable for the retail market.

With respect to human health, dietary risks of concern were identified resulting in proposed mitigation measures including cancellation of uses on apple trees when fruit are present. Canadian maximum residue limits (MRLs) for ethephon are currently specified for various commodities. With the proposed measures to minimize risk, Canadian MRLs for ethephon on apples, apple juice, citrus fruits, grapes, and raisins are being proposed to be revoked.

Risks of concern were also identified for certain occupational exposures to ethephon, resulting in the addition of engineering controls, additional personal protective equipment (PPE), limiting the amount of product handled in a day, and lengthening the restricted-entry interval (REI) as additional risk reduction measure.

In the environment, ethephon at high enough concentrations can pose risks to birds, mammals and terrestrial plants. It is however not expected to affect the environment when used according to the proposed label directions, which include advisory statements and spray buffer zones.

Proposed Regulatory Decision for Ethephon

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, products containing ethephon are being proposed for continued registration in Canada, while risk mitigation measures are required to be in place to further protect human health and the environment.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of ethephon, further risk mitigation measures as summarized below for product labels are being proposed.

Human Health

To protect consumers, workers handling ethephon, and those entering treated areas, the following risk mitigation measures are proposed:

- Cancellation of uses on apple trees when fruit are present.
- Revocation of the existing MRLs for apple, apple juice, citrus fruit, grape, and raisin such that they will be subject to the general maximum residue limit (GMRL).
- Requirement for additional PPE and engineering controls when mixing/loading and applying to various crops.
- Restrictions on amount handled per day.
- Requirement for lengthened REIs for some postapplication activities.
- Requirement for a statement to promote best management practices to minimize human exposure from spray drift or spray residues resulting from drift.

Environment

- Environmental hazard statements for birds, mammals and non-target plants.
- To reduce the potential for runoff of ethephon to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are required. In addition, a vegetative strip between the treatment area and the edge of a water body is recommended to reduce runoff of ethephon to aquatic areas
- Terrestrial spray buffer zones for the protection of non-target plants.

International Context

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments from member countries can work together to share experiences and seek solutions to common problems.

Ethephon is currently acceptable for use in other OECD member countries, including the European Union, the United States, and Australia. As of 29 September 2017, no decision by an OECD member country to prohibit all uses of ethephon for health or environmental reasons has been identified.

Next Steps

The public, including manufacturers and stakeholders, are encouraged to submit additional information that could be used to refine risk assessments (exposure data or use information) during the 90-day public consultation period.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document, which could result in revised risk mitigation measures. The re-evaluation decision document will include final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with the PMRA's responses.

Science Evaluation

1.0 Introduction

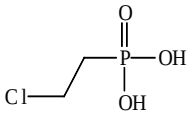
Ethephon is a plant growth regulator belonging to the phosphonate family. It is readily absorbed by the plant stimulating release of ethylene, which is a natural plant hormone. Ethylene directly influences several physiological processes (ripening, maturation, etc.).

Ethephon is used on cereals (spring wheat, winter wheat and barley) to increase resistance to lodging (stem breakage) through straw shortening and strengthening. It is also used on fruits (apples, sour and sweet cherries and blueberries) to promote fruit maturity (early and uniform ripening and colouring of mature fruits) and loosening of fruits for easy harvesting. On tobacco plants it is used to reduce curing time and promote colour development. For greenhouse ornamental production, it is used to stimulate lateral branching leading to fuller plants.

Following the re-evaluation announcement for ethephon, the technical registrant and primary data provider in Canada indicated continued support for all uses included on the labels of end-use products, and stakeholders including user groups and Provincial specialists were consulted regarding the use pattern of ethephon.

2.0 Technical Grade Active Ingredient

2.1 Identity

Common Name	Ethephon
Function	Plant growth regulator
Chemical Family	Ethylene generator
Chemical Name	
1 International Union of Pure and Applied Chemistry (IUPAC)	2-chloroethylphosphonic acid
2 Chemical Abstracts Service (CAS)	(P)-(2-chloroethyl) phosphonic acid
CAS Registry Number	16672-87-0
Molecular Formula	$C_2H_6ClO_3P$
Structural Formula	

Molecular Weight	144.5
Purity of the Technical Grade Active Ingredient	91.7%
Registration Number	19205

2.2 Physical and Chemical Properties

Property	Result
Vapour pressure at 25°C	< 0.01 mPa
Ultraviolet (UV) / visible spectrum	Not expected to absorb at $\lambda > 300$ nm
Solubility in water at 20-25°C	8×10^5 mg/L
n-Octanol/water partition coefficient at 25°C	log $K_{ow} < -2.2$
Dissociation constant at 20-25°C	p*K*a = 2.5

2.3 Registered Uses

Appendix I lists all ethephon products that are registered under the authority of the *Pest Control Products Act* as of 28 August 2017. One technical grade active ingredient, one manufacturing concentrate and four commercial-class products are registered. Appendix II lists all the commercial-class uses for which ethephon is presently registered.

3.0 Human Health Assessment

3.1 Toxicology Summary

A detailed review of the toxicology database for ethephon was conducted. The database is complete and consists of the full array of toxicity studies currently required for hazard assessment purposes. The majority of studies were conducted in the 1970s and 1980s with a few studies performed more recently. The majority of the toxicity studies were conducted with technical ethephon with a purity range from 70 to 75%. Since the technical ethephon that is currently registered has a significantly higher purity (91.7%) than what was previously tested, it is expected that the available toxicity studies address the potential toxicity of both the impurities as well as the technical ethephon. All of the studies that were used in the current re-evaluation were conducted in accordance with the accepted international testing protocols and Good Laboratory Practices in place at that time. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to ethephon.

Ethephon is an organophosphonate pesticide. In mammals, it inhibits cholinesterase activity and produces organophosphate-like signs of toxicity, including salivation, increased urination and defecation. In the ethephon database, cholinesterase inhibition typically occurred following repeated dosing at lower doses than those producing clinical signs of toxicity.

In orally-dosed rats, radio-labelled ethephon was rapidly and extensively absorbed via the gastrointestinal tract. Excretion of ethephon was also rapid, with the majority of the administered dose eliminated within the first twelve hours. Elimination occurred mainly via the urine and expired air (in the form of ethylene), with a small amount excreted via the feces. There were no significant differences in the elimination pattern between sexes or dosing regimens. Ethephon was widely distributed throughout the body of rats; however, the amount retained in tissues and the residual carcass was low. The highest concentrations of radiolabeled ethephon were identified in the liver, with lesser amounts in blood, kidneys, bone, spleen, lungs and heart. There was no indication that ethephon bioaccumulates.

Ethephon was extensively metabolized, with the disodium salt of ethephon being the major component in the urine and feces of rats. Fractions other than those containing the disodium salt of ethephon individually accounted for a small percentage of the administered radioactivity. A more recent study in rats revealed the presence of the metabolite 2-hydroxyethyl phosphonic acid (HEPA) in the kidneys and liver, although at much lower levels than unchanged ethephon. There were no major sex differences noted in the toxicokinetic profile. The supplemental toxicokinetics study in dogs suggested that the absorption, distribution and excretion patterns were similar to the rat.

Ethephon was of low acute toxicity via the oral and inhalation routes of exposure in rats and it was slightly toxic to rabbits in an acute dermal toxicity study. Ethephon was corrosive to the skin of rabbits and on the basis of these results, as well as the eye irritation noted in the acute inhalation study, was considered corrosive to the eyes. Ethephon was not a potential skin sensitizer when tested in guinea pigs using the Buehler method. Clinical signs of toxicity in the acute toxicity studies were consistent with those of cholinesterase inhibitors and included salivation, constricted pupils, piloerection, hypothermia, prostration, unsteady gait and tremors. When the metabolite HEPA was tested in an acute oral toxicity study conducted with rats, it was found to be of low acute toxicity with only transient diarrhea noted at a high dose level.

The most sensitive indicator of exposure to ethephon was the inhibition of cholinesterase activity. In repeat-dose dietary studies in various species (mouse, rat and dog), the dog appeared to be the most sensitive with respect to dose levels of ethephon producing cholinergic signs and cholinesterase inhibition. Repeat-dose oral toxicity studies in the mouse, rat and dog did not indicate any clear sex sensitivity. Erythrocyte cholinesterase inhibition was noted only following several weeks of repeated oral exposure. In these studies, cholinesterase inhibition quickly plateaued and the inhibition remained constant for the remainder of the study. In rabbits exposed dermally to ethephon, measurements for cholinesterase activity were not conducted; therefore, no conclusions can be made concerning the sensitivity of this route to cholinesterase inhibition. A repeat-dose inhalation toxicity study was not available.

With extended duration of exposure, the dog was the most sensitive species, with gastrointestinal irritation occurring at the dose levels that also produced cholinesterase inhibition.

Ethephon did not induce delayed neurotoxicity in the hen when tested up to lethal doses. In acute and subchronic neurotoxicity studies, erythrocyte cholinesterase inhibition was noted in rats after only a few weeks of exposure. Clinical signs of neurotoxicity appeared only after erythrocyte cholinesterase was significantly inhibited and included abnormal breathing, pinpoint pupils, fur staining, decreased activity, piloerection, poor condition and impaired gait; mortalities occurred at higher doses. No evidence of neuropathology was noted in any of the available studies.

An assessment of mutagenic potential in a variety of bacterial and mammalian in vitro and in vivo studies was performed for ethephon. Positive results with bacteria have been recorded in in vitro studies with *Salmonella typhimurium* (TA1535) and *Saccharomyces cerevisiae* but ethephon was not mutagenic in other strains of *Salmonella typhimurium* and *Escherichia coli*. Ethephon was not mutagenic to mammalian cells in in vitro testing, and it was negative in the dominant lethal test in rats and the micronucleus assay in mice. The overall weight of evidence suggests that ethephon is not genotoxic.

Dietary carcinogenicity studies were conducted in mice and rats. In the first of two dietary carcinogenicity studies in rats, there was an increased incidence of pancreatic islet cell adenomas and carcinomas in both high-dose male and female animals. However, without histopathological examinations conducted in the low- and mid-dose groups, it was unclear as to whether these effects were treatment-related and the study was considered supplemental. In the more recent and robust dietary carcinogenicity study in rats, there was no evidence of carcinogenicity, despite employing higher dose levels than the first study. In female mice, there was equivocal evidence of carcinogenicity with a slight, non-statistically significant increase in the incidence of thymic lymphosarcomas. This slight increase occurred at a dose level exceeding the limit dose of testing and was within the historical control range.

In gavage developmental toxicity studies in rats, fetal malformations (absent tail and microphthalmia) and reduced fetal weight were noted only at a dose level that produced significant maternal toxicity (mortalities, decreased body weight gain, clinical signs); this dose was well in excess of the limit dose of testing. No effects were noted on the rat fetus at non-maternally toxic levels. No treatment-related malformations were observed in gavage developmental toxicity studies in rabbits. Increased fetal resorptions and decreased fetal viability occurred at dose levels causing mortality in the rabbit dams. In a 2-generation reproductive toxicity study in rats, dietary administration of ethephon resulted in decreased body weight and body weight gain and loose feces in offspring, at similar doses to those causing parental toxicity (decreased body weight and body weight gain), indicating no sensitivity of the fetus following in utero exposure, or of the young animal with post-natal exposure. No effects of exposure to ethephon were noted on fertility, gestation, mating, organ weights or histopathology in any of the examined generations.

Although ethephon demonstrated neurotoxic properties, a developmental neurotoxicity study was not available. Furthermore, cholinesterase measurements were not taken in the fetus or young animal to investigate susceptibility of the young. In response to USEPA concerns on the lack of data indicating that ethephon does not cross the blood brain barrier in the young, the registrant indicated that ethephon was unlikely to partition into the nervous system due to its low lipophilicity. They also stated that the ethephon molecule does not contain a good leaving group to react with the cholinesterase of the nervous system, citing a lack of brain cholinesterase inhibition in rats, mice and dogs in support of this assertion. The registrant also stated that ethephon has a short residence time in the body. Contrary to the registrant's assertion, brain cholinesterase inhibition was noted in mice (albeit at a high dose level in the long-term study), in one 13-week rat study (other rat studies showed no inhibition), and in the most recently conducted 13-week dog study. Further, ethephon's small molecular size suggests potential to cross the blood-brain barrier, particularly the less-developed barrier of the young. For these reasons, uncertainty remains with regards to potential adverse effects in the young, and this has been reflected through the application of a database uncertainty factor.

Human studies of limited quality were available for ethephon; however, it was determined that these studies were clearly assessing systemic toxicity. In accordance with Science Policy Note SPN2016-01, *Restricted Use of Human Studies with Pesticides for Regulatory Purposes*, these studies have not been used in the re-evaluation of ethephon.

Results of the acute and repeated dose studies conducted on laboratory animals with ethephon technical, along with the toxicology endpoints for use in the human health risk assessment, are summarized in Appendix III, Tables 1 and 2.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children and potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the exposure of, and toxicity to, infants and children, the ethephon database included two developmental toxicity studies in rats, two developmental toxicity studies in rabbits and a multi-generation reproduction study in rats. A developmental neurotoxicity study with a comparative cholinesterase component (dams versus pups), or a comparative cholinesterase study was not available. The lack of cholinesterase measurements in the young animal represents a significant data gap for a pesticide with an established neurotoxic mode of action. This has been addressed through the application of a 3-fold uncertainty factor for database deficiency.

With respect to potential pre-and post-natal toxicity, in the existing database there was no indication of increased susceptibility of the offspring compared to parental animals in the rat reproduction study. The pre-natal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of fetuses to in utero exposure. In rats, effects on the fetuses were observed only at a dose level that resulted in mortality of the dams and exceeded the limit dose for testing. In rabbits, maternal toxicity occurred at lower dose levels than in rats, which may reflect a greater sensitivity of the rabbit to substances that are irritating when administered via the oral route. In the rabbit, increases in resorptions and decreased fetal viability were observed. These effects are considered serious endpoints; however, the degree of concern is lessened by the fact that they occurred only in the presence of significant maternal toxicity, including mortality. Accordingly, the *Pest Control Products Act* factor was reduced to 3-fold for exposure scenarios using the fetal endpoint for risk assessment. For scenarios not using the fetal endpoint for risk assessment, the *Pest Control Products Act* factor was reduced to 1-fold.

3.2 Dietary Exposure and Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet. Exposure to ethephon from potentially treated imported foods is also included in the assessment. 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. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The PMRA considers limiting use of a pesticide when exposure exceeds 100% of the reference dose. The PMRA's Science Policy Note SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide*, presents detailed acute and chronic risk assessment procedures.

Residue estimates used in the dietary risk assessment may be based conservatively (using upper bound estimates) on the maximum residue limits (MRLs), or the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency (CFIA) National Chemical Residue Monitoring Program and the United States Department of Agriculture's Pesticide Data Program (USDA's PDP). Theoretical and experimental processing factors, as well as specific information regarding the percent of crops treated may also be incorporated to the greatest extent possible.

In situations where the need to mitigate dietary exposure has been identified, the following options are considered. Dietary exposure from Canadian agricultural uses can be mitigated through changes in the use pattern. Revisions of the use pattern may include such actions as

reducing the application rate or the number of seasonal applications, establishing longer pre-harvest intervals (PHIs), and/or removing uses from the label. The mitigation of dietary exposure that may arise from treated imports is generally achieved through the amendment or specification of MRLs.

Sufficient information was available to adequately assess the dietary exposure and risk to ethephon. Acute and chronic dietary (food and drinking water) exposure and risk assessments for ethephon were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™; Version 4.02, , 05-10-c) program which incorporates food consumption data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) dietary survey for the years 2005-2010 available through the Centers for Disease Control and Prevention's National Center for Health Statistics. Further details on the consumption data are available in Science Policy Note SPN2014-01, *General Exposure Factor Inputs for Dietary, Occupational and Residential Exposure Assessments*. For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendices IV and V.

The acute and chronic exposure estimates are considered to be refined (more precise) as percent crop treated, experimental processing factors and domestic/import data were used to the extent possible. However, the assessments retained a certain level of conservatism due to the use of MRLs/tolerances or anticipated residues (from crop field trials).

3.2.1 Determination of Acute Reference Dose (ARfD)

Acute Reference Dose for Females 13-49 Years of Age

To estimate acute (1 day) dietary risk for females of child-bearing age (13-49 years), an oral (gavage) developmental toxicity study in the rabbit was selected. The developmental NOAEL of 50 mg/kg bw/day was selected based on an increased number of early resorptions and a decreased number of live fetuses occurring at the next dosage level of 100 mg/kg bw/day. Both the resorptions and fetal viability are endpoints that could result from an acute exposure and therefore are relevant in the establishment of an acute reference dose. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. An additional uncertainty factor of 3-fold was applied to account for data deficiencies, as discussed previously. The *Pest Control Products Act* factor was reduced to 3-fold as discussed under the *Pest Control Products Act* Hazard Characterization Section. Therefore, the composite assessment factor was 1,000.

ARfD: ♀ **13-49 =** $\frac{\textbf{50 mg/kg bw/day}}{\textbf{1,000}}$ **= 0.05 mg/kg bw**

Acute Reference Dose for the General Population (Excluding Females 13-49 Years of Age)

For the remainder of the population, a maternal NOAEL of 50 mg/kg bw/day was selected from an oral (gavage) developmental toxicity study in the rabbit. At the next dosage level, an increased number of mortalities were noted in the dams within the first few days of dosing, indicating that these mortalities could be the result of a single dose of ethephon. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. An additional uncertainty factor of 3-fold was applied to account for data deficiencies, as discussed previously. The *Pest Control Products Act* factor was reduced to 1-fold as discussed under the *Pest Control Products Act* Hazard Characterization Section. Therefore, the composite assessment factor was 300.

ARfD: General population= $\frac{\text{50 mg/kg bw/day}}{\text{300}}$ = 0.17 mg/kg bw

These values were considered to be protective of all populations (excluding females 13-49 years of age), including infants and children.

3.2.2 Acute Dietary Exposure and Risk Assessment

The acute dietary risk from food and drinking water was calculated considering the highest ingestion of residues of ethephon that would be likely on any one day, and using food and water consumption, and food and drinking water residue values. The expected intake of residues is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the estimated exposure is less than the ARfD, the acute dietary exposure is not of concern.

The acute assessment was conducted using anticipated residues (from crop field trials); MRLs/tolerances for commodities for which no anticipated residues were available; and experimental processing factors when available. Theoretical processing factors were used when experimental processing factors were not available. The metabolite HEPA was also considered in the assessment. Drinking water contribution to the exposure was accounted for by direct incorporation of the acute estimated environmental concentration (EEC) value, obtained from water modelling (see Section 3.3), into the dietary exposure evaluation model (DEEM).

Based on the current use pattern, the acute dietary (food and drinking water) exposure estimates at the 95th percentile for the general population and all subpopulations (including females 13-49 years of age) range from 15% to 127% of the ARfD, and therefore are of concern. The highest exposed subpopulation was children 1-2 years of age.

With the proposed mitigation measures (see Appendix VIII), the acute dietary (food and drinking water) exposure estimates at the 95th percentile for the general population and all subpopulations (including females 13-49 years of age) range from 11% to 37% of the ARfD, and therefore are

not of concern. Drinking water contributed to 8% of the total acute exposure for the most exposed subpopulation.

3.2.3 Determination of Acceptable Daily Intake (ADI)

To estimate risk from repeat dietary exposure, the most suitable study was a 2-year dietary toxicity study in the dog. A NOAEL of 0.86 mg/kg bw/day was established on the basis of effects on the gastrointestinal tract and clinical chemistry, as well as the occurrence of soft stools at the next dose level of 7.6 mg/kg bw/day. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. An additional uncertainty factor of 3-fold was applied to account for data deficiencies, as discussed previously. The *Pest Control Products Act* factor was reduced to 1-fold as discussed under the *Pest Control Products Act* Hazard Characterization Section. Therefore, the composite assessment factor was 300.

$$\textbf{ADI} = \frac{\textbf{0.86 mg/kg bw/day}}{\textbf{300}} = \textbf{0.003 mg/kg bw/day}$$

This ADI provides a margin of greater than 17,000 to the developmental NOAEL (increased resorptions, decreased live fetuses and fetal viability) and greater than 6,800 to the NOAEL for maternal and offspring toxicity. The ADI also provides a margin of greater than 5,800 to the NOAEL for lymphosarcomas in the female mice. It is thus considered protective of all populations including pregnant women, infants and children.

3.2.4 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated using the average consumption of different foods and drinking water, and the average residue values on those foods and in drinking water. This estimated exposure to ethephon was then compared to the ADI. When the estimated exposure is less than the ADI, the chronic dietary exposure is not of concern.

The chronic assessment was conducted using percent crop treated data and domestic/import statistics; anticipated residues (from crop field trials); MRLs/tolerances for commodities for which no anticipated residues were available; and experimental processing factors when available. Theoretical processing factors were used when experimental processing factors were not available. The metabolite HEPA was also considered in the assessment. Drinking water contribution to the exposure was accounted for by direct incorporation of the chronic EEC value obtained from modelling (see Section 3.3) into DEEM.

Based on the current use pattern, the chronic exposure estimates for the general population and all subpopulations range from 42% to 643% of the ADI, and therefore are of concern. The highest exposed subpopulation was children 1-2 years of age.

With the proposed mitigation measures (see Appendix VIII), the chronic exposure estimates for the general population and all subpopulations range from 23% to 98% of the ADI, and therefore are not of concern. Drinking water contributed to 1% of the total chronic exposure for the most exposed subpopulation.

3.2.5 Cancer Assessment

The potential carcinogenicity of ethephon has been investigated in mice and rats. Ethephon was not considered carcinogenic in rats. In mice, there was equivocal evidence of carcinogenicity with a slight non-statistically significant increase in the incidence of thymic lymphosarcomas in females. Overall, the endpoints selected for non-cancer risk assessment are protective of any residual concerns regarding the carcinogenic potential of ethephon.

3.2.6 Cancer Dietary Exposure and Risk Assessment

A separate quantitative cancer assessment was not required (see Section 3.2.5).

3.3 Exposure from Drinking Water

Residues of ethephon in potential drinking water sources were estimated from modelling.

3.3.1 Concentrations in Drinking Water

Estimated Concentrations in Drinking Water Sources: Level 1 Modelling

Estimated environmental concentrations (EECs) of ethephon in potential drinking water sources (groundwater and surface water) were generated using computer simulation model Pesticide in Water Calculator (PWC) V1.5001. EECs of ethephon in groundwater were calculated to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using PWC are average concentrations in the top one metre of the water table. EECs of ethephon in surface water were also calculated using the PWC model, which simulates pesticide runoff from a treated field into an adjacent water body and the fate of the combined residue within that water body. Pesticide concentrations in surface water were estimated in a vulnerable drinking water source, a small reservoir.

Level 1 drinking water EECs were determined using conservative (that is, resulting in upper bound estimates) assumptions with respect to environmental fate, application rate and timing, and geographic scenario. Seventeen initial application dates between mid-April and early November were modelled. The model was run for 50 years for all scenarios. The daily surface water EEC (124 µg/L) was used in the acute assessment and the yearly surface water EEC (1.4 µg/L) was used for the chronic assessment.

3.3.2 Drinking Water Exposure and Risk Assessment

Drinking water exposure estimates were combined with food exposure estimates, with EEC values incorporated directly in the dietary (food and drinking water) assessments. Please refer to Sections 3.2.2 and 3.2.4 for details and conclusions.

3.4 Occupational and Non-Occupational Exposure and Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating 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.

3.4.1 Toxicology Endpoint Selection for Occupational and Non-Occupational Risk Assessment

3.4.1.1 Short-, Intermediate- and Long-term dermal and inhalation routes

For occupational short- and intermediate-term dermal and inhalation assessment, the NOAEL of 1.8 mg/kg bw/day from the 13-week dietary toxicity study in the dog was selected. A dose-related inhibition of erythrocyte cholinesterase activity was noted at the next dose level. The target Margin of Exposure (MOE) is 300 accounting for standard uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and an additional 3-fold uncertainty factor to account for data deficiencies, as discussed previously. This MOE is protective of other endpoints in the database.

For occupational long-term dermal and inhalation assessment, the NOAEL of 0.86 mg/kg bw/day from the two-year dietary toxicity study in the dog was selected. The target MOE is 300 accounting for standard uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and an additional 3-fold uncertainty factor to account for data deficiencies, as discussed previously. This MOE is protective of other endpoints in the database.

Dermal Absorption

Given that ethephon is corrosive, a dermal absorption value of 80% was used for mixers and loaders who would be handling the concentrated product. For all other exposure scenarios where exposure would be to a diluted product, a dermal absorption value of 3% was used.

3.4.2 Non-Occupational Exposure and Risk Assessment

Non-occupational (residential) risk assessment involves estimating risks to the general population, including youth and children, during or after pesticide application.

Since there are no domestic-class products containing ethephon registered, a residential handler assessment was not required. Also, postapplication exposure was assumed not to occur since it is unlikely that a plant growth regulator would be applied on residential fruit trees by a commercial applicator.

3.4.3 Occupational Exposure and Risk Assessment

There is potential for exposure to ethephon in occupational scenarios from workers handling ethephon during the application process and potential for postapplication exposure from workers entering areas previously treated with ethephon.

3.4.3.1 Handler Exposure and Risk Assessment

There are potential exposures to mixers, loaders, and applicators. The following scenarios were assessed:

- Open mixing/loading of liquids
- Airblast liquid application (open cab) to apples, highbush blueberries, and cherries (sour and sweet)
- Groundboom liquid application (open cab) to lowbush blueberries, spring barley, spring wheat, tobacco, tomatoes (field only), and winter wheat
- Aerial liquid application to lowbush blueberries, spring barley, spring wheat, tomatoes (field only) and winter wheat
- Backpack liquid application to greenhouse potted ornamentals
- Manually pressurized handwand liquid application to greenhouse potted ornamentals
- Mechanically pressurized handwand liquid application to greenhouse potted ornamentals

Exposure from mixing, loading and applying ethephon is expected to be intermittent short-to-intermediate-term in duration.

Handler exposure was estimated based on different levels of PPE and engineering controls**:**

- Baseline PPE: long pants, long sleeved shirts and chemical-resistant gloves (unless specified otherwise)
- Mid-level PPE: cotton coveralls over long pants, long sleeved shirts and chemical-resistant gloves
- Maximum PPE: chemical-resistant coveralls over long sleeves and long pants and chemical-resistant gloves
- Respirator: a respirator with NIOSH approved organic vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides.
- Engineering Controls: closed mixing and loading, and/or closed cabs

No chemical-specific handler exposure data were available for ethephon.

Dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database Version 1.1 (PHED) and the Agricultural Handlers Exposure Task Force (AHETF) studies. The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of PPE. The AHETF was formed in 2001 with the objective of providing more up-to-date generic exposure studies compared to the PHED studies.

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

Inhalation exposures were based on light inhalation rates (17 L/min), except for backpack applicator scenarios, which were based on moderate inhalation rates (27 L/min).

MOEs for mixer/loader/applicators are outlined in Appendix VI, Table 1. MOEs are presented for mixer/loader/applicators wearing a single layer (chemical-resistant headgear for airblast application), chemical-resistant gloves, and a respirator during mixing and loading, which is consistent with the PPE specified on the registered labels for the end-use products (EPs) of ethephon. In addition, it was assumed that mixer/loader/applicators would be using groundboom or airblast equipment with an open cab. For scenarios that did not meet the target MOEs, further mitigation was required.

Appendix VI, Tables 2 and 3 present the proposed mitigation for mixer/loader/applicator scenarios that did not meet the target MOEs in Appendix VI, Table 1. For all scenarios, except for greenhouse potted ornamentals and tobacco, a closed mixing and loading system is proposed to mitigate mixer/loader exposure. It is also proposed to restrict the amount handled per day for certain scenarios.

3.4.3.2 Postapplication Worker Exposure and Risk Assessment

The postapplication occupational risk assessment considered exposures to workers who enter treated sites to conduct agronomic activities involving foliar contact (for example, hand harvesting). Based on the use pattern, there is potential for short- to intermediate-term postapplication exposure to ethephon residues for workers.

Potential exposure to postapplication workers was estimated using updated activity-specific transfer coefficients (TCs), and default dislodgeable foliar residue (DFR) values, since chemical-specific DFR data were not available (see below). The DFR refers to the amount of residue that can be dislodged or transferred from a surface, such as leaves of a plant. The TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from data generated in field exposure studies. The TCs are specific to a given crop and

activity combination (for example, harvesting apples) and reflect standard agricultural work clothing worn by adult workers. Activity-specific TCs from the Agricultural Re-Entry Task Force (ARTF) were used. Postapplication exposure activities for agricultural crops include (but are not limited to): harvesting, pruning and scouting. For more information about estimating worker postapplication exposure, refer to PMRA's Regulatory Proposal PRO2014-02, U*pdated Agricultural Transfer Coefficients for Assessing Occupational Postapplication Exposure to Pesticides*.

Since no chemical-specific DFR studies were available for ethephon, default values were used (peak DFR of 25% of the application rate for all crops, with 10% dissipation per day for outdoor crops). For further information on these default values, refer to the PMRA's Science Policy Note SPN2014-02, *Estimating Dislodgeable Foliar Residues and Turf Transferrable Residues in Occupational and Residential Postapplication Exposure Assessments.*

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely enter after application to perform tasks involving hand labour. An REI is the duration of time that must elapse in order for residues to decline to a level at which there are no risk concerns for postapplication worker activities (for example, in the case of ethephon, performance of a specific activity that results in exposures above the target MOE of 300).

The PMRA is primarily concerned with the potential for dermal exposure for workers performing postapplication activities in crops treated with a foliar spray. Based on the vapour pressure of ethephon, inhalation exposure is not likely to be of concern provided that the minimum 12-hour REI is followed.

To achieve the target MOEs for postapplication workers in agricultural scenarios, some REIs are proposed to be increased in length. Calculated REIs ranged from 12 hours to 15 days. Although some REIs may be considered long, these are generally for infrequent activities and therefore, potentially feasible. The postapplication exposure assessment is outlined in Appendix VI, Table 4.

3.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). For ethephon, the aggregate assessment consisted of combining food and water exposure only (see Sections 3.2.2 and 3.2.4), since residential exposure is not expected to occur.

3.6 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. While ethephon produces some organophosphate-like toxicity in animals, it is an organophosphonate and not an organophosphate. Unlike the organophosphates, ethephon does not have a leaving group, which is required for the insecticidal mode of action. For the current evaluation, the PMRA did not identify information indicating that ethephon shares a common mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative risk assessment at this time.

3.7 Incident Reports – Human Health

No human or domestic animal incident reports were received as of 22 August 2017.

4.0 Environmental Assessment

4.1 Fate and Behaviour in the Environment

A summary of environmental fate data for ethephon is presented in Appendix VII, Table 1.

Terrestrial Fate

Ethephon can enter the terrestrial environment when it is used as a plant growth regulator on a variety of crops. Laboratory aerobic biotransformation studies show that ethephon is non-persistent to moderately persistent in soils with DT_{50} values ranging from 4.2 to 83.4 days (with a representative 80th percentile DT_{50} of 56.8 days based on 7 soils). Under anaerobic conditions, ethephon is non-persistent in soils with DT_{50} values ranging from 4.0 to 4.6 days. Ethylene gas and 2-HEPA are produced by the breakdown of ethephon in soil and are non-persistent in aerobic and anaerobic soils (DT_{50} of 7.3 days). Ethylene is not considered to be a compound of environmental concern. In a field dissipation study, ethephon was shown to be slightly persistent in soil and was generally found in upper soil horizons (< 60 cm depth). Additional field dissipation studies were conducted in ecoregions that are not equivalent to Canadian ecoregions and supplement the Canadian field studies. These supplemental studies indicate that ethephon is non-persistent to slightly persistent and is mostly found in the upper 0-15 cm soil depth. Foliar dissipation studies indicate that ethephon is released in the form of ethylene with DT_{50} values ranging from 1.0 to 5.6 days. Phototransformation is not expected to be an important route of dissipation on soils.

Although no North American monitoring data were available for ethephon and its transformation products, modelling data show no risk of concern to groundwater. In addition, studies on mobility (adsorption/desorption, soil thin-layer chromatography, soil column leaching, criteria of Cohen and GUS score) all indicate that ethephon and 2-HEPA are expected to have low to slight mobility in soil and that they have a low potential to leach to groundwater.

Aquatic Fate

Ethephon can enter the aquatic environment through drift and run-off from the site of application. In aerobic aquatic environments, ethephon does not persist, breaking down rapidly and sorbing to sediment (DT_{50} < 3 days). In anaerobic aquatic environments, ethephon is non-persistent (DT_{50} < 9.25 days). Major transformation products in aquatic environments include ethylene gas and 2-HEPA. Information on half-lives of transformation products in the aquatic environment was not available for review. Direct photolysis is not expected to be an important route of dissipation for ethephon in water, with transformation being driven by hydrolysis at pH >5.

Monitoring data were not available for ethephon or 2-HEPA; therefore, exposure concentrations could not be estimated based on water monitoring data.

Ethephon and 2-HEPA are not expected to bioaccumulate in biological tissue in aquatic environments.

Atmospheric Fate

Ethephon and the transformation products 2-HEPA and ethylene are not expected to be subject to long range transport in the atmosphere. In addition, ethephon and 2-HEPA are not expected to bioaccumulate in animal tissue based on low Log K_{ow}s of -1.83 and -2.05, respectively. As such, the potential risk of ethephon to be exposed and to negatively impact terrestrial and aquatic organisms in remote areas is low.

4.2 Environmental Risk Characterization

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 (i.e. protection at the community, population, or individual level). Toxicity data for ethephon are presented in Appendix VII, Tables 2 to 9. EECs are presented in Appendix VII, Tables 10 to 12.

Initially, a screening level risk assessment is performed to identify 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 and sensitive toxicity endpoints. For characterizing acute risk, acute toxicity values (LC_{50}, LD_{50}, and EC_{50}) from the relevant toxicity studies are divided by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity. Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (10 for fish, 2 for aquatic invertebrates). The EC_{50} is the effective concentration estimated to cause an effect to 50 percent of the test population. Similarly, the LC_{50} or LD_{50} is the lethal concentration or lethal dose estimated to cause mortality to 50% of the test population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

Integration of the environmental exposure and ecotoxicology is achieved by comparing exposure concentrations with concentrations at which adverse effects occur to derive a risk quotient. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/(toxicity/uncertainty factor – if applicable)), and the risk quotient is then compared to the level of concern (Appendix VII, Table 2.). The LOC =1 for all organisms with the exception of honeybees (acute LOC = 0.4) and beneficial terrestrial arthropods (LOC = 2).

If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the RQ exceeds the LOC, then a “presumption of risk” exists, and a more refined assessment for effects, exposure and risk characterization may be conducted to better characterize the potential risk in the environment. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Non-Target Terrestrial Organisms

For assessment of risk, toxicity endpoints from the most sensitive test species were used as surrogates for the wide range of species that can be potentially exposed following exposure to ethephon. Toxicity information was available for earthworms, honeybees, predator and parasitic arthropods, birds, terrestrial plants.

At the screening level, risks to earthworms, honeybees and predators were not of concern (Appendix VII, Table 13). Potential risks to birds, mammals and terrestrial plants were identified at the screening level and are discussed further below. No ecotoxicological tests were conducted on the transformation products except for earthworm acute toxicity where the calculated RQ for 2-HEPA was lower than the LOC.

Birds and Mammals

Results of the screening level risk assessment for birds and mammals are presented in Appendix VII, Table 14. The screening level includes only the most sensitive feeding guilds and the most conservative exposure (use in apple orchards, and assuming maximum residue concentration on food items). At the screening level, risks of concern were identified on an acute and reproduction basis for most sizes of birds and mammals feeding on the treated area. For birds

and mammals feeding off the treated area, risks of concern were identified for small- and medium-sized birds (both acute and reproduction), large birds (reproduction) and mammals (reproduction). Given results obtained at the screening level, the risk was further characterized to include more feeding guilds and considering a wider range of exposure.

An expanded risk assessment was first conducted for the orchard airblast scenario (Appendix VII, Table 15) and is discussed further below. Expanded assessments were also conducted for other crops and application scenarios (Appendix VII: Tables 16-27); these indicated generally low risks to birds and mammals and are not further discussed.

For the orchard airblast scenario, acute risk quotients were generally low considering both maximum and mean residue concentrations. With maximum residue concentrations, acute risk quotients slighly exceeded the level of concern for small and medium insectivore birds, large herbivore birds and small herbivore mammals; the LOC was not exceeded for other animal sizes and feeding guilds. With mean residue concentrations, the acute risk quotients were lower, reaching only 2.1 (on-field) and 1.2 (off-field) for small sized birds. Based on these values, small birds would need to consume 48% (1/RQ × 100) of contaminated food sources on-field, and 83% of contaminated insects off-field to reach the LOC. It is unlikely that small birds would have a diet composed of more than 48% contaminated insects as birds are mobile and will eat insects from other areas, such as uncontaminated insects entering the field (where the pesticide has been applied) from adjacent non-treated habitats. Also, birds will feed in areas outside of the treated fields, thereby reducing their exposure to contaminated food sources on-field. In addition, ethephon is short lived on plant leaves (DT_{50} of 5.2 days) and it is not expected to bioaccumulate in living organisms (such as insects). A brief review of ethephon dissipation from food sources indicate that a RQ above 1 would be maintained for only 3 days on-field and 1.8 days off-field for small insectivores in the apple scenario. Overall, acute risks to birds and mammals are considered to be low.

In terms of bird reproduction, risk quotients calculated using the maximum residue concentrations were above the level of concern for several of small and medium sized birds, with a maximum RQ of 9.4 observed for small insectivore birds feeding on the treated field. Using mean residue concentrations, the highest on-field RQs were 6.5 (small-sized insectivorous birds) and 5.1 (medium-sized insectivorous birds), indicating that these birds would need to consume 15% (small-sized birds) and 20% (medium-sized birds) of contaminated insects in their diet to reach the LOC. The off-field RQ values (3.8 for small-sized insectivorous birds and 3.0 for medium-sized insectivorous birds) indicate that birds would need to consume 26% (small-sized birds) and 33% (medium-sized birds) of contaminated insects in their diet to reach LOC. For reproduction, the number of days above RQ of 1 would be about 17 days for small insectivores on field and about 13 days off-field. Although the possibility that small birds could have a diet essentially composed of more than 26% contaminated insects cannot be ruled out, reproductive exposure is expected to be low because ethephon is applied as a single application in the middle of the growing season. In addition, birds are not expected to be present during field treatments due to high levels of farm activity in apple orchards which tend to repel them from on-field site and decrease their exposure.

The reproduction risk quotients for mammals were higher than for birds. Using the maximum residue concentrations, risk quotients up to 15 were observed (medium-sized herbivorous mammals feeding on the treated area). Based on mean nomogram residues, the highest RQ value was 5.5 (small insectivore and medium herbivorous mammals). This value indicates that small- and medium-sized mammals would need to consume 18% on-field contaminated insects and 18% on-field contaminated short grass in their diet to reach LOC. It is possible that small and medium-sized mammals could have a diet essentially composed of more than the required contaminated insects or short grass in their diet even though food source can be located outside of the treated fields. Mammalian herbivores (especially medium and large sized) are not expected to be present in treated fields due to levels of farm activity in apple orchards which tend to repel herbivores from fields and decrease their exposure. Although a potential reproduction risk exists for both on-field and off-field mammals, exposure is expected to be low and limited to the period of a single treatment of ethephon. As a result, the impact on mammal offspring is not expected to be a concern.

Due to the limited persistence of ethephon in the environment and biota, the repelling effect of farm equipment and the mid-summer to late-season timing of application during the growing season, risks to birds and mammals following acute oral and reproduction exposure to ethephon are expected to be low. Potential acute risks to birds would be restricted to on-field exposure of only a few guilds. Potential reproduction risk to birds, if any, would be restricted to the on-field exposure of insectivores. In addition, ethephon has been used for many years in Canada and no incidents related to birds or mammals from the use of ethephon had been reported, supporting the fact that ethephon poses low risk to birds and mammals. Risks from secondary poisoning to birds and mammals are considered to be low as ethephon is not expected to bioaccumulate.

Although risks to birds and mammals are expected to be low, hazard statements to inform users of the potential risks to birds and mammals are required on the ethephon product labels.

Terrestrial Plants

Being a plant growth regulator, ethephon is relatively toxic to terrestrial vascular plants. For the apple orchard scenario, risk quotientswere above the LOC for seedling emergence and vegetative vigour (RQ of 12 and 3, respectively; see Appendix VII, Table 13). Terrestrial buffer zones are required to protect non-target plants from spray drift during application of ethephon.

4.2.2 Risks to Non-Target Aquatic Organisms

A summary of aquatic toxicity data for freshwater invertebrates, freshwater fish, freshwater algae and vascular plants, estuarine/marine invertebrates, fish and algae is presented in Appendix VII, Table 9. Risks to aquatic organisms are not of concern (Appendix VII, Table 13).

4.3 Incident Reports - Environment

The PMRA database was searched for all incidents involving the active ingredient ethephon as of 22 August 2017. There was one environmental incident reported for this active ingredient in which water used to put out a fire at a chemical distribution warehouse entered nearby streams causing fish mortality. Several chemicals were released into the waterway, and it remains unclear as to which active ingredient was responsible for the fish kill; ethephon was not suspected of being responsible for the incident.

Environmental incident reports were also obtained from the USEPA Ecological Incident Information System (EIIS). Eight cases have been reported in EIIS for ethephon, as of 5 October 2015. Most involved plant damage after having been directly treated with a product containing ethephon.

5.0 Value

Ethephon is registered for use as a plant growth regulator in a variety of field crops and potted greenhouse ornamentals. Ethephon is especially of value for field tomatoes intended for processing, since growers use a one-pass mechanical harvest, and all fruits need to be at the same stage of ripening when harvested. It is also of value in the production of greenhouse ornamentals, as it promotes lateral branching, which is desirable for the retail market.

The use on trees bearing apples is proposed for cancellation; although there are no alternatives for apples for the promotion of early red colouring and apple ripening and to loosen processing apples for easier harvesting, ethephon is not widely used for this claim. There are also no alternatives for claims listed on ethephon for barley, blueberries, cherries and tomatoes. As such ethephon is considered an important tool for producers for these commodities.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, ethephon and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[1] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

[1] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

- Ethephon and the major transformation products 2-HEPA and ethylene do not meet Track 1 criteria. See Appendix VII, Table 28 for comparison with Track 1 criteria. Ethephon is not expected to be subject to long range atmospheric transport and it does not meet the bioaccumulation criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical grade active ingredient and formulants and contaminants in the end-use products are compared against the list maintained in the *Canada Gazette*.[2] The list is used as described in the PMRA Notice of Intent NOI2005-01[3] and is based on existing policies and regulations, including Regulatory Directives DIR99-03 and DIR2006-02,[4] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Impurities of human health or environmental concern are not expected to be present in the product.

7.0 Conclusion

Ethephon is a plant growth regulator used commercially in a variety of crops including cereals, apples, sweet and sour cherries, blueberries, field tomatoes, tobacco, as well as in potted greenhouse ornamentals.

With respect to human health, risks of concern were identified for certain dietary and occupational exposures to ethephon, resulting in the proposal to cancel the use on apple trees when fruit are present, and revocation of the existing MRLs for apple, apple juice, citrus fruit, grape, and raisin such that they will be subject to the general maximum residue limit (GMRL) of 0.1 ppm (subsection B.15.002(1) of the Food and Drugs Regulations. Additional mitigation measures are proposed for some of the remaining uses, including longer REIs. Exposure from these remaining uses is unlikely to affect human health when used according to the proposed label directions.

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2 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

3 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New *Pest Control Products Act*.

4 DIR2006-02, *PMRA Formulants Policy. Formulants Policy and Implementation Guidance Document*

Ethephon enters the environment when used outdoors. It is unlikely to affect the environment when used according to the proposed label directions, which include advisory statements and spray buffer zones.

List of Abbreviations

ADI	acceptable daily intake
AHETF	Agricultural Handlers Exposure Task Force
a.i.	active ingredient
ALAT	alanine aminotransferase activity
ALP	alkaline phosphatase
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
ATPD	area treated per day
BAF	bioaccumulation factor
BCF	bioconcentration factor
BChE	brain cholinesterase
bw	body weight
bwg	body weight gain
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CFIA	Canadian Food Inspection Agency
ChE	cholinesterase
CHO	Chinese hamster ovary
cm	centimetre(s)
C_{max}	maximum concentration
CR	chemical resistant
DACO	data code
DEEM-FCID	Dietary Exposure Evaluation Model - Food Commodity Intake Database™
DFR	dislodgeable foliar residue
DT_{50}	time required to observe a 50% decline in concentration
EChE	erythrocyte cholinesterase
EC_{50}	median effective concentration
EDE	estimated daily exposure
EEC	estimated environmental concentration
EIIS	Ecological Incident Information System
EP	end use product
F_0	parental generation
F_{1a} and F_{1b}	first generation
F_{2a} and F_{2b}	second generation
fc	food consumption
fe	food efficiency
FOB	functional observational battery
g	gram(s)
GD	gestation day
GI	gastrointestinal
GMRL	general maximum residue limit
ha	hectare
Hct	hematocrit
HEPA	2-hydroxyethylphosphonic acid

HG	handgun
Hgb	hemoglobin
hr(s)	hour(s)
HW	handwand
IC_{50}	median inhibitory concentration
IUPAC	International Union of Pure and Applied Chemistry
i.v.	intravenous
kg	kilogram(s)
K_d	soil-water partition coefficient
K_{oc}	organic carbon partition coefficient
K_{ow}	n-octanol/water partition coefficient at 25°C
L	litre(s)
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observed adverse effect level
mg	milligram(s)
min(s)	minute(s)
mL	millilitre(s)
M/L/A	mixer/loader/applicator
MOE	margin of exposure
MRL	maximum residue limit
N/A	not applicable
NHANES/WWEIA	National Health and Nutrition Examination Survey/What We Eat in America
NOAEC	no observed adverse effect concentration
NOEC	no observed effect concentration
NOEL	no observed effect level
NOAEL	no observed adverse effect level
N/S	not stated
PChE	plasma cholinesterase
PHED	Pesticide Handlers Exposure Database
PHI	pre-harvest internal
PMRA	Pest Management Regulatory Agency
PND	postnatal day
PPE	personal protective equipment
Ppm	parts per million
PWC	Pesticide in Water Calculator
RBC	red blood cells
REI	restricted-entry interval
SDH	sorbitol dehydrogenase
TC	transfer co-efficient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
wk(s)	week(s)
wt(s)	weight(s)

µg	microgram
µM	micromolar
USDA's PDP	United States Department of Agriculture's Pesticide Data Program
USEPA	United States Environmental Protection Agency
UV	ultraviolet
yr(s)	year(s)
♂	male
♀	female
↑	increased
↓	decreased

Appendix I Registered Products Containing Ethephon[1]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
19205	Technical	Bayer CropScience Inc.	Technical Ethephon	Solid	Ethephon: 90.22%
19206	Manufacturing Concentrate	Bayer CropScience Inc.	Base 250	Solution	Ethephon: 71.3% by weight
11580	Commercial	Bayer CropScience Inc.	Ethrel Liquid Plant Growth Regulator	Solution	Ethephon: 240 g/L
18685	Commercial	Bayer CropScience Inc.	Cerone Brand Plant Regulator Lodging Control for Cereals	Solution	Ethephon: 480 g/L
29593	Commercial	Bayer CropScience Inc.	Florel Plant Growth Regulator	Solution	Ethephon: 240 g/L
30686	Commercial	Bayer CropScience Inc.	Proxy Plant Growth Regulator	Solution	Ethephon: 240 g/L

[1] As of 28 August 2017, excluding discontinued products or products with a submission for discontinuation

Appendix II Registered Commercial Uses of Ethephon in Canada

Sites	Pest(s) / Claims	Formulation Type	Application Methods and Equipment[2]	Application Rate (g a.i./ha)[2]		Maximum Number of Applications per Year[2]	Minimum Application Interval (Days)[2]
				Maximum Single	Maximum Cumulative		
Use Site Category 6: Greenhouse Non-Food Crops							
Greenhouse Potted Ornamentals – Finished Plants	Increase lateral branching	Solution	[Hydraulic sprayer (high volume) or back pack sprayer (low volume)]	(49.92 g a.i. /100 Litres of water)	(199.68 g a.i. /100 Litres of water)	4 [4 applications per cycle; typically 1 cycle per year]	10
Greenhouse Potted Ornamentals – Stock Plants	Increase lateral branching	Solution	[Hydraulic sprayer (high volume) or back pack sprayer (low volume)] {For poinsettia: low pressure sprayer with coarse spray}	(49.92 g a.i. /100 Litres of water)	(199.68 g a.i. /100 Litres of water)	4 [4 applications per cycle; typically 1 cycle per year]	14
Greenhouse Potted Ornamentals New Guinea Impatiens – Finished Plants	Increase lateral branching	Solution	[Hydraulic sprayer (high volume) or back pack sprayer (low volume)]	(24.96 g a.i. /100 Litres of water)	(99.84 g a.i. /100 Litres of water)	4 [4 applications per cycle; typically 1 cycle per year]	10
Greenhouse Potted Ornamentals New Guinea Impatiens – Stock Plants	Increase lateral branching	Solution	[Hydraulic sprayer (high volume) or back pack sprayer (low volume)]	(24.96 g a.i. /100 Litres of water)	(99.84 g a.i. /100 Litres of water)	4 [4 applications per cycle; typically 1 cycle per year]	14
Use Site Category 13 and 14: Terrestrial Feed Crops and Terrestrial Food Crops							
Apples	Promote early red colouring and apple ripening without loosening	Solution	Airblast sprayer	(840)	(840)	1	Not applicable
Apples	Increase flowering of young apple trees (non-bearing)	Solution	Airblast sprayer	[510]	[510]	1	Not applicable
Apples	Increase flowering of young apple trees (non-bearing)	Solution	Airblast sprayer (concentrate sprayer)	(3360)	(3360)	1	Not applicable
Apples	Loosen processing apples for easier harvesting	Solution	Airblast sprayer	(1320)	(1320)	1	Not applicable
Spring Barley – 2 row cultivars	Reduce lodging	Solution	Ground or aerial sprayer	(360) In Prairie dryland: maximum of 300	(360) In Prairie dryland: maximum of 300	1	Not applicable

Sites	Pest(s) / Claims	Formulation Type	Application Methods and Equipment[2]	Application Rate (g a.i./ha)[2]		Maximum Number of Applications per Year[2]	Minimum Application Interval (Days)[2]
				Maximum Single	Maximum Cumulative		
Spring Barley – 6 row cultivars	Reduce lodging	Solution	Ground or aerial sprayer	(480) In Prairie dryland: maximum of 300	(480) In Prairie dryland: maximum of 300	1	Not applicable
Spring Wheat	Reduce lodging	Solution	Ground or aerial sprayer	(360) In Prairie dryland: maximum of 300	(360) In Prairie dryland: maximum of 300	1	Not applicable
Winter Wheat – Eastern Canada	Reduce lodging	Solution	Ground or aerial sprayer	(600)	(600)	1	Not applicable
Use Site Category 14: Terrestrial Food Crops							
Blueberry - highbush	For concentration of maturity and earlier fruit colouring	Solution	Airblast sprayer	(2040)	(2040)	1	Not applicable
Blueberry - lowbush	Control of black barrenberry	Solution	Ground or aerial sprayer	(2040)	(2040)	1	Not applicable
Cherries - Sour	Loosen fruit for easy removal by hand or machine and promote early uniform fruit maturity	Solution	Airblast sprayer	(660)	(660)	1	Not applicable
Cherries - Sweet	Loosen fruit for easy removal by hand or machine and promote early uniform fruit maturity	Solution	Airblast sprayer	(1320)	(1320)	1	Not applicable
Tobacco – Flue cured	Reduce curing time and promote colour development in the upper 6-7 leaves (tips and undertips)	Solution	Ground sprayer	(900)	(900)	1	Not applicable
Field Tomatoes	Promote earlier uniform and concentrated tomato ripening – mainly for fruit intended for processing	Solution	Ground and aerial sprayer	(1536)	(1536)	1	Not applicable

[1] As of August 28, 2017, excluding discontinued products or products with a submission for discontinuation

[2] All information is derived from registered product labels, except for information provided by registrants which is indicated by [ ], or other stakeholders which is indicated by { } and data calculated by PMRA which is indicated by ( ).

Appendix III Toxicity Profile and Reference Values for Health Risk Assessment

Table 1 Toxicology Reference Values for Use in Health Risk Assessment for Ethephon

Exposure Scenario	Endpoint	Study	CAF[a] or Target MOE
Acute Dietary	♀ 13-49 yrs: Developmental NOAEL = 50 mg/kg bw/day (↑ number of early resorptions and ↓ number of live fetuses)	Developmental toxicity study - rabbit	1,000
	ARfD ♀13-49 yrs = 0.05 mg/kg bw		
	General population: Maternal NOAEL = 50 mg/kg bw/day (↑ number of mortalities in dams)	Developmental toxicity study - rabbit	300
	ARfD general population = 0.17 mg/kg bw		
Chronic Dietary (all populations)	NOAEL = 0.86 mg/kg bw/day (soft stools, effects on gastrointestinal tract and clinical chemistry)	2-yr dietary toxicity study - dog	300
	ADI = 0.003mg/kg bw/day		
Short- and Intermediate-term Dermal[b] and Inhalation[c]	NOAEL = 1.8 mg/kg bw/day (inhibition of erythrocyte cholinesterase activity)	13-wk dietary toxicity study - dog	300
Cancer	Equivocal increase in thymic lymmphosarcomas in female mice. Endpoints selected for the non-cancer risk assessment are protective of this equivocal finding.		

[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 dermal absorption factor 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

Table 2 Toxicology Profile for Ethephon

NOTE: Effects noted below are known or assumed to occur in both sexes unless otherwise specified. Depression of PChE is not considered by the PMRA to be a toxicologically adverse effect; it can be viewed as a marker of exposure. Depression of EChE can be viewed as a surrogate for adverse changes in the peripheral nervous tissue in acute and some short-term studies. In studies of longer duration, depression of EChE is not considered by the PMRA to be a toxicologically adverse effect. Effects noted below are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Effects on organ weights are known or assumed to reflect changes in absolute weight and relative (to bodyweight) weight unless otherwise noted.

Study Type/Animal/ PMRA No.	Study Results
Toxicokinetic Studies	
Sprague-Dawley rats Single oral (gavage) dose of 50 or 1,000 mg/kg bw ^{14}C-ethephon Multiple oral (gavage) doses of 50 mg/kg bw/day (non-radiolabelled ethephon administered for 14 days followed 24 hrs later by a single dose of ^{14}C-ethephon)	

Study Type/Animal/ PMRA No.	Study Results
Single intravenous dose of 50 mg/kg bw ^{14}C-ethephon PMRA Nos. 1540653, 1540650, 1618452, 1618449, 1618450, 2694461	**Single and multiple oral dosing:** **Absorption**: Ethephon was rapidly absorbed via the gastrointestinal tract (78-84%) within 120 hrs. **Distribution**: ≥50 mg/kg bw: C_{max} reached in 1.3-1.9 hrs and 1.0-2.5 hrs in males and females, respectively and the half-life of blood clearance was 7-9 hrs and 4-7 hrs in ♂ and ♀, respectively. The highest tissue concentrations of radioactivity (time of sample N/S) were found in the liver, blood, kidneys, bone, spleen, lungs and heart with no significant differences between single and multiple oral dosing. **Metabolism**: ≥50 mg/kg bw (/day): ethephon was extensively metabolised with the disodium salt of ethephon being identified as the major component in urine and feces (84-87% and 47-59% of the total radioactivity in urine and feces, respectively, time of sample N/S). Ethylene was a primary metabolite in expired air. Fractions other than that containing the disodium salt of ethephon (that is monosodium salt of ethephon) individually accounted for ≤6.0% of the administered radioactivity. 2-hydroxyethyl phosphonic acid (HEPA) was identified in the kidneys and liver at much lower levels than the parent ethephon (no further information was available). **Excretion**: ≥50 mg/kg bw (/day): 86-90% of the administered radioactivity recovered within 120 hrs post-dosing, principally in urine (48-55%), expired air (~20%) and feces (~5%) with the majority of the dose recovered within the first 24 hrs. I.V. dosing: 50 mg/kg bw: biliary excretion was minimal since <2% of the administered dose was recovered in feces.
Sprague-Dawley rats (♂ only) Single oral (gavage) dose of 1,137 mg/kg bw ^{14}C-ethephon PMRA No. 1668456	**Distribution**: The greatest retention of administered radioactivity was found in rats sacrificed 2 hrs post-dosing (80%) with the majority found in the GI tract (62%), stomach contents (31%), carcass and remaining viscera (13%) and selected organs (3%). By 24 hrs post-dosing, there was a rapid 9 in the amount of the compound retained with 0.2% of the dose in the GI tract, 0.8% in the carcass and 0.1% in the selected organs. In all animals, the liver was the organ of highest concentration of radioactivity at 2 hrs post-dosing. In rats sacrificed at 12, 24, 48 or 72 hrs post-dosing, the liver and the kidneys both contained the highest concentrations of radioactivity. **Excretion**: Ethephon was rapidly excreted with approximately 87% of the administered radioactivity recovered in the excreta within 12 hrs and an additional 11% excreted by 24 hrs post-dosing. The urine was the major pathway of excretion (60%) along with 30% of the administered radioactivity excreted as ethylene in expired air, 8% recovered in the feces and less than 0.5% expired as carbon dioxide. The total amount of the administered dose excreted was 99% by 48 hrs post-dosing.

Study Type/Animal/ PMRA No.	Study Results
Beagle dogs (♂ only) Single oral (capsule) dose of 180 mg/kg bw ^{14}C-ethephon PMRA No. 1668455 <u>180 mg/kg bw</u>: 2/3 dogs vomited 15-30 mins post-dosing; therefore, the results in general represent the one dog that did not vomit following test compound administration. **Absorption**: Absorption was rapid with peak blood levels of radioactivity noted within 2-3 hrs. **Distribution**: At sacrifice, a maximum of 0.25% of the administered radioactivity was found in certain organs with the liver containing the majority. C_{max} reached by 2 hrs post-dosing with only traces of radioactivity observed after 22 hrs. **Excretion**: The rate of elimination of ^{14}C-ethephon could not be reliably determined. In 2 dogs, 42% and 33% of the radioactivity appeared in the urine 12-24 hrs following dosing (the other animal that vomited 0.5 hrs after dosing had less than 2% of the dose in the urine) with a significant drop in the amount of radioactivity in the urine during the next 24 hrs (1%). Ethephon was also excreted via expired air as ethylene (30%) during the first 12 hrs post-dosing. In 2 dogs, 3-4% of the administered radioactivity was excreted in the feces in the first 24 hrs post-dosing. The amount excreted as carbon dioxide was negligible. **Supplemental**.	
Acute Toxicity Studies	
Oral Wistar rats	**LD_{50} = 3,730/2,210 mg/kg bw (♂/♀)** **Combined LD_{50} = 3,030 mg/kg bw** Clinical signs of toxicity included sluggishness, piloerection, emaciation, prostration and unkempt appearance. **Low acute toxicity**.
Inhalation Sprague-Dawley rats	**LC_{50} > 3.34 mg/L** Clinical signs of toxicity included unkempt fur, ocular and respiratory irritation, bright red extremities, hypothermia, tremors, slow surface-righting and absent tail pinch reflexes. Necropsy findings included discolouration of the lungs, liver, salivary glands and thymic region, brain hemorrhage, gaseous stomach and intestines. **Low acute toxicity**.
Dermal New Zealand White rabbits	**LD_{50} = 1,710/1,390 mg/kg bw (♂/♀)** **Combined LD_{50} = 1,560 mg/kg bw** Clinical signs of toxicity included salivation, prostration, pinpoint pupils and unsteady gait. Necropsy findings included red lungs and tracheas, mottled livers and intestines filled with paste-like fecal matter.

Study Type/Animal/ PMRA No.	Study Results
	Slightly acutely toxic.
Dermal Irritation New Zealand White rabbits	1 hr: erythema 4 hrs: spots of necrosis and edema (4/6 animals) and contact erythema (6/6 animals). Ethephon was corrosive to the skin of rabbits. **Extremely irritating**.
Dermal Sensitization (Buehler test) Dunkin Hartley guinea pigs	**Not a potential skin sensitizer**.
Dermal Sensitization (Maximization Test) Dunkin Hartley guinea pigs	"Doubtful" macroscopic reactions (15/20 ethephon-treated animals). Histopathological examination of these lesions showed irritation in 9 animals. No reactions of cutaneous sensitization observed in the 20 ethephon-treated animals but the irritation noted in 9 of them may have hidden possible reactions of cutaneous sensitization. **No definitive conclusion as to the sensitizing potential of ethephon can be made from this study.** **Supplemental**.
Short-Term Toxicity Studies	
4-wk Range-finding Oral (dietary) CD-1 mice	≥530/630 mg/kg bw/day (♂/♀): 9 PChE and EChE activity; ≥1,800/2,200 mg/kg bw/day (%/&): 9 BChE (wk 4) activity (♂); ≥4,500/5,900 mg/kg bw/day (%/&):9 bw (wk 1) and bwg (throughout study); 10,000/15,000 mg/kg bw/day (%/&): 9 fc (wk 1), 9 bw (throughout), 9 absolute spleen wt; 9 BChE activity (wk 2), 9 absolute heart wt, 8 relative brain, kidney and lung wts (♂); 9 relative spleen wt (♀). BChE activity not inhibited at any dose level in ♀.
4-wk Oral (dietary) CD-1 mice	**NOAEL = 51/69 mg/kg bw/day** ♂/♀ ≥181/210 mg/kg bw/day (♂/♀): 9 EChE activity; 546/635 mg/kg bw/day (♂/♀): 8 ALP (♂); 9 SDH (♀). BChE activity not inhibited at any dose level.
30-day Oral (dietary) Albino ICR mice	≥68 mg/kg bw/day: 9 PChE and EChE activity; ≥270 mg/kg bw/day: 9 relative liver wt (♂).

Study Type/Animal/ PMRA No.	Study Results
	BChE measurements not performed. **Supplemental**.
4-wk Oral (dietary) Sprague-Dawley rats	**NOAEL = 52/59 mg/kg bw/day** ♂/♀ ≥106/120 mg/kg bw/day (♂/♀): 9 EChE activity; ↓ PChE activity (♂). BChE activity not inhibited at any dose level.
4-week Range-finding Oral (dietary) Sprague-Dawley rats	∃962/996 mg/kg bw/day: 9 PChE and EChE activity; 9 bw and bwg (♀); ∃2,300/2,488 mg/kg bw/day: 8 incidence of diarrhea on day 28 (1♂ and 1♀); 9 bw and bwg (♂); 4,673/4,900 mg/kg bw/day: 8 incidence of diarrhea starting from day 10 (13♂s and 7♀s); 9 BChE activity (♂). BChE activity not inhibited at any dose level in ♀.
13-wk Oral (gavage) Rats (strain N/S)	**LOAEL = 50 mg/kg bw/day** ≥50 mg/kg bw/day: 9 PChE and BChE activity (no further information available); 200 mg/kg bw/day: 9 relative liver, absolute and relative ovarian wts (♀). EChE activity not inhibited at any dose level.
13-wk Oral (gavage) Rats (strain N/S)	≥750 mg/kg bw/day: 9 bwg and urinary pH; 1,500 mg/kg bw/day: 8 mortalities, 8 incidence of vacuolation in liver parenchymal cells, diminished size of liver cell nuclei, 8 size of Kupffer cells and renal tubular necrosis. ChE measurements not performed. **Supplemental**.
52-wk Oral (dietary) Beagle dogs	**NOAEL = 27/30 mg/kg bw/day (♂/♀)** 54/50 mg/kg bw/day (♂/♀): 9 bwg, 8 incidence of soft stools and lumbar spinal cord hemorrhage (1♂ and 1♀), 9 relative spleen wt; 8 incidence of intratubular proteinaceous material in kidneys (1/5) (♂);8 incidence of mineralization and tubular regeneration of the kidneys (1/5) (♀). ChE measurements not performed.
21-day Dermal New Zealand White rabbits	≥25 mg/kg bw/day: 8 incidence of dermal irritation (erythema and desquamation); ≥75 mg/kg bw/day: 8 incidence of skin fissuring;

Study Type/Animal/ PMRA No.	Study Results
	150 mg/kg bw/day: 8 incidence of slight edema, acanthosis and chronic active inflammation. ChE measurements not performed. Pathological examination limited to kidney, liver and skin of control and high-dose animals. **Supplemental.**
Chronic Toxicity/Oncogenicity Studies	
78-wk Oral (dietary) CD-1 mice Highest dose group sacrificed in first wk of study due to extensive morbidity and mortality	**NOAEL = 140/170 mg/kg bw/day (♂/♀)** 1,480/1,780 mg/kg bw/day (♂/♀): 8 incidence of mineralization of the brain and fibrosis of the heart (♂); 9 bw and bwg, 9 BChE at interim sacrifice (♀). **Neoplastic effects**: Thymic region lymphosarcoma: slightly 8 incidence in high-dose ♂ (1/67, 0/27, 2/25 and 3/70 at 0, 14, 140 or 1,480 mg/kg bw/day, respectively, no statistical significance); 8 incidence in high-dose ♀ (1/68, 2/19, 3/16 and 5/68 at 0, 17, 170 or 1,780 mg/kg bw/day, respectively). All lymphosarcomas in ♀: 2/68, 3/27, 4/16 and 5/68 at 0, 17, 170 or 1,780 mg/kg bw/day, respectively). Submitted historical control data showed that the incidence of thymic region lymphosarcomas was within the historical control range. BChE activity not inhibited at any dose level. **Equivocal evidence of carcinogenicity in mice at a dose that exceeded the limit dose of testing.**
104-wk Oral (dietary) Sprague-Dawley rats	**Source A** ≥12.5/16.0 mg/kg bw/day (♂/♀): 9 EChE activity; 9 bw (wk 60 onwards) (♂); 9 survival (♀); 129/171 mg/kg bw/day (♂/♀): 8 incidence of focal necrosis of the liver, atrophy of the spleen, congestion of the lungs, hypospermia, hyperplasia of the parathyroid and squamous ulceration of the stomach (♂); 9 bw (wk 64 onwards), 8 incidence of subacute gastritis of stomach, mucosal ulceration of stomach, squamous ulceration of stomach and endometrial cysts of the uterus (♀). **Source B** 12.5/16.0 mg/kg bw/day (♂/♀): 9 bw (wks 20-68) (♂); 9 ALP (♀). **Neoplastic effects**: Brain gliomas: 8 incidence in high-dose ♂ and ♀ (♂: 0/50, 1/1, not examined and 2/50 (4.0%) in 0, 1.2, 12.5 and 129 mg/kg bw/day, respectively; ♀: 0/50, not examined, 1/3 and 3/49 (6.1%) in 0, 1.6, 16.0 or 171 mg/kg bw/day, respectively). Historical control data: 0 - 5.26%; therefore, the incidence of brain gliomas in the present study is slightly higher than historical control range.

Study Type/Animal/ PMRA No.	Study Results
	Pancreatic islet cell adenomas and carcinomas: 8 incidence in high-dose ♂ (adenomas: 1/50, 2/48, 0/50 and 3/48, carcinomas: 0/50, 0/48, 0/50 and 2/48 at 0, 1.2, 12.5 and 129 mg/kg bw/day, respectively); 8 incidence in high-dose ♀ (adenomas: 1/50, 0/48, 0/50 and 2/50, carcinomas: 1/50, 1/48, 0/50 and 3/50 at 0, 1.6, 16.0 and 171 mg/kg bw/day, respectively). Submitted historical control data for 12 studies compiled in 1994 showed that the pancreatic islet cell adenomas for both sexes were within the historical control ranges; however, no carcinomas were seen in males or females of the 12 historical control studies. BChE activity not inhibited at any dose level. **Supplemental therefore a conclusion on the potential carcinogenicity of ethephon could not be determined.**
104-wk Oral (dietary) Sprague Dawley rats	**NOAEL = 131/161 mg/kg bw/day (♂/♀)** ≥446/543 mg/kg bw/day (♂/♀): 9 bwg (♂: throughout; ♀: wks 3-61) and fe, 9 urine pH; 9 bw (♂: wks 23-71) (♂); 1,420/1,790 mg/kg bw/day (♂/♀): 9 bw (♂ and ♀: throughout); 9 glucose, 8 relative kidney wts, 8 incidence of thyroglossal duct cysts; 8 incidence of loose stools, biliary hyperplasia and liver cholangiofibrosis (♂); 9 bwg (♀: throughout), 8 absolute kidney wts, 8 incidence of glomerulosclerosis and nephritis, mammary gland ectasia, ovary stromal cell hyperplasia and lymph node hemosiderosis (♀). **Recovery**: Recovery noted for altered parameters except for bw and EChE activity. BChE activity not inhibited at any dose level. **Ethephon not carcinogenic to rats.**
2-yr Oral (dietary) Beagle dogs	**NOAEL = 0.86/0.86 mg/kg bw/day (♂/♀)** **Source A** ≥7.6/8.4 mg/kg bw/day (♂/♀): 9 EChE activity, 9 ALP, 8 glucose, 8 incidence of thickening/hypertrophy of the smooth muscle of the stomach and duodenum, 8 incidence of soft stools; 42.0/47.8 mg/kg bw/day (♂/♀): 9 bw and fc (wks 1-4), 8 incidence of emesis, 8 ALAT; 9 Hgb, Hct & RBC (2/6 ♀). **Source B** 7.6/8.4 mg/kg bw/day (♂/♀): 9 bw, 9 PChE and EChE activity; 8 glucose (♂). BChE activity not inhibited at any dose level.

Study Type/Animal/ PMRA No.	Study Results
	Supplemental.
Genotoxicity Studies	
Reverse mutation Salmonella typhimurium strains	TA1535: positive with and without activation; TA98, TA100, TA1537 and TA1538: negative with and without activation. **Positive**.
Bacterial DNA damage Escherichia coli	**Negative**.
Gene mutation Saccharomyces cerevisiae	**Positive**.
Mitotic crossing over Saccharomyces cerevisiae	**Negative.** **Supplemental**.
DNA repair test Rat hepatocytes	**Negative**.
Unscheduled DNA synthesis Rat hepatocytes	**Negative**.
Chromosomal aberration CHO cells	**Negative**.
Forward gene	

Study Type/Animal/ PMRA No.	Study Results
mutation CHO cells	**Negative (3 studies)**.
In vivo Dominant lethal test Sprague-Dawley rats	**Negative.**
In vivo Micronucleus assay CD-1 Charles River mice	**Negative.**
Reproductive/Developmental Toxicity Studies	
2-Generation Oral (dietary) Reproduction Sprague-Dawley rats	**Parental: NOAEL = 19.8/23.7 mg/kg bw/day** ♂/♀ **F_0:** 2,264/2,568 mg/kg bw/day: 8 incidence of loose stools, 9 bw and bwg; 8 mortality (1♂: day 60) (♂); 9 fc (*pre-mating*) (♀). **F_1:** ≥198/245 mg/kg bw/day: 9 bw (♂: *pre-mating*; ♀: *gestation*) and bwg (♂ & ♀: *pre-mating*); 2,221/2,519 mg/kg bw/day: 8 incidence of loose stools, 9 bw and bwg, 9 fc (*pre-mating*); 1 mortality (1♂: day 189), 8 relative testes wt (♂);8 relative ovary wt (♀). **Offspring: NOAEL = 23.7 mg/kg bw/day** ♂/♀ **F_{1a} and F_{1b}:** ≥260 mg/kg bw/day: 9 bwg (PNDs 0-7) (F_{1a}); 9 bwg (PNDs 14-21) (F_{1a}) and 8 incidence of loose feces (F_{1b}) (♂); 2,568 mg/kg bw/day: 9 pup survival (PNDs 0-4), 9 bw and bwg (PNDs 0-28); 8 incidence of loose feces (F_{1b}) (♀). **F_{2a} and F_{2b}:** ≥198/245 mg/kg bw/day: 9 bw (PNDs 7-28) (F_{2b}), 9 bwg (PNDs 4-28) (F_{2b}); 2,221/2,519 mg/kg bw/day: 9 pup survival (PNDs 0-4) (F_{2b}), 9 bw and bwg (PNDs 0-28). **Reproductive: NOAEL = 220/260 mg/kg bw/day** ♂/♀ **F_{1a} and F_{1b}:**

Study Type/Animal/ PMRA No.	Study Results
	2,264/2,568 mg/kg bw/day: 9 birth wts, 8 number of stillborn pups (F_{1b}). **F_{2a} and F_{2b}:** 2,221/2,519 mg/kg bw/day: 9 birth wts, 8 number of stillborn pups (F_{2b}). **No evidence of sensitivity of the young; however, ChE measurements were not performed.**
Range-finding Oral (gavage) Developmental Sprague-Dawley rats	No treatment-related effect on fetal/embryonic survival, implantation rate, resorptions or fetal wt at any dose level. ≥900 mg/kg bw/day: 9 maternal bw; ≥1,350 mg/kg bw/day: 9 maternal survival. ChE measurements not performed. **Supplemental.**
Range-finding Oral (gavage) Developmental Sprague-Dawley rats	≥300 mg/kg bw/day: 9 bwg (GD 6-9); ≥600 mg/kg bw/day: 9 survival; 1,200 mg/kg bw/day: 8 incidence of sacrificed ♀ (2♀), 9 bw, 8 incidence of urine stains, thinness, dyspnea, few or no feces, small thymuses and necrosis of the stomach, ChE measurements not performed. **Supplemental.**
Oral (gavage) Developmental Sprague-Dawley rats	**Maternal: NOAEL = 500 mg/kg bw/day** No treatment-related effects observed at any dose level. **Developmental: NOAEL = 500 mg/kg bw/day** No treatment-related effects observed at any dose level. **No evidence of teratogenicity or sensitivity of the young; however, ChE measurements were not performed.**
Oral (gavage) Developmental Charles River rats	**Maternal: NOAEL = 600 mg/kg bw/day** 1,800 mg/kg bw/day: 8 mortalities (14/25, GD7-19), 8 incidence of dry red matter around mouth and nose, laboured breathing, excessive salivation, matting and staining of the anogenital region in dams that died, 9 bwg, 8 incidence of hydronephrosis in surviving dams (2♀), GI tract distended with gas (1♀) and enlarged/discoloured spleen with focal lymphoid hyperplasia and enlarged/discoloured liver with focal parenchymal fibrosis (1♀). **Developmental: NOAEL = 600 mg/kg bw/day** The total number of fetuses available was 227, 269, 290 and 130 from 0, 200, 600 and 1,800 mg/kg bw/day, respectively. 1,800 mg/kg bw/day: 9 fetal wt (2/9 litters), 2/9 viable litters had

Study Type/Animal/ PMRA No.	Study Results
	malformations (absent tail and microphthalmia in 2 separate fetuses from 1 litter and 3 folded retinas in 3 fetuses from another litter), 8 incidence of fetal resorptions (equivocal due to the small number of litters remaining for examination). **No evidence of teratogenicity or sensitivity of the young; however, ChE measurements were not performed.**
Range-finding Oral (gavage) Developmental New Zealand White rabbits	1,000 mg/kg bw/day: 8 incidence of constricted pupils, depression, ataxia and anorexia; 1♀ found dead after 2 doses and other ♀ found dead after 3 doses, 8 incidence of pale intestines with a grayish-blue tinge (both ♀s), dark brown and denuded pyloric regions of the stomach (both ♀s), grayish-tan margins of intermediate lobes in the liver (both ♀s) and striated cortices of the kidneys (1♀). ChE measurements not performed. **Supplemental**.
Oral (gavage) Developmental New Zealand White rabbits	**Maternal: NOAEL = 50 mg/kg bw/day** ≥100 mg/kg bw/day: 8 mortalities (4 and 8♀ dead/sacrificed moribund at 100 and 250 mg/kg bw/day, respectively); 250 mg/kg bw/day: 8 incidence of depression, ataxia, laboured respiration, eye discharge, thin and cyanotic appearance, 9 bwg and fc (GDs 7-17), 9 uterine and ovarian wts, 8 incidence of pale, 'mushy consistency' kidneys, red/dark brown areas on mucosal area of stomach, duodenum and large intestine. **Developmental: NOAEL = 50 mg/kg bw/day** ≥100 mg/kg bw/day: 8 mean incidence of resorptions, 9 mean number of live fetuses and fetal viability; 250 mg/kg bw/day: 9 mean implantation efficiency. **No evidence of teratogenicity or sensitivity of the young; however, ChE measurements were not performed.**
Oral (gavage) Developmental New Zealand White rabbits	**Maternal: NOAEL = 125 mg/kg bw/day** 250 mg/kg bw/day: 8 mortalities (19/22♀), 8 incidence of ataxia and prostration (17/22♀), 9 activity and yellow/brown staining of the anogenital areas, 9 bw and bwg, 8 incidence of erosions and reddened areas of the stomach. **Developmental: NOAEL = 125 mg/kg bw/day** 250 mg/kg bw/day: 8 number of early resorptions and post-implantation losses, 9 number and % of live fetuses/doe and 9 fetal wt. **No evidence of teratogenicity or sensitivity of the young; however, ChE measurements were not performed.**

Study Type/Animal/ PMRA No.	Study Results
Neurotoxicity Studies	
Acute Oral (gavage) Neurotoxicity Sprague-Dawley rats Observations made for 15 days	**LOAEL = 500 mg/kg bw/day** ≥500 mg/kg bw: 8 incidence of pupillary constriction/pinpoint pupils; ≥1,000 mg/kg bw: 9 fc; 9 total motor activity (♂);8 mortality (1/12♀), 8 incidence of abnormal respiration and breathing sounds (1♀); 2,000 mg/kg bw: 9 bw (day 7), slightly 9 fc, 8 incidence of urination in the open field, abnormal breathing (1♂) (♂);8 mortalities (2/12♀, red/brown muzzle, fur staining, gasping, laboured breathing, pallor, cold to touch and 9 activity prior to death), 9 body temperature, 1♀ with multiple signs of neurotoxicity (including ptosis, lacrimation, urinary staining, decreased motor and locomotor activity and arousal levels, piloerection, abnormal body tone, thin appearance and an altered visual placing response), 8 incidence of an abnormal response to the visual placing test, dark, discoloured ingesta and multiple dark, raised areas of the gastric mucosa of the stomach (1♀) (♀). No treatment-related neuropathological lesions noted. ChE measurements not performed.
1-wk Range-finding Oral (gavage) Neurotoxicity Sprague-Dawley rats FOB performed prior to dosing and 0.5, 1, 2, 4, 6, 8 and 24 hrs post-dosing	≥250 mg/kg bw: 9PChE activity (maximum suppression 4-8 hrs after treatment); 1,000 mg/kg bw: 9 bw (1♂, days 0-1); 2,000 mg/kg bw: 9 bw (all ♂, 1♀). On the basis of these study findings, the times selected as appropriate for application of the FOB in the main acute neurotoxicity study were 5-5.5 hrs post- dosing and for testing of motor activity were 5.5-6 hrs post-dosing. **Supplemental**.
2-wk Range-finding Oral (gavage) Neurotoxicity Sprague-Dawley rats FOB performed prior to dosing at 2 days, prior to study initiation and on days 2, 8 and 15	≥100 mg/kg bw/day: 9 PChE activity; 8 incidence of abnormal respiratory sounds (1♂); ≥300 mg/kg bw/day: 8 incidence of pinpoint pupils; 8 incidence of abnormal respiratory sounds (1♀); ≥600 mg/kg bw/day: 8 mortalities (days 2-10), 8 incidence of fur and snout staining, skin pallor, dehydration, cold to touch, 9 activity, weak appearance and abdominal distension, 9 bw and fc; 8 incidence of diarrhea (♂); 1,000 mg/kg bw/day: 8 incidence of impaired gait; 8 incidence of diarrhea (♀). Gross pathological changes such as dilatation of the stomach and intestine,

Study Type/Animal/ PMRA No.	Study Results
	dark, raised and/or depressed areas in the stomach, dark areas on the thymus and small spleen or thymus were noted in animals that died prior to study termination. EChE unaffected by exposure to ethephon while BChE measurements not performed. **Supplemental**.
13-wk Oral (gavage) Neurotoxicity Sprague-Dawley rats FOB performed prior to treatment as well as prior to dosing on days 4, 8 and 13 PChE and EChE activity measured prior to dosing and in wks 4, 8 and 13	**NOAEL = 75 mg/kg bw/day** No treatment-related effect detected in grip strength, hind-limb splay, body temperature, motor activity, gross or histological lesions of the nervous tissue. ≥75 mg/kg bw/day: 9 PChE activity (♂ at study termination; ♀ throughout) (not considered adverse); ≥150 mg/kg bw/day: 9 EChE activity (♀ at 4 and 8 wks) (♀); 400/300 mg/kg bw/day: 8 mortalities (3♂ and 3♀ wks 5-10), 8 incidence of abnormal respiratory sounds, breathing and poor condition (weak, thin, dehydrated), 9 body temperature, bw and fc; 9 PChE (♂ at 4 wks) and EChE activity (♂ at study termination), 8 incidence of increased difficulty to remove from the home cage, more vocal during removal, cold to the touch and fur staining around the head, 9 absolute brain wt (♂).
Acute Range-finding Oral (gavage) Neurotoxicity White Leghorn chickens	First Run: 2,150 mg/kg bw: 50% mortality; ≥3,160 mg/kg bw: 100% mortality. **LD_{50} = 2,280 mg/kg bw.** Second Run: 3,160 mg/kg bw: lethargy and anorexia (1 bird recovered by day 3); 4,640 mg/kg bw: 100% mortality (4/4 birds died within 17 hrs). **LD_{50} = 3,850 mg/kg bw**
42-day Oral (gavage) Delayed Neurotoxicity White Leghorn chickens	First test group: 2,508 mg/kg bw: 8 mortalities (41/50 within 20 hrs, 3/9 within 21 days). Second test group: ≥3,160 mg/kg bw: 8 mortalities (low-dose: 10/30 within 24 hrs, 1/20 at 48 hrs after receiving the 2nd dose; high-dose: 28/30 within 24 hrs, 1/2 at day 8), 8 incidence of lethargy and anorexia (low-dose: for 48 hrs after 1st dose, for 24 hrs following 2nd dose; high-dose: for 72 hrs), 9 bw and fc. Full recovery noted in ethephon-exposed birds. Necropsy findings: Treatment-related effects noted in ethephon-exposed birds that died prematurely included diffuse red discolouration with severe dilatation of the vessels of the GI tract, diffuse light gray discolouration with transparent gel

Study Type/Animal/ PMRA No.	Study Results
	circumscribing the crop area and a hard texture in the crop area. Birds surviving to termination had healed areas of excoriation in crop area (6/21). **No evidence of delayed neurotoxicity**.
4-wk Oral (dietary) Beagle dogs	**LOAEL = 6 mg/kg bw/day** ≥6 mg/kg bw/day: 9 PChE (not considered adverse) and EChE activity; 14 mg/kg bw/day: 8 incidence of thin appearance (1/3). BChE activity not inhibited at any dose level.
13-wk Oral (dietary) Beagle dogs	**NOAEL = 1.8 mg/kg bw/day** ≥3.5/3.5 mg/kg bw/day: 9 EChE activity (♂: days 25-87; ♀: days 10-87); 12.9/15.5 mg/kg bw/day: 9 EChE activity (♂: days 10-87; ♀: days 3-87); 9 bwg (♂); 9 BChE activity (♀). EChE inhibition is considered adverse at 3.5 mg/kg bw/day because the inhibition was noted on study day 25 in ♂s and day 10 in ♀s, earlier than the 28-day time-point for EChE activity. BChE activity not inhibited in ♂s at any dose level.
Special Toxicity Studies	
Mechanistic basis for inhibition of butyryl-cholinesterase Various mammalian species including humans	In vitro, the sensitivity of plasma butyrylcholinesterase to ethephon (90 min pre-incubation at 25°C) is greatest for dogs, humans and mice (IC_{50}=6-23µM), intermediate for chickens, rabbits, rats and guinea pigs (IC_{50}=26-53µM) and lowest for pigs and horses (IC_{50}=92-172µM). Ethephon is unique among inhibitors of butyrylcholinesterase in that the phosphorylation appears to be due to the dianionic form of the chemical. This species phosphorylates the esteratic site of the enzyme, apparently at serine-198 of the human enzyme, to produce inactive phosphoenzyme. There is evidence that the phosphorylation is slowly reversible.
Specificity of Ethephon as a Butyrylcholinesterase inhibitor and phosphorylating agent Swiss Webster mice and humans	Of all of the esterases considered, butyrylcholinesterase remained the most sensitive *in vitro* and *in vivo* to ethephon. Butyrylcholinesterase inhibition continues to be the most sensitive marker of ethephon exposure.
In vivo pulmonary adenoma bioassay Strain A mice	Ethephon suppressed the spontaneous development of lung tumours in strain A mice and inhibited the development of lung tumours in response to urethane, a carcinogen that was active in the pulmonary adenoma bioassay.

Study Type/Animal/ PMRA No.	Study Results
Metabolite Toxicity Study - 2-hydroxyethylphosphonic acid (HEPA)	
Acute Oral Toxicity Study Wistar rats	**LD_{50} > 2,000 mg/kg bw** 2,000 mg/kg bw: 8 incidence of diarrhea (observed on day 2); lethargy (1♂ 30 mins post-dosing) (♂). **Low acute toxicity**.

Appendix IV Dietary Exposure and Risk Estimates

Table 1 Summary of Acute Dietary Exposure and Risk from Ethephon and the Metabolite HEPA, Based on the Current Use Pattern

Population Subgroup	Acute Dietary (95th percentile)[1]			
	Food only		Food + Water	
	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw)	%ARfD
All Infants (<1 year old)	0.130779	77	0.140058	82
Children 1-2 years old	0.214154	126	0.215620	127
Children 3-5 years old	0.138631	82	0.140361	83
Children 6-12 years old	0.064682	38	0.067681	40
Male 13-19 years old	0.029731	17	0.032601	19
Male 20-49 years old	0.023556	14	0.027390	16
Adults 50-99 years old	0.022297	13	0.025373	15
Female 13-49 years old	0.024332	49	0.027875	56

[1] Acute Reference Dose (ARfD): Females 13-49 years of age = 0.05 mg/kg bw; General population (excluding females 13-49 years of age) = 0.17 mg/kg bw.

Table 2 Summary of Acute Dietary Exposure and Risk from Ethephon and the Metabolite HEPA, with the Proposed Mitigation Measures

Population Subgroup	Acute Dietary (95th percentile)[1]			
	Food only		Food + Water	
	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw)	%ARfD
All Infants (<1 year old)	0.025193	15	0.034677	20
Children 1-2 years old	0.042586	25	0.047312	28
Children 3-5 years old	0.037984	22	0.043032	25
Children 6-12 years old	0.025156	15	0.028368	17
Male 13-19 years old	0.016189	10	0.018948	11
Male 20-49 years old	0.015274	9	0.019438	11
Adults 50-99 years old	0.014965	9	0.018067	11
Female 13-49 years old	0.014726	29	0.018451	37

[1] Acute Reference Dose (ARfD): Females 13-49 years of age = 0.05 mg/kg bw; General population (excluding females 13-49 years of age) = 0.17 mg/kg bw.

Table 3 Summary of Chronic Dietary Exposure and Risk from Ethephon and the Metabolite HEPA, Based on the Current Use Pattern

Population Subgroup	Chronic Dietary[1]			
	Food only		Food + Water	
	Exposure (mg/kg bw/day)	%ADI	Exposure (mg/kg bw/day)	%ADI
General Population	0.002565	86	0.002593	86
All Infants (<1 year old)	0.009486	316	0.009592	320
Children 1-2 years old	0.019254	642	0.019293	643

Population Subgroup	Chronic Dietary[1]			
	Food only		Food + Water	
	Exposure (mg/kg bw/day)	%ADI	Exposure (mg/kg bw/day)	%ADI
Children 3-5 years old	0.011420	381	0.011451	382
Children 6-12 years old	0.003936	131	0.003959	132
Youth 13-19 years old	0.001515	51	0.001535	51
Adults 20-49 years old	0.001237	41	0.001265	42
Adults 50+ years old	0.001238	41	0.001265	42
Females 13-49 years old	0.001284	43	0.001311	44

[1]Acceptable Daily Intake (ADI): 0.003 mg/kg bw/day.

Table 4 Summary of Chronic Dietary Exposure and Risk from Ethephon and the Metabolite HEPA, with the Proposed Mitigation Measures

Population Subgroup	Chronic Dietary[1]			
	Food only		Food + Water	
	Exposure (mg/kg bw/day)	%ADI	Exposure (mg/kg bw/day)	%ADI
General Population	0.000911	30	0.000940	31
All Infants (<1 year old)	0.000922	31	0.001028	34
Children 1-2 years old	0.002904	97	0.002943	98
Children 3-5 years old	0.002813	94	0.002845	95
Children 6-12 years old	0.001278	43	0.001301	43
Youth 13-19 years old	0.000664	22	0.000684	23
Adults 20-49 years old	0.000676	23	0.000704	24
Adults 50+ years old	0.000768	26	0.000795	27
Females 13-49 years old	0.000676	23	0.000703	23

[1]Acceptable Daily Intake (ADI): 0.003 mg/kg bw/day.

Appendix V Food Residue Chemistry Summary

Metabolism in Livestock and Plants

The nature of the residue in plant and animal commodities is adequately understood. Studies based on the total dose applied indicate that ethephon is decomposed to ethylene. Metabolism studies in hens, cotton, tomato, and wheat, based on the total radioactive residues remaining in the food commodity, identified the parent 2-chloroethylphosphonic acid and the metabolite 2-hydroxyethylphosphonic acid (HEPA) as the major residues. The available metabolism study in goat was not adequate to characterize the metabolism of ethephon in ruminant commodities; however, given the use pattern, it is not required for this review.

Residue Definition

The residue definition in plant and animal commodities for enforcement purposes is ethephon per se, which is consistent with PMRA's previous reviews and the established residue definitions in other jurisdictions. The residue definition for risk assessment purposes is the parent, 2-chloroethylphosphonic acid, and the metabolite, 2-hydroxyethylphosphonic acid.

Analytical Methodology

Analytical methods for ethephon have been previously reviewed and deemed acceptable for data collection, enforcement and multi-residue analysis. Quantitation of the residues of ethephon is performed by gas chromatography or gas-liquid chromatography coupled with a flame photometric detector or alkali thermionic detector. The current crop field trials do not include HEPA analytical methods or analysis.

Magnitude of the Residue

Sufficient information was available to assess the dietary exposure and risk from exposure to ethephon and the metabolite HEPA. Although the commodities with Canadian uses do not have data specifically meeting the geographic requirements specified by the PMRA "Residue Chemistry Guidelines" (Regulatory Directives DIR98-02 and DIR2010-05) and some do not have the total required number of trials provided, the available data was deemed adequate by the PMRA in previous reviews to support the current use patterns. The current crop field trials did not include the metabolite HEPA; however, adjustment factors from the metabolism studies were used where possible and additional crop field trials are not required at this time.

Crop Rotation Studies

Adequate data and foreign reviews were available for confined crop rotation. As low residues of ethephon and HEPA (<0.01 ppm) were found in most rotational crop samples at an exaggerated application rate, field crop rotation studies were not required.

Processing Studies

Processing studies were previously reviewed and deemed adequate. Experimental processing factors from these studies were applied in the risk assessment for apple juice, coffee, grape juice, raisins, pineapple juice, tomato paste, tomato puree, tomato juice, wheat bran and wheat germ.

Livestock, Poultry, Egg and Milk Residue Data

Ethephon is registered for use on two livestock feed commodities: barley and wheat. Adequate livestock feeding data and foreign reviews were available.

Adequacy of the Food Residue Database

Adequate data or foreign reviews were available to conduct a dietary risk assessment for ethephon and the metabolite HEPA.

Appendix VI Agricultural Mixer/Loader/Applicator and Postapplication Risk Assessment

Table 1 M/L/A Sort-to-Intermediate Term Exposure and Risk Assessment

Crop	Application Equipment	Applicator	Application Rate (kg a.i./ha or g a.i./L)	ATPD (Ha or L/day)	Exposure (mg/kg a.i./day)[A]			Combined MOE[B] Target = 300
					Dermal	Inhalation	Total	
PPE as per Registered Lables: Open M/L, Single Layer, CR Gloves, Open Cab (CR Headgear Airblast), and Respirator for M/L								
Greenhouse Potted Ornamentals*	Manually Pressurized HW	Farmer/Custom	0.5 g a.i./L	150 L	7.08×10^{-4}	4.24×10^{-5}	7.50×10^{-4}	2400
	Backpack	Farmer/Custom	0.5 g a.i./L	150 L	4.08×10^{-3}	5.82×10^{-5}	4.14×10^{-3}	435
	Mechanically Pressurized HG	Farmer/Custom	0.5 g a.i./L	3800 L	1.06×10^{-1}	3.59×10^{-3}	1.10×10^{-1}	**16**
Apple	Airblast	Farmer/Custom	3.36 kg a.i./ha	20 ha	4.98×10^{-2}	7.68×10^{-3}	5.74×10^{-2}	**31**
Highbush Blueberries	Airblast	Farmer/Custom	2.04 kg a.i./ha	20 ha	3.02×10^{-2}	4.66×10^{-3}	3.49×10^{-2}	**52**
Lowbush Blueberries	Groundboom	Farmer/Custom	2.04 kg a.i./ha	26 ha	3.15×10^{-2}	1.16×10^{-3}	3.27×10^{-2}	**55**
	Aerial	Mixer/Loader		200 ha	0.239	3.21×10^{-4}	0.239	**8**
		Applicator			1.48×10^{-3}	3.57×10^{-4}	1.83×10^{-3}	981
Sour Cherries	Airblast	Farmer/Custom	0.66 kg a.i./ha	20 ha	9.78×10^{-3}	1.51×10^{-3}	1.13×10^{-2}	**160**
Sweet Cherries	Airblast	Farmer/Custom	1.32 kg a.i./ha	20 ha	1.95×10^{-2}	3.02×10^{-3}	2.26×10^{-2}	**80**
Spring Barley	Groundboom	Farmer	0.48 kg a.i./ha	107 ha	3.05×10^{-2}	1.12×10^{-3}	3.17×10^{-2}	**57**
		Custom		360 ha	1.03×10^{-1}	3.76×10^{-3}	1.06×10^{-1}	**17**
	Aerial	Mixer/Loader		400 ha	1.12×10^{-1}	1.51×10^{-4}	1.12×10^{-1}	**16**
		Applicator			6.96×10^{-4}	1.68×10^{-4}	8.63×10^{-4}	2084
Spring Wheat	Groundboom	Farmer	0.36 kg a.i./ha	107 ha	2.29×10^{-2}	8.40×10^{-4}	2.37×10^{-2}	**76**
		Custom		360 ha	7.71×10^{-2}	2.82×10^{-3}	7.99×10^{-2}	**23**
	Aerial	Mixer/Loader		400 ha	8.42×10^{-2}	1.13×10^{-4}	8.44×10^{-2}	**21**
		Applicator			5.22×10^{-4}	1.26×10^{-4}	6.48×10^{-4}	2779
Tobacco	Groundboom	Farmer/Custom	0.9 kg a.i./ha	26 ha	1.39×10^{-2}	5.10×10^{-4}	1.44×10^{-2}	**125**
Field Tomato	Groundboom	Farmer/Custom	1.536 kg a.i./ha	26 ha	2.37×10^{-2}	8.70×10^{-4}	2.46×10^{-2}	**73**
	Aerial	Mixer/Loader		200 ha	1.80×10^{-1}	2.42×10^{-4}	1.80×10^{-1}	**10**
		Applicator			1.11×10^{-3}	2.69×10^{-4}	1.38×10^{-3}	1303
Winter Wheat	Groundboom	Farmer	0.6 kg a.i./ha	107 ha	3.82×10^{-2}	1.40×10^{-3}	3.96×10^{-2}	**45**
		Custom		360 ha	1.28×10^{-1}	4.71×10^{-3}	1.33×10^{-1}	**14**
	Aerial	Mixer/Loader		400 ha	1.40×10^{-1}	1.89×10^{-4}	1.41×10^{-1}	**13**
		Applicator			8.69×10^{-4}	2.1×10^{-4}	1.08×10^{-3}	1668

M/LA = mixer/loader /applicator, N/A = Not Applicable, HW = Handwand, HG = handgun, ATPD = Area Treated per Day, MOE = Margin of Exposure

* Even though a respirator is specified on the label for mixing and loading, Exposure estimates are based on no respirator since the inhalation unit exposure value is representative of combined mixing/loading and application.

[A] Dermal, Inhalation and Total Exposure (mg/kg bw/day) were calculated using the following formulas: Dermal Exposure (mg/kg bw/day) = (Application Rate (kg a.i./ha or g a.i./L) × Area Treated per Day (Ha or

L/day) × Unit Exposure (µg of exposure/kg ai handled) × Dermal Absorption (80% for mixing and loading and handheld scenarios, 3% for application) × Conversion Factor (1 mg/1000 µg)) ÷ Body Weight (80 kg); Inhalation Exposure (mg/kg bw/day) = (Application Rate (kg a.i./ha or g a.i./L) × Area Treated per Day (Ha or L/day) × Unit Exposure (µg of exposure/kg ai handled) × Conversion Factor (1 mg/1000 µg)) ÷ Body Weight (80 kg); Total Exposure = Dermal Exposure (mg/kg bw/day) + Inhalation Exposure (mg/kg bw/day)

[B] Combined MOE was calculated using the following formula: NOAEL (mg/kg bw/day)/Total Exposure (mg/kg bw/day). Based on an oral NOAEL of 1.8 mg/kg bw/day from the 13 week dietary study in the dog, target MOE of 300.

Table 2 M/L/A Short-to-Intermediate Term Exposure and Risk Assessment with Mitigation

Crop	Application Equipment	Applicator	Application Rate (kg a.i./ha or g a.i./L)	ATPD (Ha or L/day)	Exposure (mg/kg a.i./day)[A]			Combined MOE[B] Target = 300	Restriction on Amount Handled (kg ai)
					Dermal	Inhalation	Total		
Open M/L, CR coveralls over a single layer, CR gloves, and a respirator.									
Greenhouse Potted Ornamentals	Mechanically Pressurized HW	Farmer/Custom	0.5 g a.i./L	3800 L	3.47×10^{-2}	3.59×10^{-4}	3.51×10^{-2}	**51**	0.33 kg ai (650 L)
Closed M/L, CR coveralls over a single layer, CR gloves, open cab application with CR headgear and respirator.									
Apple	Airblast	Farmer/Custom	3.36 kg a.i./ha	20 ha	7.89×10^{-3}	8.57×10^{-4}	8.75×10^{-3}	**206**	46 kg ai (13.7 ha)
Closed M/L (CR coveralls over a single layer, CR gloves) and closed cab application (coveralls over a single layer, CR gloves).									
Apple	Airblast	Farmer/Custom	3.36 kg a.i./ha	20 ha	5.56×10^{-3}	3.61×10^{-4}	5.92×10^{-3}	304	N/A
Closed M/L, CR coveralls over a single layer, CR gloves, open cab application with CR headgear and respirator.									
Highbush Blueberries	Airblast	Farmer/Custom	2.04 kg a.i./ha	20 ha	4.79×10^{-3}	5.20×10^{-4}	5.31×10^{-3}	339	N/A
Closed M/L (CR coveralls over a single layer, CR gloves) and closed cab application (coveralls over a single layer, CR gloves).									
Highbush Blueberries	Airblast	Farmer/Custom	2.04 kg a.i./ha	20 ha	3.38×10^{-3}	2.19×10^{-4}	3.60×10^{-3}	501	N/A
Closed M/L, CR coveralls over a single layer, CR gloves, and open cab application.									
Lowbush Blueberries	Groundboom	Farmer/Custom	2.04 kg a.i./ha	26 ha	4.34×10^{-3}	1.19×10^{-3}	5.53×10^{-3}	326	N/A
Closed M/L (CR coveralls over a single layer, CR gloves) and closed cab application (coveralls over a single layer, CR gloves).									
Lowbush Blueberries	Groundboom	Farmer/Custom	2.04 kg a.i./ha	26 ha	4.19×10^{-3}	1.13×10^{-4}	4.31×10^{-3}	418	N/A
Closed M/L, CR coveralls over a single layer, and CR gloves.									
Lowbush Blueberries	Aerial	Mixer/Loader	2.04 kg a.i./ha	200 ha	3.16×10^{-2}	5.61×10^{-4}	3.21×10^{-2}	**56**	78 kg ai (38 ha)
Closed M/L, coveralls over a single layer, CR gloves, and open cab application with CR headgear.									
Sour Cherries	Airblast	Farmer/Custom	0.66 kg a.i./ha	20 ha	2.05×10^{-3}	1.52×10^{-3}	3.57×10^{-3}	505	N/A
Closed M/L, coveralls over a single layer, CR gloves and closed cab application.									
Sour Cherries	Airblast	Farmer/Custom	0.66 kg a.i./ha	20 ha	1.34×10^{-3}	7.10×10^{-4}	1.41×10^{-3}	1277	N/A

Crop	Application Equipment	Applicator	Application Rate (kg a.i./ha or g a.i./L)	ATPD (Ha or L/day)	Exposure (mg/kg a.i./day)[A]			Combined MOE[B] Target = 300	Restriction on Amount Handled (kg ai)
					Dermal	Inhalation	Total		
Closed M/L, CR coveralls over a single layer, CR gloves, and open cab application with CR headgear and a respirator.									
Sweet Cherries	Airblast	Farmer/Custom	1.32 kg a.i./ha	20 ha	3.10×10^{-3}	3.37×10^{-4}	3.44×10^{-3}	524	N/A
Closed M/L (CR coveralls over a single layer, CR gloves) and closed cab application (coveralls over a single layer, CR gloves).									
Sweet Cherries	Airblast	Farmer/Custom	1.32 kg a.i./ha	20 ha	2.18×10^{-3}	1.42×10^{-4}	2.33×10^{-3}	774	N/A
Closed M/L, CR coveralls over a single layer, CR gloves, and a respirator during open cab application.									
Spring Barley	Groundboom	Farmer	0.48 kg a.i./ha	107 ha	4.20×10^{-3}	1.78×10^{-4}	4.38×10^{-3}	411	N/A
		Custom		360 ha	1.41×10^{-2}	6.00×10^{-4}	1.47×10^{-2}	**122**	70 kg ai (147 ha)
Closed M/L (CR coveralls over a single layer, CR gloves) and closed cab application (coveralls over a single layer, CR gloves).									
Spring Barley	Groundboom	Farmer	0.48 kg a.i./ha	107 ha	4.06×10^{-3}	1.09×10^{-4}	4.17×10^{-3}	432	N/A
Spring Barley	Groundboom	Custom	0.48 kg a.i./ha	360 ha	1.36×10^{-2}	3.67×10^{-4}	1.40×10^{-2}	**128**	74 kg ai (155 ha)
Closed M/L, CR coveralls over a single layer, and CR gloves.									
Spring Barley	Aerial	Mixer/Loader	0.48 kg a.i./ha	400 ha	1.49×10^{-2}	2.64×10^{-4}	1.51×10^{-2}	**119**	78 kg ai (161 ha)
Closed M/L, CR coveralls over a single layer, CR gloves, and a respirator during open cab application.									
Spring Wheat	Groundboom	Farmer	0.36 kg a.i./ha	107 ha	3.15×10^{-3}	1.34×10^{-4}	3.29×10^{-3}	548	N/A
		Custom		360 ha	1.06×10^{-2}	4.50×10^{-4}	1.11×10^{-2}	**163**	70 kg ai (195 ha)
Closed M/L (CR coveralls over a single layer, CR gloves) and closed cab application (coveralls over a single layer, CR gloves).									
Spring Wheat	Groundboom	Farmer	0.36 kg a.i./ha	107 ha	3.05×10^{-3}	8.19×10^{-5}	3.13×10^{-3}	576	N/A
		Custom		360 ha	1.02×10^{-2}	2.75×10^{-4}	1.05×10^{-2}	**171**	74 kg ai (205 ha)
Closed M/L, CR coveralls over a single layer, and CR gloves.									
Spring Wheat	Aerial	Application	0.36 kg a.i./ha	400 ha	1.11×10^{-2}	1.98×10^{-4}	1.13×10^{-2}	**159**	78 kg ai (215 ha)
Open M/L, CR coveralls over a single layer, CR gloves, open cab application, and a respirator.									
Tobacco	Groundboom	Farmer/Custom	0.9 kg a.i./ha	26 ha	6.07×10^{-3}	6.76×10^{-5}	6.14×10^{-3}	**293***	N/A
Open M/L (CR coveralls over a single layer, CR gloves, and a respirator), and closed cab application (coveralls).									
Tobacco	Groundboom	Farmer/Custom	0.9 kg a.i./ha	26 ha	6.01×10^{-3}	3.60×10^{-5}	6.04×10^{-3}	**298***	N/A
Closed M/L, single layer, and CR gloves.									
Tobacco	Groundboom	Farmer/Custom	0.9 kg a.i./ha	26 ha	4.66×10^{-3}	5.24×10^{-4}	5.18×10^{-3}	347	N/A
Closed M/L, coveralls over a single layer, CR gloves, and open cab application.									
Tomato	Groundboom	Farmer/Custom	1.536 kg a.i./ha	26 ha	4.05×10^{-3}	8.94×10^{-4}	4.94×10^{-3}	364	N/A
Closed M/L, CR coveralls over a single layer, and CR gloves.									
Tomato	Aerial	Mixer/Loader	1.536 kg a.i./ha	200 ha	2.38×10^{-2}	4.22×10^{-4}	2.42×10^{-2}	**74**	78 kg ai (50 ha)

Crop	Application Equipment	Applicator	Application Rate (kg a.i./ha or g a.i./L)	ATPD (Ha or L/day)	Exposure (mg/kg a.i./day)[A]			Combined MOE[B] Target = 300	Restriction on Amount Handled (kg ai)
					Dermal	Inhalation	Total		
Closed M/L, CR coveralls over a single layer, CR gloves, and a respirator during open cab application.									
Winter Wheat	Groundboom	Farmer	0.6 kg a.i./ha	107 ha	5.25×10^{-3}	2.23×10^{-4}	5.48×10^{-3}	329	N/A
		Custom		360 ha	1.77×10^{-2}	7.51×10^{-4}	1.84×10^{-2}	**98**	70 kg ai (117 ha)
Closed M/L (CR coveralls over a single layer, CR gloves) and a closed cab (coveralls over a single layer)									
Winter Wheat	Groundboom	Custom	0.6 kg a.i./ha	360 ha	1.72×10^{-2}	4.59×10^{-4}	1.75×10^{-2}	**103**	74 kg ai (123 ha)
Closed M/L, CR coveralls over a single layer, and CR gloves.									
Winter Wheat	Aerial	Mixer/Loader	0.6 kg a.i./ha	400 ha	1.86×10^{-2}	3.30×10^{-4}	1.89×10^{-2}	**95**	78 kg ai (129 ha)

M/L/A = mixer/loader/applicator, N/A = Not Applicable, HW = Handwand, ATPD = Area Treated per Day, MOE = Margin of Exposure
* Margin of exposure is considered to be acceptable even though it is slightly less than the target MOE of 300.
[A] Dermal, Inhalation and Total Exposure (mg/kg bw/day) were calculated using the following formulas: Dermal Exposure (mg/kg bw/day) = (Application Rate (kg a.i./ha or g a.i./L) × Area Treated per Day (Ha or L/day) × Unit Exposure (µg of exposure/kg ai handled) × Dermal Absorption (80% for mixing and loading and handheld scenarios, 3% for application) × Conversion Factor (1 mg/1000 µg)) ÷ Body Weight (80 kg); Inhalation Exposure (mg/kg bw/day) = (Application Rate (kg a.i./ha or g a.i./L) × Area Treated per Day (Ha or L/day) × Unit Exposure (µg of exposure/kg ai handled) × Conversion Factor (1 mg/1000 µg)) ÷ Body Weight (80 kg); Total Exposure = Dermal Exposure (mg/kg bw/day) + Inhalation Exposure (mg/kg bw/day)
[B] Combined MOE was calculated using the following formula: NOAEL (mg/kg bw/day)/Total Exposure (mg/kg bw/day). Based on an oral NOAEL of 1.8 mg/kg bw/day from the 13 week dietary study in the dog, target MOE of 300.

Table 3 Summary of Minimum Mitigation Measures for Mixers, Loaders and Applicators Required to Reach Target MOEs.

Crop	Application Equipment	Mix/Load Mitigation	Application Mitigation	Amount Handled per Day Restrictions
Greenhouse Potted Ornamentals	Manually Pressurized Handwand, Backpack	Single Layer + Respirator	Single Layer	N/A
	Mechanically Pressurized Handwand	Max PPE + Respirator	Max PPE + Respirator	0.33 kg ai (650 L)
Apples	Airblast – Open Cab	Closed M/L, Max PPE	Max PPE + CR Headgear + Respirator	46 kg ai (approx. 13.7 ha at high rate)
	Airblast – Closed Cab	Closed M/L, Max PPE	Mid-Level PPE	N/A
Highbush Blueberries, Sweet Cherries	Airblast – Open Cab	Closed M/L, Max PPE	Max PPE + CR Headgear + Respirator	N/A
	Airblast - Closed Cab	Closed M/L, Max PPE	Mid-Level PPE	N/A

Crop	Application Equipment	Mix/Load Mitigation	Application Mitigation	Amount Handled per Day Restrictions
Lowbush Blueberries	Groundboom – Open Cab	Closed M/L, Max PPE	Max PPE	N/A
	Groundboom – Closed Cab	Closed M/L, Max PPE	Mid-Level PPE	N/A
	Aerial	Closed M/L, Max PPE	Single Layer	For mixer/loaders, 78 kg ai (38 ha)
Sour Cherries	Airblast – Open Cab	Closed M/L, Mid-Level PPE	Mid-Level PPE + CR Headgear	N/A
	Airblast – Closed Cab	Closed M/L, Max PPE	Mid-Level PPE	N/A
Spring Barley, Spring Wheat, Winter Wheat	Groundboom- Open Cab	Closed M/L, Max PPE	Max PPE + Respirator	70 kg ai (146 ha – spring barley, 194 ha – spring wheat, 117 ha – winter wheat)
	Groundboom- Closed Cab	Closed M/L, Max PPE	Mid-Level PPE	74 kg ai (154 ha – spring barley, 206 ha – spring wheat, 123 ha – winter wheat)
	Aerial	Closed M/L, Max PPE	Single Layer	For mixer/loaders, 78 kg ai (163 ha – spring barley, 217 ha – spring wheat, 130 ha – winter wheat)
Tobacco	Groundboom- Open Cab	Open M/L + Max PPE + Respirator OR Closed M/L + Single Layer	Open M/L + Max PPE + Respirator OR Closed M/L + Single Layer	N/A
	Groundboom – Closed Cab	Open M/L + Max PPE + Respirator OR Closed M/L + Single Layer	Open M/L + Mid-Level PPE OR Closed M/L + Single Layer	N/A
Tomatoes	Groundboom – Open or Closed Cab	Closed M/L + Mid-Level PPE	Mid-Level PPE	N/A
	Aerial	Closed M/L + Max PPE	Single Layer	For mixer/loaders, 78 kg ai (50 ha)
	Aerial	Closed M/L + Max PPE	Single Layer	For mixer/loaders, 78 kg ai (50 ha)

N/A - Not Applicable, restrictions on amount handled per day were not required to reach target MOEs.
Single Layer: long pants, long sleeved shirts and chemical-resistant gloves (unless specified otherwise)
Mid-level PPE: cotton coveralls over long pants, long sleeved shirts and chemical-resistant gloves
Max PPE: chemical-resistant coveralls over long sleeves and long pants and chemical-resistant gloves

Table 4 Occupational Postapplication Exposure Estimates, MOEs, REIs

Crop	Activity	Max Rate (kg a.i./ha)	Peak DFR[A] (µg/cm²)	TC (cm²/hr)	Dermal Exposure (mg/kg bw/day)[B]	Dermal MOE[C]	REI[D] (Days)
Greenhouse Potted Ornamentals	All Activities	0.5	3.65	230	2.52×10^{-3}	715	12 hrs
Apples (non-bearing)[E]	Hand Pruning, Scouting, Training	3.36	8.4	580	1.46×10^{-2}	**123**	8
	All Other Activities			230	5.80×10^{-3}	311	12 hrs
Apples	Hand Fruit Thinning	1.32	3.3	3000	2.97×10^{-2}	**61**	15
	Hand Harvesting			1400	1.39×10^{-2}	**130**	8
	All Other Activities			580	5.74×10^{-3}	313	12 hrs
Highbush Blueberries	Hand Set Irrigation	2.04	5.1	1750	2.68×10^{-2}	**67**	14
	Hand Harvesting			1400	2.14×10^{-2}	**84**	12
	Hand Pruning, Hand Weeding, Scouting, Bird Control, Frost Control			640	9.79×10^{-3}	**184**	5
	Transplanting			230	3.52×10^{-3}	312	12 hrs
Lowbush Blueberries	Hand Set Irrigation	2.04	5.1	1750	2.68×10^{-2}	**67**	14
	Hand Harvesting, Scouting			1100	1.68×10^{-2}	**107**	10
	Transplanting			230	3.52×10^{-3}	512	12 hrs
Sour Cherries	Hand Harvesting	0.66	1.65	1400	6.93×10^{-3}	260	1
	All Other Activities			580	2.87×10^{-3}	627	12 hrs
Sweet Cherries	Hand Fruit Thinning	1.32	3.3	3000	2.97×10^{-2}	**61**	15
	Hand Harvesting			1400	1.39×10^{-2}	**130**	8
	All Other Activities			580	5.74×10^{-3}	313	12 hrs
Spring Barley	All Activities	0.48	1.2	1100	3.96×10^{-3}	455	12 hrs
Spring Wheat	All Activities	0.36	0.9	1100	2.97×10^{-3}	606	12 hrs
Tobacco	Hand Set Irrigation	0.9	2.25	1750	1.18×10^{-2}	152	6
	All Other Activities			800	5.40×10^{-3}	333	12 hrs
Tomatoes	Hand Set Irrigation	1.536	3.84	1750	2.02×10^{-2}	**89**	12
	Hand Harvesting, Tying/Training			1100	1.27×10^{-2}	**142**	7
	All Other Activities			230	2.65×10^{-3}	679	12 hrs
Winter Wheat	All Activities	0.6	1.5	1100	4.95×10^{-3}	364	12 hrs

Bolded numbers indicate where MOE is below the target MOE.

[A] Peak DFR (µg/cm²) calculated on the day of application for all field crops (maximum number of application is 1), and the day of the 4th application assuming a 10 day minimum interval for greenhouse

ornamentals (maximum number of applications for greenhouse ornamentals is 4, 10 day minimum interval). DFR values calculated using the standard default of 25% of the application rate, and 10% daily dissipation for outdoor field crops.

[B] Dermal Exposure (day 0) (mg/kg bw/day) = $\frac{\text{Peak DFR } (\mu g/cm^2) \times \text{TC } (cm^2/hr) \times \text{Duration (8 hrs)} \times \text{DA (3\%)}}{\text{Body Weight (80 kg)}}$

[C] Based on an oral NOAEL of 1.8 mg/kg bw/day from the oral 13-week dietary toxicity study in the dog, target MOE of 300.

[D] Refers to restricted entry level and is the number of days following application that exposure to workers performing postapplication activities is greater than the target MOE.

[E] As the high rate of 3.36 kg a.i./ha is only for use to increase flowering of young (non-bearing) apple trees, hand fruit thinning and hand harvesting were not assessed, as these activities are not expected to occur; the lower rate of 1.32 kg a.i./ha for apples was used to assess these activities.

Appendix VII Environmental Exposure and Risk Assessment

Table 1 Fate and Behaviour of Ethephon and Transformation Products in Terrestrial and Aquatic Environments

Type of study	Details	Temp (ºC)	pH[4]	Reported DT_{50} (days)	Calculated DT_{50} by PMRA (days)	Kinetic model used by PMRA	Comments[3, 5, 6]	PMRA#
ETF Hydrolysis	14.4 mg/L (97.5% ETF)	25	5	73.5	70.8	SFO	Values determined with pseudo first order kinetics	2715165, 1618457
	12.7 mg/L (97.5% ETF)		7	2.4	1.8	SFO		
	11.6 mg/L (97.5% ETF)		9	1.0	0.9	SFO		
	2 mg/L (93.6% ETF)	25	3	Stable	5755.0	SFO	Stable in acidic milieu and rapidly broken down in neutral and alkaline milieu	2715166
			7	0.3	2.8	SFO		
			10	0.1	1.5	SFO		
	20 mg/L (93.6% ETF)		3	Stable	Stable	SFO		
			7	0.2	2.7	SFO		
			10	0.03	2.2	SFO		
	2 mg/L (93.6% ETF)	35	3	Stable	499.0	SFO		
			7	0.1	0.8	SFO		
			10	0.02	0.9	SFO		
	20 mg/L (93.6% ETF)		3	Stable	Stable	SFO		
			7	0.1	0.8	SFO		
			10	0.02	1.1	SFO		
	1000 mg/L of Base 250 (71.3% ETF)	25	4	Stable	106.0	SFO	The TGAI Cerone (71.3% ethephon) was used. DT50 was calculated using % concentration by titration of sodium hydroxide (Control Method 1023)	2715186
			5	Stable	494.0	SFO		
			6	> 2.3	14.2	SFO		
			7	> 2.3	3.1	SFO		
			8	> 1.3	1.5	SFO		
ETF Phototransformation on soil	New Jersey sandy loam, 1,1% OM, irradiated.	25	6.1	5.1	3.8	SFO	Soils not sterilized. SFO kinetics. No strong acidic soils tested	2715168
	New Jersey sandy loam, 1.1% OM, dark	25	6.1	8.0	8.6	SFO		
	Net half-life due to irradiation alone at 24 hr	25	6.1	28.6	6.8[1]	SFO		
	Clay loam (ADAS), 3.4% OM, irradiated.	20	6.9	19.1	24.7	SFO	Soil not sterilized. Overall recoveries range from 78.6 to 101.6 % AR. No acidic soils tested	2715167
	Clay loam (ADAS), 3.4% OM, dark	20	6.9	24.7	28.7	SFO		
	Net half-life due to irradiation alone at 24 hr	20	6.9	NR	177.2[1]	SFO		
ETF Phototransformation in water	1.0 mg/L (98.0% ETF)	25	7.5	0.7	0.7[2]	SFO	High pH hydrolysis is probably driving the breakdown of ETF rather than light	2715172
	14.4 mg/L (97.5% ETF) 12 hr irradiation/day	25	5	61.0	30.2	SFO	Not an important route of dissipation	2715173 1618457
	14.4 mg/L (97.5% ETF) 12 hr darkness/day			111.0	53.9	SFO		
	14.4 mg/L (97.5% ETF) 12 hours net half-life			139.0	67.5	SFO		

Type of study	Details	Temp (ºC)	pH[4]	Reported DT_{50} (days)	Calculated DT_{50} by PMRA (days)	Kinetic model used by PMRA	Comments[3, 5, 6]	PMRA#
ETF Phototransformation in air	12 hours of sunlight 24 hours of sunlight	NA	NA	10.2 5.1	NR	NA	Rapid atmospheric photo-oxidation breakdown of ETF. No long range transport expected	2715174
ETF Aerobic soil biotransformation	Royston Clay loam (UK)	20	8.2	6.0	17.90	t_R IORE	Non-persistent	2715175
	Soil 00/14, sandy loam	20	6.8	12.7	23.00	t_R IORE	Non-persistent	2715176 2715177
	Soil 00/15, sandy silt loam	20	5.9	22.0	83.40	SFO	Slightly persistent	
	Soil 00/16, clay loam	20	7.6	2.4	4.24	SFO	Non-persistent	
	Soil 00/18, clay loam	20	6.9	9.2	78.30	Slow $t_{1/2}$	Non-persistent	
	Soil 00/18, clay loam	10	6.9	42.1	58.00	SFO	Slightly persistent	
	New Jersey, US, sandy loam	25	6.1	7.50	12.88	SFO	Non-persistent	2715179
	PMRA 80th centile half-life at 20ºC				56.77		Moderately persistent	
ETF Anaerobic soil biotransformation	Clay loam system, Ongar, UK	20	7.3	4.05	4.02	t_R IORE	Non-persistent	2715180
	Dryden pond system (silt loam), NY, US	25	6.1	5.30	4.56	t_R IORE	Non-persistent	2715181
2-HEPA Anaerobic soil biotransformation	Clay loam system, Ongar, UK	20	7.3	NR	7.27	SFO	Non-persistent	2715180
ETF aerobic aquatic biotransformation	Kellmetschweiher water system (sterile high dose)	22.7	7.5-8.2	23.50	1.22	t_R IORE	Slightly persistent	2694471
	Kellmetschweiher water system (non-sterile high dose)	23.7	8.2-8.3	19.00	0.99	t_R IORE	Slightly persistent	
	Kellmetschweiher water system (non-sterile low dose)	23.4	8.2-8.3	21.10	1.11	t_R IORE	Slightly persistent	
	Manningtree river system	20	8.9 (w), 7.4 (s)	2.50 [3.00]	2.50	SFO	Non-persistent	2694470 2715187
	Ongar, Roding river system	20	6.8 (w), 8.2 (s)	1.60 [2.70]	1.61	SFO	Non-persistent	
	PMRA 80th centile half-life at 20ºC				1.97			
ETF anaerobic aquatic biotransformation	North Carolina Clayton loamy sand water phase	25	5	-	8.52	SFO	Non-persistent	2715182
	North Carolina Clayton loamy sand, whole system	25	5	8.00	9.25	SFO	Non-persistent	
	Flooded silt loam sediment	25	NR	5.30	NA	NR	Non-persistent	1618452
	PMRA 80th centile half-life at 20ºC				Stable			
ETF Foliar dissipation	Ethylene release from leaves	20	NR	1.1-5.6	-	-		2805267
		30	7	< 1.0	-	-		2805268

Type of study	Medium	Temp (ºC)	pH	OC (%)	PMRA Kd value	PMRA Koc value	Comments	PMRA#
ETF Soil adsorption / desorption	Sandy loam	25	6.0	3.4	57.3	1676.0	Low mobility	2715183 1518452
	Clay	25	5.2	1.7	53.1	3220.0	Slightly mobile	
	Sandy loam	25	4.6	0.7	29.8	4078.0	Immobile	
	Silt loam	25	5.3	0.4	2.4	608.0	Low mobility	
	Loamy sand	25	5.2	0.2	7.2	3117.0	Slightly mobile	
	PMRA 20th centile				6.2	1462.4	Low mobility	
2-HEPA Soil adsorption / desorption	Leland MS Silt loam	25	6.0	0.5	64.0	5656.0	Immobile	2715185 1618457
	Raleigh NC Sandy loam	25	6.3	0.7	5.0	1464.0	Low mobility	
	Clayton NC Loamy sand	25	7.1	0.3	188.8	12055.0	Immobile	
	Leland MS Clay	25	6.3	1.1	16.6	2313.0	Slightly mobile	
	Clayton NC pond sediment	25	5.9	1.6	8.0	1499.0	Low mobility	
	PMRA 20th centile				7.4	1492.0	Low mobility	
Type of study	**Medium**	**Temp (ºC)**	**pH**	**Rf value – 2,4-D**	**Rf value – PDIC[8]**	**Rf value - ETF**	**Comments**	**PMRA#**
ETF Thin Layer Chromatography	Georgia sugar sand[7]	NR	6.3	0.90	NA	0.50	Intermediate mobility	2694496
	Nesaminy silt loam[7]	NR	6.5	0.84	NA	0.39		
	Florida Belle-glade muck[7]	NR	5.1	0.24	NA	0.35		
	Silt	NR	NR	NA	0.9	0.66		2805270
	Loam	NR	NR	NA	0.73	0.59		
	Clay	NR	NR	NA	0.61	0.20		
	Sand	NR	NR	NA	0.95	NR		
	Mean			0.66	0.80	0.45		--
	Index value			4	4	3		
Type of study	**Properties**	**Criteria of Cohen *et al.*, (1984) indicating a potential for leaching**			**Value**		**Comments**	**PMRA#**
ETF Criteria of Cohen (1984)	Solubility in water	> 30 mg/L			800 000 mg/L		Criterion met	1618457
	K_d	< 5 and usually < 1 or 2			6.2 mL/g		Criterion not met	2715183 1518452
	K_{oc}	< 300			1462.4 mL/g		Criterion not met	2715183 1518452
	Henry's law constant	$< 10^{-2}$ atm.m^3/mol			1.43×10^{-12} atm m^3/mole		Criterion met	1618457
	pKa	Negatively charged (either fully or partially) at ambient pH			pKa_1 = 2.82 (21ºC) pKa_2 = 7.21 (21ºC)		Criterion not met	1618457
	Hydrolysis half-life	> 140 d (> 20 weeks)			2.07 d at pH 7		Criterion not met	2715165 1618457 2715166 2715186
	Soil phototransformation half-life	> 7 d (1 week)			28.6 d		Criterion met	2715168 2715167
	Soil biotransformation half-life (non-sterile)	> 14 to 21 days (> 2 to 3 weeks)			DT_{50} 56.8 days		Criterion met	2715175 2715176 2715177 2715179
	PMRA Interpretation						Only 4 criteria over 8 were met suggesting ethephon has limited potential for leaching	
ETF GUS Score	PMRA repr. DT_{50} in soil = 56.8 d; PMRA 20th centile Koc = 1462.4 mL/g; GUS = log10 (56.8) × (4 – log 10(1462.4)) ;					GUS score = 1.4	Ethephon is not expected to leach	
ETF volatilization	Vapour pressure = 1×10^{-3} Pa at 25ºC						Overall, ethephon is not considered to be volatile and is not expected to have a long range of transport in the atmosphere	
	Henry's Law Constant = 1.43×10^{-12} atm m^3/mole							

Type of study	Medium	pH	Reported DT_{50} (day)	Max soil depth detection (cm)	Comments	PMRA#
Terrestrial Field Dissipation, Canadian equivalent ecoregion	Ephrata, Washington, USA Timmerman coarse sandy loam, ecoregion 10.1.2	7.1-8.2	25.0	60	Ethephon residue level found after the application show dissipation within four months to near non-detected levels (0.022 ug/g equivalent to 0.053 kg a.i./ha).	2694473 1518452 1618457
Terrestrial Field Dissipation, Foreign non-equivalent ecoregion	San Juan Bautista, CA, USA, Sorrento silt loam, ecoregion 11.1.1	7.7-8.1	11.7	0-15	Only traces of ethephon (<0.03 ug/g) residues detected in the next 30	2694473 1618452
	Clayton, NC, USA, Norfolk loamy sand, ecoregion 8.3.4	4.8-6.8	6.8	0-15	Non-detect levels (0.035 ug/g equivalent to 0.085 kg a.i./ha) in 15 cm after 30 days	
	Clay, USA	NR	3.3	NR, 4.3% extractable after 28 d	No information on maximum depth detection in soils	2805270
	Loam, USA	NR	4.9	NR, 3.9% extractable after 28 d		
	Sand USA	NR	9.7	NR, 16.8% extractab. after 28 d		
	Soil 20/330, Germany	NR	31.0	0-10 (after 158 d)	All residues found in the upper 10 cm depth of soils	2694497
	Soil 30/330, Germany	NR	21.0	0-5 (after 100 d)		
	Soil 60/330, Germany	NR	14.0	0-5 (after 25 d)		
	Soil 70/330, Germany	NR	17.0	0-5 (after 26 d)		
	Beijing city soil, A, China	NR	2.6	NR	No information on maximum depth and level detection in soils	2805269
	Beijing city soil, B, China	NR	3.0-5.7	NR		
	Shandong soil, China	NR	1.1-1.7	NR		
	Anhui soil, China	NR	3.2-3.3	NR		
Bioaccumulation	Bluegill sunfish (*Lepomis macrochirus*) exposed at 0.01 mg/L and 1.0 mg/l of ethephon for 28 d.				Low bioconcentration factor of 3-5 and low potential for bioaccumulation	2715197
	Octanol/water partition coefficient	25ºC	Log K_{ow} range between -1.89 (pH 7) and -0.63 (pH 2)		Low potential for bioaccumulation	1618457
		NR	K < 0.00626			1618352
	In exposed rat, ethephon is rapidly absorbed, but very rapidly excreted, mainly via urine (50-60% within 120 hours) and expired air (20% within 120 hours). The amount retained in tissues and residual carcass is reported to be low (<0.5%)					1618457

NR = Not reported; NA = Not applicable;
[1] DT_{50} from SFO, then adjusted for the dark sample using the equation: $DT_{50} = 1/((1/DT_{50}, \text{irradiated}) - (1/DT_{50}, \text{dark}))$;
[2] Not calculated by the PMRA because hydrolysis drives the chemical reaction at tested pH;
[3] Based on classification of Goring et al. 1975 for soils;
[4] For pH, (w) = water phase; (s) = sediment phase; [ ] = reported DT_{50} value by EFSA 2006 and ECHA 2012;
[5] Classification of McEwen and Stephenson and based on reported and PMRA DT_{50} values for water;
[6] Classification of McCall *et al.* 1981 for adsorption/desorption;
[7] Visual reading of TLC graph by PMRA;
[8] PDIC = potassium 3,4-dichloro-5-isothiozole carboxylate in TLC study.

Table 2 PMRA Levels of Concern for the Environmental Risk Assessment

Organism Group	Exposure	Endpoint	Uncertainty Factor	Level of concern
Terrestrial habitat				
Earthworms	acute	LC_{50}	0.5	1
Bees	acute	LD_{50} or LC_{50}	none	0.4
Beneficial Insects	acute	LR_{50}	none	2
Birds/Mammals	acute oral	LD_{50}	0.1	1
	chronic	NOEL (NOEC converted to dose)	none	1
Vascular Plants	acute	EC_{25}	none	1
Aquatic habitat				
Invertebrates (pelagic and benthic)	acute	EC_{50}	0.5	1
	chronic	NOEC	none	1
Fish	acute	LC_{50}	0.1	1
	chronic	NOEC	none	1
Amphibians	acute	fish LC_{50}	0.1	1
	chronic	fish NOEC	none	1
Aquatic vascular plants	acute	EC_{50}	0.5	1
	chronic	NOEC	none	1
Algae	acute	EC_{50}	0.5	1
	chronic	NOEC	none	1

Table 3 Toxicity of Ethephon and 2-HEPA to Earthworms

Species	Formulation Type	Reported Endpoint	Toxicity Value	Comment	Degree of Toxicity	PMRA#
Acute Toxicity						
Ethephon						
Earthworm *Eisenia foetida*	EXP 31039[1] (34.2% purity)	14-d LC_{50} NOEC	>342 mg a.i../kg soil 342 mg a.i../kg soil	--	NA	2715191
2-HEPA						
Earthworm *Eisenia foetida*	AE F0202071 (95.9% purity)	14-d LC_{50} NOEC	>959 mg a.i./kg soil 959 mg a.i./kg soil	--	NA	2715190
Reproduction Toxicity						
Ethephon						
Earthworm *Eisenia foetida*	Ethephon Base 250 (71.4% purity)	NOEC	**200 mg a.i. /kg soil**	No effect on reproduction at highest test concentration	NA	2715206

NA = Not available. Purity was found by dividing 468 g ethephon/L by density of 1369 g EXP31039/L = 34.2%
Values in **bold** were selected for the risk assessment.

Table 4 Toxicity of Ethephon to Pollinators (Bees)

Species	Formulation Type	Reported Endpoint[1]	Toxicity Value	Degree of Toxicity[2]	PMRA#
Adult Acute Oral					
Apis mellifera, carnica L.	Ethephon Technical (73.6%)	48-hr LD_{50} NOED	> 110 µg a.i./bee (HDT)[3] ≥ 110 µg a.i./bee (HDT)	Relatively non-toxic	2715192
Apis mellifera L.	Ethephon Technical	LD_{50}	> 116.5 µg a.i./bee	Relatively non-toxic	1618457
Bombus terrestris L.	Ethephon Technical (73.6%)	48-hr LD_{50} NOED	> 167 µg a.i./bee (HDT)[3] ≥ 167 µg a.i./bee (HDT)	Relatively non-toxic	2715193
Adult Acute Contact					
Apis mellifera, carnica L.	Ethephon Technical (73.6%)	48-hr LD_{50} NOED	> 100 µg a.i./bee (HDT) ≥ 100 µg a.i./bee (HDT)	Relatively non-toxic	2715192
Bombus terrestris L.	Ethephon Technical (73.6%)	48-hr LD_{50} NOED	> 100 µg a.i./bee (HDT)[3] ≥ 100 µg a.i./bee (HDT)	Relatively non-toxic	2715194
Larval Test					
Apis mellifera carnica Pollmann	Ethephon Technical (73.6%)	LD_{50} NOED	> 100 µg a.i./bee (HDT) ≥ 100 µg a.i./bee (HDT)	NA	2694474

[1] NOED = No Observable Effect Dose; [2] Acute and oral toxicity classifcation based on Atkins *et al.* 1981; [3] (HDT) = Highest Dose Tested.

Table 5 Effects of Ethephon to Beneficial Predators and Parasitoids

From EFSA 2006 (PMRA#1618457)

Species	Test type, substrate	Max. recommended test dose (g a.i./ha)	Actual dose tested (g a.i./ha)	Overall effect at respective dose in test
Beneficial predators				
Foliage dwelling predators				
Chrysoperla carnea	Laboratory, glass plate	480 (cereals)	726	-3.4% (less mortality than in the control); 60.1% reduction in reproduction activity
Ground dwelling predatory species				
Poecilus cupreus	Laboratory, sand	480 (cereals)	726	0% (mortality); 0% (reproduction)
Predatory mites				
Typhlodromus pyri	Laboratory, glass plate	480 (cereals)	726	17.7 % (mortality); no significant adverse effects on reproduction (R=0.67)
Extended laboratory studies				
Chrysoperla carnea	Extended lab, maize leaves	480 (cereals)	726	-4.1% (less mortality than in the control); 1.33% (reproduction)
Typhlodromus pyri	Extended lab	480 (cereals)	836	-0.2% (mortality); 17% (reproduction)

Species	Test type, substrate	Max. recommended test dose (g a.i./ha)	Actual dose tested (g a.i./ha)	Overall effect at respective dose in test
Beneficial parasitoids				
Parasitoids				
Aphidius rhopalosiphi	Laboratory, glass plate	480 (cereals)	726	87.2% (mortality); -5.4% (slight increase of parasitism efficiency)
Aphidius rhopalosiphi	Extende Lab. Barley seedlings	480 (cereals)	1440	0% (mortality); 7.1% (reproduction)

Table 6 Toxicity of Ethephon and its Formulations to Birds

Species	Formulation Type	Reported Endpoint	Toxicity Value	Degree of Toxicity[1]	PMRA#
Acute Oral					
Bobwhite quail, *Colinus virginianus*	EXP 31039 (34.5% purity)	14-d LD_{50} NOAEL	>690 mg a.i./kg bw 476 mg a.i./kg bw	Slightly toxic	2715198
Bobwhite quail, *Colinus virginianus*	Ethephon technical (base # 250, Assume 73% purity)[4]	14-d LD_{50}	1072 mg Technical ethephon/kg bw[2] 783 mg a.i./kg bw	Slightly toxic	2715199
Bobwhite quail, *Colinus virginianus*	Technical Amchem 68-250 (endpoint expressed in mg a.i./kg bw)	14-d LD_{50}	**912 mg a.i./kg bw[3]**	Slightly toxic	2715200
Bobwhite quail, *Colinus virginianus*	Assume ethephon technical (unknown purity)	LD_{50}	764 mg/kg bw[2]	Slightly toxic	EFSA 2006 (1618457)
Mallard duck, *Anas platyrhynchos*	Assume ethephon technical (unknown purity)	LD_{50} NOEL	1425 mg /kg bw[2] 450 mg a.i./kg bw	Slightly toxic Moderately toxic	EFSA 2006 (1618457)
Acute Dietary					
Bobwhite quail, *Colinus virginianus*	Ethrel	8-d LC_{50}	>1000 mg a.i./kg bw	Slightly toxic	2715201
Bobwhite quail, *Colinus virginianus*	Ethrel	8-d LC_{50} NOEL	>450 mg a.i./kg bw >530 mg a.i./kg bw	Highly toxic Moderately toxic	EFSA 2006 (1618457)
Mallard duck, *Anas platyrhynchos*	Ethephon technical	5-d LC_{50}	>1000 mg a.i./kg bw	Slightly toxic	2715202
Mallard duck, *Anas platyrhynchos*	Ethephon technical	5-d LC_{50}	>10 000 mg a.i./kg bw	Practically non-toxic	2715203
Reproduction					

Species	Formulation Type	Reported Endpoint	Toxicity Value	Degree of Toxicity[1]	PMRA#
Bobwhite quail, *Colinus virginianus*	Ethephon Base 250 (73% purity)	154-d NOEL 154-d NOAEL 154-d LOAEL	**29 mg a.i./kg bw/d** 87 mg a.i./kg bw/day **>87 mg a.i./kg bw/day**	-	2694489
Mallard duck, *Anas platyrhynchos*	Ethephon Base 250 (73% purity)	154-d NOAEL LOAEL	88 mg a.i./kg bw/day >88 mg a.i./kg bw/day	-	2694491
Japanese quail	Assume ethephon technical	42-d NOEL	159 mg a.i./kg bw	-	EFSA 2006 (1618457)

[1] Oral and DietaryToxicity classification of bird; Hazard Evaluation Division, Standard Evaluation Procedure, US EPA, 1985; [2] No information concerning the source and purity of ethephon; [3] No information concerning the source but LD_{50} expressed in terms of 2-chloroethylphosphonic acid; [4]Assume 73% purity based on same product tested in reproduction studies; Values in **bold** were selected for the risk assessment.

Table 7 Toxicity of Ethephon and its Formulations to Mammals

Relevant studies for the environmental assessment, drawn from the health evaluation

Study Type/Animal/ PMRA No.	Study Results
Acute Toxicity Studies	
Oral Wistar rats PMRA No. 1161191	**LD_{50} = 3,730/2,210 mg/kg bw (♂/♀)** **Combined LD_{50} = 3,030 mg/kg bw** Clinical signs of toxicity included sluggishness, piloerection, emaciation, prostration and unkempt appearance. **Low acute toxicity**.
Reproductive/Developmental Toxicity Studies	
2-Generation Oral (dietary) Reproduction Sprague-Dawley rats PMRA No. 1130086	**Parental: NOAEL = 19.8/23.7 mg/kg bw/day** ♂/♀ **F_0:** 2,264/2,568 mg/kg bw/day: 8 incidence of loose stools, 9 bw and bwg; 8 mortality (1♂: day 60) (♂); 9 fc (*pre-mating*) (♀). **F_1:** ≥198/245 mg/kg bw/day: 9 bw (♂: *pre-mating*; ♀: *gestation*) and bwg (♂ & ♀: *pre-mating*); 2,221/2,519 mg/kg bw/day: 8 incidence of loose stools, 9 bw and bwg, 9 fc (*pre-mating*); 1 mortality (1♂: day 189), 8 relative testes wt (♂);8 relative ovary wt (♀). **Offspring: NOAEL = 23.7 mg/kg bw/day** ♂/♀ **F_{1a} and F_{1b}:** ≥260 mg/kg bw/day: 9 bwg (PNDs 0-7) (F_{1a}); 9 bwg (PNDs 14-21) (F_{1a}) and 8 incidence of loose feces (F_{1b}) (♂); 2,568 mg/kg bw/day: 9 pup survival (PNDs 0-4), 9 bw and bwg (PNDs 0-28); 8 incidence of loose feces (F_{1b}) (♀). **F_{2a} and F_{2b}:** ≥198/245 mg/kg bw/day: 9 bw (PNDs 7-28) (F_{2b}), 9 bwg (PNDs 4-28) (F_{2b}); 2,221/2,519 mg/kg bw/day: 9 pup survival (PNDs 0-4) (F_{2b}), 9 bw and bwg (PNDs 0-

Study Type/Animal/ PMRA No.	Study Results
	28). **Reproductive: NOAEL = 220/260 mg/kg bw/day ♂/♀** **F_{1a} and F_{1b}:** 2,264/2,568 mg/kg bw/day: 9 birth wts, 8 number of stillborn pups (F_{1b}). **F_{2a} and F_{2b}:** 2,221/2,519 mg/kg bw/day: 9 birth wts, 8 number of stillborn pups (F_{2b}). **No evidence of sensitivity of the young; however, ChE measurements were not performed.**

Table 8 Effects of Ethephon on Plant Seedling Emergence and Vegetative Vigour

Species	Test type	Reported endpoint	Measured endpoint	Symbol	Toxicity value (kg a.i./ha)	PMRA#
Ethephon Technical (Base A-250)						
Seedling emergence EC_{25}						
Brassica oleraea capitata	Tier II	EC_{25}	Shoot length	=	0.28	2694494
Lolium perenne	Tier II	EC_{25}	Shoot length	=	0.29	2694495
Daucus carota	Tier II	EC_{25}	Shoot length (NOE)	>	0.36	2694495
Avena sativa	Tier II	EC_{25}	Shoot length	=	0.90	2694494
Solanum lycopersicum	Tier II	EC_{25}	Shoot length	=	1.04	2694494
Glycine max	Tier II	EC_{25}	Shoot length	=	1.68	2694494
Zea mays	Tier II	EC_{25}	Shoot length	>	2.02	2694494
Cucumis sativus	Tier II	EC_{25}	Shoot length (NOE)	>	2.02	2694494
Allium cepa	Tier II	EC_{25}	Shoot length (NOE)	>	2.02	2694494
Lactuca sativa	Tier II	EC_{25}	Shoot length	=	2.32	2694494
Vegetative vigour EC_{25}						
Daucus carota	Tier II	EC_{25}	Shoot weight	=	1.12	2694495
Lactuca sativa	Tier II	EC_{25}	Root weight	=	1.46	2694494
Solanum lycopersicum	Tier II	EC_{25}	Shoot length	=	1.46	2694494
Brassica oleraea capitata	Tier II	EC_{25}	Shoot weight	=	1.57	2694494
Zea mays	Tier II	EC_{25}	Shoot weight (NOE)	>	2.24	2694494
Allium cepa	Tier II	EC_{25}	Shoot weight (NOE)	>	2.35	2694494
Lolium perenne	Tier II	EC_{25}	Shoot weight (NOE)	>	2.35	2694495
Avena sativa	Tier II	EC_{25}	Shoot weight (NOE)	>	2.58	2694494
Glycine max	Tier II	EC_{25}	Shoot length	=	2.58	2694494
Cucumis sativus	Tier II	EC_{25}	Shoot weight	=	3.58	2694494

NOE = No observed effect

Table 9 Toxicity of Ethephon to Aquatic Organisms

Test Compound	System	Species	Exposure	Duration (d)	Toxicity Value[1] (mg a.i./L)	PMRA #
Freshwater Organisms						
Freshwater Invertebrates						
Ethrel (88.3% purity)	Static	Midge larvae, *Chironomus tentans*	Acute	2	EC_{50} = 165	2694478
Ethrel (88.3% purity)	Static	Scud, *Gammarus fasciatus*	Acute	2	EC_{50} = 92.5	2694478
Ethephon (98% purity)	Renewal	Water flea, *Daphnia magna*	Acute	2	EC_{50} > 131	2805271
Ethephon Technical (73.6% purity)	Static-renewal	Water flea, *Daphnia magna*	Acute	3	EC_{50} > 90.5	2694477
Ethrel Technical (88.3% purity)	Static	Water flea, *Daphnia magna*	Acute	2	EC_{50} = 31.7	2694478
Ethephon (72.1% purity)	Renewal	Water flea, *Daphnia magna*	Acute	2	EC_{50} > 416 NOEC = 416	2694476
Freshwater Invertebrates						
Ethephon (72.1% purity)	Renewal	Water flea, *Daphnia magna*	Chronic	21	NOEC = 11.2	2694479
Ethephon Technical (71.2% purity)	Flow through	Water flea, *Daphnia magna*	Chronic	21	EC_{50} > 160 NOEC = 67.0	2694481
Freshwater Fish Acute Exposure						
Ethephon Base 250 (72% purity)	Semi static	Rainbow trout, *Onchorhynchus mykiss*	Acute	3	LC_{50} = 750	2715195
Ethrel (unknown purity)	Static	Rainbow trout, *Onchorhynchus mykiss*	Acute	3	LC_{50} = 357	2715196
Ethrel (unknown purity)	Static	Bluegill, *Lepomis macrichirus*	Acute	3	LC_{50} = 311	2715196
Freshwater Fish Chronic Exposure						
Ethephon Base 250 (71.4% purity)		Fathead minnow, *Pimephales promelas*	ELS	34	NOEC = 43	2694487
Freshwater Algae and Aquatic Vascular Plant Exposure						
Ethephon Base 250 (72.1% purity)	Static	Green algae, *Chlorella vulgaris*	Acute	3	EbC_{50} = 20.9	2694492
Ethephon Technical (73.6% purity)	Static	Freshwater diatom, *Navicula pelliculosa*	Acute	4	ErC_{50} > 3.2	2715204
Ethephon Technical (73.6% purity)	Semi static	Freshwater vasc.plant, *Myriophyllum spicatum*	Acute	14	ErC_{50} > 70.7	2715205

Test Compound	System	Species	Exposure	Duration (d)	Toxicity Value[1] (mg a.i./L)	PMRA #
Saltwater Organisms						
Estuarine/Marine Invertebrates						
Ethrel (88.3% purity)	Static	Grass shrimp, *Palaemonetes vulgaris*	Acute	1	EC_{50} = 419	2694478
Ethrel (88.3% purity)	Static	Mud crab, *Neopanope texana*	Acute	1	EC_{50} = 465	2694478
Ethrel (88.0% purity)	Static	Atlantic oyster, *Crassostrea virginica*	Acute	2 2	EC_{50} > 10 < 49 NOEC = 10	2694483
Base A-250 (72.2% purity)	Flow through	Atlantic oyster, *Crassostrea virginica*	Acute	4	EC_{50} = 60	2694484

Test Compound	System	Species	Exposure	Duration (d)	Toxicity Value[1] (mg a.i./L)	PMRA #
Estuarine/Marine Fish						
Ethephon (73.8% purity)	Flow through	Sheepshead minnow, *Cyprinodon variegatus*	Acute	4	LC_{50} > 102	2694500
Estuarine/Marine Algae						
Ethephon (71.9 % purity)	Static	Marine diatom, *Skeletonema costatum*	Acute	5	EC_{50} > 1.3	2694493

Table 10 Ethephon EECs in Soil

For the Canadian use pattern and using a DT_{50} of 56.8 days.

Crop, Max rate (g a.i./ha)	Soil EEC, 15 cm depth (mg a.i./kg soil)	Application Equipment, Droplet size, % drift	Refined Soil EEC, 15 cm depth with drift (mg a.i./kg soil)
Apple (non-bearing trees), 1 × 3360	1.49	Late Airblast, Fine, 59	0.88
Highbush blueberry, 1 × 2040	0.91	Late airblast, Fine, 59	0.54
Lowbush blueberry, 1 × 1536	0.68	Groundboom, Medium, 6 Aerial, Medium, 23	0.04 0.17
Field tomato, 1 × 1536	0.68	Groundboom, Medium, 6 Aerial, Medium, 23	0.04 0.17
Sweet cherry, 1 × 1320	0.59	Late airblast, Fine, 59	0.35
Tobacco, 1 × 900	0.40	Groundboom, Medium, 6	0.02
Sour cherry, 1 × 660	0.29	Late airblast, Fine, 59	0.17
Winter wheat, 1 × 600	0.27	Groundboom, Coarse, 3	0.008

Crop, Max rate (g a.i./ha)	Soil EEC, 15 cm depth (mg a.i./kg soil)	Application Equipment, Droplet size, % drift	Refined Soil EEC, 15 cm depth with drift (mg a.i./kg soil)
		Aerial, Coarse, 17	0.05
Spring barley, 1 × 480	0.21	Groundboom, Coarse, 3 Aerial, Coarse, 17	0.006 0.04
Spring wheat, 1 × 360	0.16	Groundboom, Coarse, 3 Aerial, Coarse, 17	0.005 0.03

Table 11 Maximum and Mean EECs in Vegetation and Insects after Direct Maximum Airblast Rate Application of Ethephon in Apple Orchards

Food Item	Fresh/dry weight ratios	Maximum residue concentration		Mean residue concentration	
		Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg	Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg
Ethephon on Apple: 1 × 3360 g a.i./ha. Airblast - Late Season Fine - assuming a foliar dissipation of 10 days					
Short range grass	3.3	719.1 / 424.2	2372.9 / 1400	255.4 / 150.7	842.7 / 497.2
Long grass	4.4	329.3 / 194.3	1448.8 / 854.8	107.5 / 63.4	473.1 / 279.1
Broadleaf plants	5.4	406.6 / 239.9	2195.4 / 1295.3	134.4 / 79.3	725.8 / 428.2
Insects	3.8	282.2 / 166.5	1072.5 / 632.8	194.9 / 115	740.5 / 436.9
Grain and seeds	3.8	43.7 / 25.8	166 / 97.9	20.8 / 12.3	79.2 / 46.7
Fruit	7.6	43.7 / 25.8	332 / 195.9	20.8 / 12.3	158.3 / 93.4

Table 12 Ethephon EECs in Water

For the Canadian use pattern and using a DT_{50} of 1.97 days.

Crop, Max rate (g a.i./ha)	Water EEC, 15 cm depth (mg a.i./L)	Water EEC, 80 cm depth (mg a.i./L)	Application Equipment, Droplet size, % drift	Refined Water EEC, 15 cm depth with drift (mg a.i./L)	Refined Water EEC, 80 cm depth with drift (mg a.i./L)
Apple (non-bearing trees), 1 × 3360	2.24	0.42	Late Airblast, Fine, 59	1.32	0.25
Highbush blueberry, 1 × 2040	1.36	0.26	Late airblast, Fine, 59	0.80	0.15
Lowbush blueberry, 1 × 1536	1.02	0.19	Groundboom, Medium, 6 Aerial, Medium, 23	0.06 0.23	0.01 0.04
Field tomato, 1 × 1536	1.02	0.19	Groundboom, Medium, 6 Aerial, Medium, 23	0.06 0.23	0.01 0.04
Sweet cherry, 1 × 1320	0.88	0.17	Late airblast, Fine, 59	0.52	0.10

Crop, Max rate (g a.i./ha)	Water EEC, 15 cm depth (mg a.i./L)	Water EEC, 80 cm depth (mg a.i./L)	Application Equipment, Droplet size, % drift	Refined Water EEC, 15 cm depth with drift (mg a.i./L)	Refined Water EEC, 80 cm depth with drift (mg a.i./L)
Tobacco, 1 × 900	0.60	0.11	Groundboom, Medium, 6	0.04	0.007
Sour cherry, 1 × 660	0.44	0.08	Late airblast, Fine, 59	0.26	0.05
Winter wheat, 1 × 600	0.40	0.08	Groundboom, Coarse, 3 Aerial, Coarse, 17	0.01 0.07	0.002 0.01
Spring barley, 1 × 480	0.32	0.06	Groundboom, Coarse, 3 Aerial, Coarse, 17	0.01 0.05	0.002 0.01
Spring wheat, 1 × 360	0.24	0.05	Groundboom, Coarse, 3 Aerial, Coarse, 17	0.007 0.04	0.002 0.009

Table 13 Screening Level Risks to Non-target Terrestrial and Aquatic Organisms in Apple Orchard Scenario

Organism	Compound tested	Toxcity Value	EEC[5]	RQ[3]	Above LOC?[4]
Terrestrial organisms					
Earthworms					
Earthworm; *Eisenia foetida*	ETF	Acute ½ 14d-LC_{50} > 171 mg a.i./kg soil	1.49 mg a.i./kg soil	<0.009	No
	2-HEPA	Acute ½ 14d-LC_{50} > 480 mg a.i./kg soil	1.49 mg a.i./kg soil	<0.003	No
	ETF	Reproduction NOEC = 200 mg a.i./kg soil	1.49 mg a.i./kg soil	0.007	No
Predators and parasitoids					
Parasitoid; *A. rhopalosiphi*	ETF extended lab	Mortality, reproduction LD_{50} > 1440 g a.i./ha (HRT)	3360 g a.i./ha	**<2.3**	**borderline**
Predator; *T. pyri*	ETF glass plate	Mortality, reproduction LD_{50} > 726 g a.i./ha (HRT)	3360 g a.i./ha	**<4.6**	**NA**
Predator; *C. carnea*	ETF Maize leaves	Mortality, reproduction LD_{50} > 726 g a.i./ha (HRT)	3360 g a.i./ha	**<4.6**	**NA**
Pollinators					
Honey bee; *Apis mellifera*	ETF	Acute oral L_{D50} > 116.5 µg a.i./bee (HDT)[2]	96.1 µg a.i./bee	**<0.82**	**Yes**
		Acute contact L_{D50} > 100 µg a.i./bee (HDT)	8.1 µg a.i./bee	<0.08	No
		Chronic larvae NOED[1] > 100 µg a.i./bee (HDT)	40.8 µg a.i./bee	**<0.41**	**borderline**
Birds					
Bobwhite quail; *Colinus virginianus*	ETF	Acute oral 1/10 14d-LD_{50} = 91.2 mg a.i./kg bw/d	On-field (mg a.i./kg bw/d) Small insect: 273.5 Med. insect: 213.4 Large herb: 137.9	**3.0** **2.3** **1.5**	**Yes** **Yes** **Yes**

Organism	Compound tested	Toxcity Value	EEC[5]	RQ[3]	Above LOC?[4]
		Reproduction 154d-NOEL = 29.0 mg a.i./kg bw/d	On-field (mg a.i./kg bw/d) Small insect: 273.5 Med. insect: 213.4 Large herb: 137.9	**9.4** **7.4** **4.8**	**Yes** **Yes** **Yes**
Mammals					
Wistar rat; *Rattus norvegicus*	ETF	Acute oral 1/10 14d-LD_{50} = 221.0 mg/kg bw/d	On-field (mg a.i./kg bw/d) Small insect: 157.3 Medium herb: 305.1 Large herb: 163.0	0.7 **1.4** 0.7	No **Yes** No
Sprague-Dawley rat; *Rattus norvegicus*		Reproduction 154d-NOEL = 19.8 mg a.i./kg bw/d	On-field (mg a.i./kg bw/d) Small insect: 157.3 Medium herb: 305.1 Large herb: 163.0	**7.9** **15.4** **8.2**	**Yes** **Yes** **Yes**
Terrestrial vascular plants					
Cabbage; *Brassica oleracea c.*	ETF	Seedling emergence EC_{25} = 280 g a.i./ha	3360 g a.i./ha	**12.0**	**Yes**
Carrot; *Daucus carota*		Vegetative vigour EC_{25} = 1120 g a.i./ha	3360 g a.i./ha	**3.0**	**Yes**
Freshwater organisms					
Freswater invertebrate					
Water Flea; *Daphnia magna*	ETF	Acute ½ 48h-EC_{50} = 15.9 mg a.i./L	0.42	0.03	No
		Chronic 21d-NOEC = 11.2 mg a.i./L	0.42	0.04	No
Freshwater fish					
Bluegill sunfish, *Lepomis macrochirus*	ETF	1/10 Acute LC_{50} = 31.1 mg a.i./L	0.42	0.01	No
Fathead minnow, *Pimephales promelas*	ETF	Chronic ELS NOEC = 43.0 mg a.i./L	0.42	0.01	No
Amphibians (surrogate fish)					

Organism	Compound tested	Toxcity Value	EEC[5]	RQ[3]	Above LOC?[4]
Bluegill sunfish, *Lepomis macrochirus*	ETF	1/10 Acute LC_{50} = 31.1 mg a.i./L	2.24	0.07	No
Freshwater algae and vascular plants					
Green algae; *Chlorella vulgaris*	ETF	½ EbC_{50} = 10.5 mg a.i./L	0.42	0.04	No
Freshwater diatom; *Navicula pelliculosa*		½ ErC_{50} > 1.6 mg a.i./L	0.42	<0.26	No
Freswater vascular plant; *Myriophyllum spicatum*		½ ErC_{50} > 35.4 mg a.i./L	0.42	<0.01	No
Salwater organisms					
Marine/estuarine invertebrate					
Atlantic oyster; *Crassostrea virginica*	ETF	Acute ½ EC_{50} > 5.0 mg a.i./L	0.42	<0.08	No
Marine/estuarine fish					
Sheepshead minnow; Cyprinodon variegatus	ETF	Acute 1/10 LC_{50} > 51.0	0.42	<0.008	No
Marine/estuarine algae					
Marine diatom; *Skeletonema costatum*	ETF	Acute ½ EC_{50}> 0.65	0.42	<0.65	No

[1] NOED = No Observable Effect Dose; [2] HDT = Highest Dose Tested; [3] Risk quotient (RQ) = EEC / endpoint;
[4] LOC = 2 for predators and parasitoids and LOC is 0.4 for acute pollinator;
[5] For honey bee contact exposure, the exposure estimate = (2.4 µg a.i./bee)*(application rate in kg a.i./ha); for dietary exposure, the exposure estimate = (29 µg a.i./bee)*(application rate in kg a.i./ha). This is based on 98 µg a.i./g per 1 kg a.i./ha × 0.292 g/day (28.6 µg a.i./bee per kg a.i./ha); for larvae exposure, the exposure estimate = (12.15 µg a.i./bee)*(application rate in kg a.i./ha). This is based on 98 µg a.i./g per 1 kg a.i./ha × 0.124 g/day (12.15 µg a.i./bee per kg a.i./ha) for larvae;.
Bold values indicate RQ > LOC

Table 14 Screening Level Risk Assessment for Ethephon Technical to Wild Birds and Mammals in Apple Production Scenario Using Maximum Nomogram Values

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (59% drift)
Ethephon on Apple: 1 × 3360 g a.i./ha. Airblast - Late Season Fine - assuming a foliar dissipation of 5.2 days					
Birds					
Small Bird (0.02 kg)					
Acute	91.2	Insectivore	273	**3.0**	**1.8**

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (59% drift)
Reproduction	29	Insectivore	273	**9.4**	**5.6**
Medium-Sized Bird (0.1 kg)					
Acute	91.2	Insectivore	213	**2.3**	**1.4**
Reproduction	29	Insectivore	213	**7.4**	**4.3**
Large-Sized Bird (1 kg)					
Acute	91.2	Herbivore (short grass)	138	**1.5**	0.9
Reproduction	29	Herbivore (short grass)	138	**4.8**	**2.8**
Mammals					
Small Mammal (0.015 kg)					
Acute	221	Insectivore	157	0.7	0.4
Reproduction	19.8	Insectivore	157	**7.9**	**4.7**
Medium-Sized Mammal (0.035 kg)					
Acute	221	Herbivore (short grass)	305	**1.4**	0.8
Reproduction	19.8	Herbivore (short grass)	305	**15.4**	**9.1**
Large-Sized Mammal (1 kg)					
Acute	221	Herbivore (short grass)	163	0.7	0.4
Reproduction	19.8	Herbivore (short grass)	163	**8.2**	**4.9**

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 15 Further Characterization of the Risk of Ethephon Technical to Wild Birds and Mammals in Apple Orchard Scenario

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Acute LD50 / 10	91.20	Insectivore	273.49	**3.0**	161.36	**1.8**	188.84	**2.1**	111.41	**1.2**
		Granivore (grain and seeds)	42.33	0.5	24.97	0.3	20.19	0.2	11.91	0.1
		Frugivore (fruit)	84.65	0.9	49.94	0.5	40.37	0.4	23.82	0.3
Reproduction NOEL / 1	29.00	Insectivore	273.49	**9.4**	161.36	**5.6**	188.84	**6.5**	111.41	**3.8**
		Granivore (grain and seeds)	42.33	**1.5**	24.97	0.9	20.19	0.7	11.91	0.4
		Frugivore (fruit)	84.65	**2.9**	49.94	**1.7**	40.37	**1.4**	23.82	0.8
Reproduction LOAEL / 1	87.00	Insectivore	273.49	**3.1**	161.36	**1.9**	188.84	**2.2**	111.41	**1.3**
		Granivore (grain and seeds)	42.33	0.5	24.97	0.3	20.19	0.2	11.91	0.1
		Frugivore (fruit)	84.65	1.0	49.94	0.6	40.37	0.5	23.82	0.3
Medium-Sized Bird (0.1 kg)										
Acute LD50 /	91.20	Insectivore	213.43	**2.3**	125.92	**1.4**	147.37	**1.6**	86.95	1.0

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
10		Granivore (grain and seeds)	33.03	0.4	19.49	0.2	15.75	0.2	9.29	0.1
		Frugivore (fruit)	66.06	0.7	38.98	0.4	31.51	0.3	18.59	0.2
Reproduction NOEL / 1	29.00	Insectivore	213.43	**7.4**	125.92	**4.3**	147.37	**5.1**	86.95	**3.0**
		Granivore (grain and seeds)	33.03	**1.1**	19.49	0.7	15.75	0.5	9.29	0.3
		Frugivore (fruit)	66.06	**2.3**	38.98	**1.3**	31.51	**1.1**	18.59	0.6
Reproduction LOAEL / 1	87.00	Insectivore	213.43	**2.5**	125.92	**1.4**	147.37	**1.7**	86.95	1.0
		Granivore (grain and seeds)	33.03	0.4	19.49	0.2	15.75	0.2	9.29	0.1
		Frugivore (fruit)	66.06	0.8	38.98	0.4	31.51	0.4	18.59	0.2
Large-Sized Bird (1 kg)										
Acute LD50 / 10	91.20	Insectivore	62.31	0.7	36.76	0.4	43.03	0.5	25.39	0.3
		Granivore (grain and seeds)	9.64	0.1	5.69	< 0.1	4.60	< 0.1	2.71	< 0.1
		Frugivore (fruit)	19.29	0.2	11.38	0.1	9.20	0.1	5.43	< 0.1
		Herbivore (short grass)	137.86	**1.5**	81.34	0.9	48.96	0.5	28.89	0.3
		Herbivore (long grass)	84.18	0.9	49.66	0.5	27.49	0.3	16.22	0.2
		Herbivore (broadleaf plants)	127.55	**1.4**	75.26	0.8	42.17	0.5	24.88	0.3

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction NOEL / 1	29.00	Insectivore	62.31	**2.1**	36.76	**1.3**	43.03	**1.5**	25.39	0.9
		Granivore (grain and seeds)	9.64	0.3	5.69	0.2	4.60	0.2	2.71	< 0.1
		Frugivore (fruit)	19.29	0.7	11.38	0.4	9.20	0.3	5.43	0.2
		Herbivore (short grass)	137.86	**4.8**	81.34	**2.8**	48.96	**1.7**	28.89	1.0
		Herbivore (long grass)	84.18	**2.9**	49.66	**1.7**	27.49	0.9	16.22	0.6
		Herbivore (broadleaf plants)	127.55	**4.4**	75.26	**2.6**	42.17	**1.5**	24.88	0.9
Reproduction LOAEL / 1	87.00	Insectivore	62.31	0.7	36.76	0.4	43.03	0.5	25.39	0.3
		Granivore (grain and seeds)	9.64	0.1	5.69	< 0.1	4.60	< 0.1	2.71	< 0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		Frugivore (fruit)	19.29	0.2	11.38	0.1	9.20	0.1	5.43	< 0.1
		Herbivore (short grass)	137.86	**1.6**	81.34	0.9	48.96	0.6	28.89	0.3
		Herbivore (long grass)	84.18	1.0	49.66	0.6	27.49	0.3	16.22	0.2
		Herbivore (broadleaf plants)	127.55	**1.5**	75.26	0.9	42.17	0.5	24.88	0.3
Small Mammal (0.015 kg)										
Acute LD50 / 10	221.00	Insectivore	157.30	0.7	92.81	0.4	108.61	0.5	64.08	0.3
		Granivore (grain and seeds)	24.34	0.1	14.36	< 0.1	11.61	< 0.1	6.85	< 0.1
		Frugivore (fruit)	48.69	0.2	28.73	0.1	23.22	0.1	13.70	< 0.1
Reproduction NOEL / 1	19.80	Insectivore	157.30	**7.9**	92.81	**4.7**	108.61	**5.5**	64.08	**3.2**
		Granivore (grain and seeds)	24.34	**1.2**	14.36	0.7	11.61	0.6	6.85	0.3
		Frugivore (fruit)	48.69	**2.5**	28.73	**1.5**	23.22	**1.2**	13.70	0.7
Reproduction LOAEL / 1	198.00	Insectivore	157.30	0.8	92.81	0.5	108.61	0.5	64.08	0.3
		Granivore (grain and seeds)	24.34	0.123	14.36	< 0.1	11.61	< 0.1	6.85	< 0.1
		Frugivore (fruit)	48.69	0.2	28.73	0.1	23.22	0.1	13.70	< 0.1
Medium-Sized Mammal (0.035 kg)										
Acute LD50 / 10	221.00	Insectivore	137.89	0.6	81.36	0.4	95.21	0.4	56.18	0.3
		Granivore (grain and seeds)	21.34	< 0.1	12.59	< 0.1	10.18	< 0.1	6.00	< 0.1
		Frugivore (fruit)	42.68	0.2	25.18	0.1	20.36	< 0.1	12.01	< 0.1
		Herbivore (short grass)	305.08	**1.4**	180.00	0.8	108.35	0.5	63.93	0.3
		Herbivore (long grass)	186.28	0.8	109.90	0.5	60.83	0.3	35.89	0.2
		Herbivore (forage crops)	282.27	**1.3**	166.54	0.8	93.31	0.4	55.05	0.2
Reproduction NOEL / 1	19.80	Insectivore	137.89	**7.0**	81.36	**4.1**	95.21	**4.8**	56.18	**2.8**
		Granivore (grain and seeds)	21.34	**1.1**	12.59	0.6	10.18	0.5	6.00	0.3
		Frugivore (fruit)	42.68	**2.2**	25.18	**1.3**	20.36	**1.0**	12.01	0.6
		Herbivore (short grass)	305.08	**15.4**	180.00	**9.1**	108.35	**5.5**	63.93	**3.2**
		Herbivore (long grass)	186.28	**9.4**	109.90	**5.6**	60.83	**3.1**	35.89	**1.8**
		Herbivore (broadleaf plants)	282.27	**14.3**	166.54	**8.4**	93.31	**4.7**	55.05	**2.8**
Reproduction	198.00	Insectivore	137.89	0.7	81.36	0.4	95.21	0.5	56.18	0.3

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
LOAEL / 1		Granivore (grain and seeds)	21.34	0.1	12.59	< 0.1	10.18	< 0.1	6.00	< 0.1
		Frugivore (fruit)	42.68	0.2	25.18	0.1	20.36	0.1	12.01	< 0.1
		Herbivore (short grass)	305.08	**1.5**	180.00	0.9	108.35	0.5	63.93	0.3
		Herbivore (long grass)	186.28	0.9	109.90	0.6	60.83	0.3	35.89	0.2
		Herbivore (broadleaf plants)	282.27	**1.4**	166.54	0.8	93.31	0.5	55.05	0.3
Large-Sized Mammal (1 kg)										
Acute LD50 / 10	221.00	Insectivore	73.68	0.3	43.47	0.2	50.88	0.2	30.02	0.1
		Granivore (grain and seeds)	11.40	< 0.1	6.73	< 0.1	5.44	< 0.1	3.21	< 0.1
		Frugivore (fruit)	22.81	0.1	13.46	< 0.1	10.88	< 0.1	6.42	< 0.1
		Herbivore (short grass)	163.02	0.7	96.18	0.4	57.89	0.3	34.16	0.2
		Herbivore (long grass)	99.53	0.5	58.73	0.3	32.50	0.1	19.18	< 0.1
		Herbivore (broadleaf plants)	150.83	0.7	88.99	0.4	49.86	0.2	29.42	0.1
Reproduction NOEL / 1	19.80	Insectivore	73.68	**3.7**	43.47	**2.2**	50.88	**2.6**	30.02	**1.5**
		Granivore (grain and seeds)	11.40	0.6	6.73	0.3	5.44	0.3	3.21	0.2
		Frugivore (fruit)	22.81	**1.2**	13.46	0.7	10.88	0.5	6.42	0.3
		Herbivore (short grass)	163.02	**8.2**	96.18	**4.9**	57.89	**2.9**	34.16	**1.7**
		Herbivore (long grass)	99.53	**5.0**	58.73	**3.0**	32.50	**1.6**	19.18	1.0
		Herbivore (broadleaf plants)	150.83	**7.6**	88.99	**4.5**	49.86	**2.5**	29.42	**1.5**

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction LOAEL / 1	198.00	Insectivore	73.68	0.4	43.47	0.2	50.88	0.3	30.02	0.2
		Granivore (grain and seeds)	11.40	< 0.1	6.73	< 0.1	5.44	< 0.1	3.21	< 0.1
		Frugivore (fruit)	22.81	0.1	13.46	< 0.1	10.88	< 0.1	6.42	< 0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		Herbivore (short grass)	163.02	0.8	96.18	0.5	57.89	0.3	34.16	0.2
		Herbivore (long grass)	99.53	0.5	58.73	0.3	32.50	0.2	19.18	< 0.1
		Herbivore (broadleaf plants)	150.83	0.8	88.99	0.4	49.86	0.3	29.42	0.1

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 16 Maximum and Mean Residues of Ethephon From the Highbush Blueberry Scenario

Food Item	Fresh/dry weight ratios	Maximum residue concentration		Mean residue concentration	
		Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg	Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg
Ethephon on highbush blueberries: 1 × 2040 g a.i./ha. Airblast - Late Season Fine - assuming a foliar dissipation of 5.2 days					
Short range grass	3.3	436.6 / 257.6	1440.7 / 850	155 / 91.5	511.6 / 301.9
Long grass	4.4	199.9 / 118	879.6 / 519	65.3 / 38.5	287.2 / 169.5
Broadleaf plants	5.4	246.8 / 145.6	1332.9 / 786.4	81.6 / 48.1	440.6 / 260
Insects	3.8	171.4 / 101.1	651.2 / 384.2	118.3 / 69.8	449.6 / 265.3
Grain and seeds	3.8	26.5 / 15.6	100.8 / 59.5	12.6 / 7.5	48.1 / 28.4
Fruit	7.6	26.5 / 15.6	201.6 / 118.9	12.6 / 7.5	96.1 / 56.7

Table 17 Screening Level Risk Assessment of Birds and Mammals Exposed to Ethephon in the Highbush Blueberry Scenario

Animal/Endpoints	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (59% drift)
Birds					
Small Bird (0.02 kg)					
Acute	91.2	Insectivore	166	**1.8**	**1.1**
Reproduction	29	Insectivore	166	**5.7**	**3.4**
Medium-Sized Bird (0.1 kg)					
Acute	91.2	Insectivore	130	**1.4**	0.8
Reproduction	29	Insectivore	130	**4.8**	**2.6**

Animal/Endpoints	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (59% drift)
Large-Sized Bird (1 kg)					
Acute	91.2	Herbivore (short grass)	83.7	0.9	0.5
Reproduction	29	Herbivore (short grass)	83.7	**2.9**	**1.7**
Mammals					
Small Mammal (0.015 kg)					
Acute	221	Insectivore	95.5	0.4	0.3
Reproduction	19.8	Insectivore	95.5	**4.8**	**2.9**
Medium-Sized Mammal (0.035 kg)					
Acute	221	Herbivore (short grass)	185	0.8	0.5
Reproduction	19.8	Herbivore (short grass)	185	**9.4**	**5.5**
Large-Sized Mammal (1 kg)					
Acute	221	Herbivore (short grass)	99	0.5	0.3
Reproduction	19.8	Herbivore (short grass)	99	**5.0**	**3.0**

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 18 Further Characterization of the Risk of Ethephon Technical to Wild Birds and Mammals in Highbush Blueberry Scenario

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Acute LD50 / 10	91.20	Insectivore	166.05	**1.8**	97.97	**1.1**	114.65	**1.3**	67.6	0.7
		Granivore (grain and seeds)	25.70	0.3	15.16	0.2	12.26	0.1	7.2	< 0.1
		Frugivore (fruit)	51.40	0.6	30.32	0.3	24.51	0.3	14.5	0.2
Reproduction NOEL / 1	29.00	Insectivore	166.05	**5.7**	97.97	**3.4**	114.65	**4.0**	67.6	**2.3**
		Granivore (grain and seeds)	25.70	0.9	15.16	0.5	12.26	0.4	7.2	0.2
		Frugivore (fruit)	51.40	**1.8**	30.32	**1.0**	24.51	0.8	14.5	0.5
Reproduction LOAEL / 1	87.00	Insectivore	166.05	**1.9**	97.97	**1.1**	114.65	**1.3**	67.6	0.8
		Granivore (grain and seeds)	25.70	0.3	15.16	0.2	12.26	0.1	7.2	< 0.1
		Frugivore (fruit)	51.40	0.6	30.32	0.3	24.51	0.3	14.5	0.2
Medium-Sized Bird (0.1 kg)										
Acute LD50 / 10	91.20	Insectivore	129.58	**1.4**	76.45	0.8	89.47	1.0	52.8	0.6
		Granivore (grain and seeds)	20.05	0.2	11.83	0.1	9.56	0.1	5.6	< 0.1
		Frugivore (fruit)	40.11	0.4	23.66	0.3	19.13	0.2	11.3	0.1
Reproduction	29.00	Insectivore	129.58	**4.5**	76.45	**2.6**	89.47	**3.1**	52.8	**1.8**

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
NOEL / 1		Granivore (grain and seeds)	20.05	0.7	11.83	0.4	9.56	0.3	5.6	0.2
		Frugivore (fruit)	40.11	**1.4**	23.66	0.8	19.13	0.7	11.3	0.4
Reproduction LOAEL / 1	87.00	Insectivore	129.58	**1.5**	76.45	0.9	89.47	**1.0**	52.8	0.6
		Granivore (grain and seeds)	20.05	0.2	11.83	0.1	9.56	0.1	5.6	< 0.1
		Frugivore (fruit)	40.11	0.5	23.66	0.3	19.13	0.2	11.3	0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Large Sized Bird (1 kg)										
Acute LD50 / 10	91.20	Insectivore	37.83	0.4	22.32	0.2	26.12	0.3	15.4	0.2
		Granivore (grain and seeds)	5.86	< 0.1	3.45	< 0.1	2.79	< 0.1	1.6	< 0.1
		Frugivore (fruit)	11.71	0.1	6.91	< 0.1	5.58	< 0.1	3.3	< 0.1
		Herbivore (short grass)	83.70	0.9	49.39	0.5	29.73	0.3	17.5	0.2
		Herbivore (long grass)	51.11	0.6	30.15	0.3	16.69	0.2	9.8	0.1
		Herbivore (broadleaf plants)	77.44	0.8	45.69	0.5	25.60	0.3	15.1	0.2
Reproduction NOEL / 1	29.00	Insectivore	37.83	**1.3**	22.32	0.8	26.12	0.9	15.4	0.5
		Granivore (grain and seeds)	5.86	0.2	3.45	0.1	2.79	< 0.1	1.6	< 0.1
		Frugivore (fruit)	11.71	0.4	6.91	0.2	5.58	0.2	3.3	0.1
		Herbivore (short grass)	83.70	**2.9**	49.39	**1.7**	29.73	**1.0**	17.5	0.6
		Herbivore (long grass)	51.11	**1.8**	30.15	**1.0**	16.69	0.6	9.8	0.3
		Herbivore (broadleaf plants)	77.44	**2.7**	45.69	**1.6**	25.60	0.9	15.1	0.5
Reproduction LOAEL / 1	87.00	Insectivore	37.83	0.4	22.32	0.3	26.12	0.3	15.4	0.2
		Granivore (grain and seeds)	5.86	< 0.1	3.45	< 0.1	2.79	< 0.1	1.6	< 0.1
		Frugivore (fruit)	11.71	0.1	6.91	< 0.1	5.58	< 0.1	3.3	< 0.1
		Herbivore (short grass)	83.70	1.0	49.39	0.6	29.73	0.3	17.5	0.2
		Herbivore (long	51.11	0.6	30.15	0.3	16.69	0.2	9.8	0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		grass)								
		Herbivore (broadleaf plants)	77.44	0.9	45.69	0.5	25.60	0.3	15.1	0.2
Small Mammal (0.015 kg)										
Acute LD50 / 10	221.00	Insectivore	95.50	0.4	56.35	0.3	65.94	0.3	38.9	0.2
		Granivore (grain and seeds)	14.78	< 0.1	8.72	< 0.1	7.05	< 0.1	4.2	< 0.1
		Frugivore (fruit)	29.56	0.1	17.44	< 0.1	14.10	< 0.1	8.3	< 0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction NOEL / 1	19.80	Insectivore	95.50	**4.8**	56.35	**2.8**	65.94	**3.3**	38.9	**2.0**
		Granivore (grain and seeds)	14.78	0.7	8.72	0.4	7.05	0.4	4.2	0.2
		Frugivore (fruit)	29.56	**1.5**	17.44	0.9	14.10	0.7	8.3	0.4
Reproduction LOAEL / 1	198.00	Insectivore	95.50	0.5	56.35	0.3	65.94	0.3	38.9	0.2
		Granivore (grain and seeds)	14.78	< 0.1	8.72	< 0.1	7.05	< 0.1	4.2	< 0.1
		Frugivore (fruit)	29.56	0.1	17.44	< 0.1	14.10	< 0.1	8.3	< 0.1
Medium-Sized Mammal (0.035 kg)										
Acute LD50 / 10	221.00	Insectivore	83.72	0.4	49.40	0.2	57.81	0.3	34.1	0.2
		Granivore (grain and seeds)	12.96	< 0.1	7.64	< 0.1	6.18	< 0.1	3.6	< 0.1
		Frugivore (fruit)	25.91	0.1	15.29	< 0.1	12.36	< 0.1	7.3	< 0.1
		Herbivore (short grass)	185.23	0.8	109.29	0.5	65.78	0.3	38.8	0.2
		Herbivore (long grass)	113.10	0.5	66.73	0.3	36.93	0.2	21.8	< 0.1
		Herbivore (forage crops)	171.38	0.8	101.11	0.5	56.65	0.3	33.4	0.2
Reproduction NOEL / 1	19.80	Insectivore	83.72	**4.2**	49.40	**2.5**	57.81	**2.9**	34.1	**1.7**
		Granivore (grain and seeds)	12.96	0.7	7.64	0.4	6.18	0.3	3.6	0.2
		Frugivore (fruit)	25.91	**1.3**	15.29	0.8	12.36	0.6	7.3	0.4
		Herbivore (short grass)	185.23	**9.4**	109.29	**5.5**	65.78	**3.3**	38.8	**2.0**
		Herbivore (long grass)	113.10	**5.7**	66.73	**3.4**	36.93	**1.9**	21.8	**1.1**

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		Herbivore (broadleaf plants)	171.38	**8.7**	101.11	**5.1**	56.65	**2.9**	33.4	**1.7**
Reproduction LOAEL / 1	198.00	Insectivore	83.72	0.4	49.40	0.2	57.81	0.3	34.1	0.2
		Granivore (grain and seeds)	12.96	< 0.1	7.64	< 0.1	6.18	< 0.1	3.6	< 0.1
		Frugivore (fruit)	25.91	0.1	15.29	< 0.1	12.36	< 0.1	7.3	< 0.1
		Herbivore (short grass)	185.23	0.9	109.29	0.6	65.78	0.3	38.8	0.2
		Herbivore (long grass)	113.10	0.6	66.73	0.3	36.93	0.2	21.8	0.1
		Herbivore (broadleaf plants)	171.38	0.9	101.11	0.5	56.65	0.3	33.4	0.2
Large-Sized Mammal (1 kg)										
Acute LD50 / 10	221.00	Insectivore	44.74	0.2	26.39	0.1	30.89	0.1	18.2	< 0.1
		Granivore (grain and seeds)	6.92	< 0.1	4.08	< 0.1	3.30	< 0.1	1.9	< 0.1
		Frugivore (fruit)	13.85	< 0.1	8.17	< 0.1	6.60	< 0.1	3.9	< 0.1
		Herbivore (short grass)	98.97	0.4	58.40	0.3	35.15	0.2	20.7	< 0.1
		Herbivore (long grass)	60.43	0.3	35.65	0.2	19.73	< 0.1	11.6	< 0.1
		Herbivore (broadleaf plants)	91.57	0.4	54.03	0.2	30.27	0.1	17.9	< 0.1
Reproduction NOEL / 1	19.80	Insectivore	44.74	**2.3**	26.39	**1.3**	30.89	**1.6**	18.2	0.9
		Granivore (grain and seeds)	6.92	0.3	4.08	0.2	3.30	0.2	1.9	< 0.1
		Frugivore (fruit)	13.85	0.7	8.17	0.4	6.60	0.3	3.9	0.2
		Herbivore (short grass)	98.97	**5.0**	58.40	**2.9**	35.15	**1.8**	20.7	**1.0**
		Herbivore (long grass)	60.43	**3.1**	35.65	**1.8**	19.73	1.0	11.6	0.6
		Herbivore (broadleaf plants)	91.57	**4.6**	54.03	**2.7**	30.27	**1.5**	17.9	0.9
Reproduction LOAEL / 1	198.00	Insectivore	44.74	0.2	26.39	0.1	30.89	0.2	18.2	< 0.1
		Granivore (grain and seeds)	6.92	< 0.1	4.08	< 0.1	3.30	< 0.1	1.9	< 0.1
		Frugivore (fruit)	13.85	< 0.1	8.17	< 0.1	6.60	< 0.1	3.9	< 0.1
		Herbivore (short grass)	98.97	0.5	58.40	0.3	35.15	0.2	20.7	0.1
		Herbivore (long grass)	60.43	0.3	35.65	0.2	19.73	< 0.1	11.6	< 0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		Herbivore (broadleaf plants)	91.57	0.5	54.03	0.3	30.27	0.2	17.9	< 0.1

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 19 Maximum and Mean Residues of Ethephon from the Lowbush Blueberry and Tomato (Groundboom) Scenario

Food Item	Fresh/dry weight ratios	Maximum residue concentration		Mean residue concentration	
		Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg	Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg
Ethephon on lowbush blueberry and tomato: 1 × 1536 g a.i./ha. Ground Boom Sprayer, Medium - assuming a foliar dissipation of 5.2 days					
Short range grass	3.3	328.7 / 19.7	1084.7 / 65.1	116.7 / 7	385.2 / 23.1
Long grass	4.4	150.5 / 9	662.3 / 39.7	49.2 / 2.9	216.3 / 13
Broadleaf plants	5.4	185.9 / 11.2	1003.6 / 60.2	61.4 / 3.7	331.8 / 19.9
Insects	3.8	129 / 7.7	490.3 / 29.4	89.1 / 5.3	338.5 / 20.3
Grain and seeds	3.8	20 / 1.2	75.9 / 4.6	9.5 / 0.6	36.2 / 2.2
Fruit	7.6	20 / 1.2	151.8 / 9.1	9.5 / 0.6	72.4 / 4.3

Table 20 Screening Level Risk Assessment of Birds and Mammals Exposed to Ethephon in the Lowbush Blueberry and Tomato (Groundboom) Scenario

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (6% drift)
Birds					
Small Bird (0.02 kg)					
Acute	91.2	Insectivore	125	**1.4**	0.1
Reproduction	29	Insectivore	125	**4.3**	0.3
Medium-Sized Bird (0.1 kg)					
Acute	91.2	Insectivore	97.6	**1.1**	0.1
Reproduction	29	Insectivore	97.6	**3.4**	0.2
Large-Sized Bird (1 kg)					
Acute	91.2	Herbivore (short grass)	63.0	0.7	0.04
Reproduction	29	Herbivore (short grass)	63.0	**2.2**	0.1
Mammals					
Small Mammal (0.015 kg)					

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (6% drift)
Acute	221	Insectivore	71.9	0.3	0.02
Reproduction	19.8	Insectivore	71.9	**3.6**	0.2
Medium-Sized Mammal (0.035 kg)					
Acute	221	Herbivore (short grass)	139	0.6	0.04
Reproduction	19.8	Herbivore (short grass)	139	**7.0**	0.4
Large-Sized Mammal (1 kg)					
Acute	221	Herbivore (short grass)	74.5	0.3	0.02
Reproduction	19.8	Herbivore (short grass)	74.5	**3.8**	0.2

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 21 Further Characterization of the Risk of Ethephon Technical to Wild Birds and Mammals in Lowbush Blueberry and Tomato (Groundboom) Scenario

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (6% drift)		On-field		Off-field (6% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Acute LD50 / 10	91.20	Insectivore	125.0	**1.4**	7.5	< 0.1	86.3	0.9	5.2	< 0.1
		Granivore (grain and seeds)	19.3	0.2	1.2	< 0.1	9.2	0.1	0.6	< 0.1
		Frugivore (fruit)	38.7	0.4	2.3	< 0.1	18.5	0.2	1.1	< 0.1
Reproduction NOEL / 1	29.00	Insectivore	125.0	**4.3**	7.5	0.3	86.3	**3.0**	5.2	0.2
		Granivore (grain and seeds)	19.3	0.7	1.2	< 0.1	9.2	0.3	0.6	< 0.1
		Frugivore (fruit)	38.7	**1.3**	2.3	< 0.1	18.5	0.6	1.1	< 0.1
Reproduction LOAEL / 1	87.00	Insectivore	125.0	**1.4**	7.5	< 0.1	86.3	1.0	5.2	< 0.1
		Granivore (grain and seeds)	19.3	0.2	1.2	< 0.1	9.2	0.1	0.6	< 0.1
		Frugivore (fruit)	38.7	0.4	2.3	< 0.1	18.5	0.2	1.1	< 0.1
Medium-Sized Bird (0.1 kg)										
Acute LD50 / 10	91.20	Insectivore	97.6	**1.1**	5.9	< 0.1	67.4	0.7	4.0	< 0.1
		Granivore (grain and seeds)	15.1	0.2	0.9	< 0.1	7.2	< 0.1	0.4	< 0.1
		Frugivore (fruit)	30.2	0.3	1.8	< 0.1	14.4	0.2	0.9	< 0.1
Reproduction NOEL / 1	29.00	Insectivore	97.6	**3.4**	5.9	0.2	67.4	**2.3**	4.0	0.1
		Granivore (grain and seeds)	15.1	0.5	0.9	< 0.1	7.2	0.2	0.4	< 0.1
		Frugivore (fruit)	30.2	**1.0**	1.8	< 0.1	14.4	0.5	0.9	< 0.1
Reproduction LOAEL / 1	87.00	Insectivore	97.6	**1.1**	5.9	< 0.1	67.4	0.8	4.0	< 0.1
		Granivore (grain and seeds)	15.1	0.2	0.9	< 0.1	7.2	< 0.1	0.4	< 0.1
		Frugivore (fruit)	30.2	0.3	1.8	< 0.1	14.4	0.2	0.9	< 0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (6% drift)		On-field		Off-field (6% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Large-Sized Bird (1 kg)										
Acute LD50 / 10	91.20	Insectivore	28.5	0.3	1.7	< 0.1	19.7	0.2	1.2	< 0.1
		Granivore (grain and seeds)	4.4	< 0.1	0.3	< 0.1	2.1	< 0.1	0.1	< 0.1
		Frugivore (fruit)	8.8	< 0.1	0.5	< 0.1	4.2	< 0.1	0.3	< 0.1
		Herbivore (short grass)	63.0	0.7	3.8	< 0.1	22.4	0.2	1.3	< 0.1
		Herbivore (long grass)	38.5	0.4	2.3	< 0.1	12.6	0.1	0.8	< 0.1
		Herbivore (broadleaf plants)	58.3	0.6	3.5	< 0.1	19.3	0.2	1.2	< 0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (6% drift)		On-field		Off-field (6% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction NOEL / 1	29.00	Insectivore	28.5	1.0	1.7	< 0.1	19.7	0.7	1.2	< 0.1
		Granivore (grain and seeds)	4.4	0.2	0.3	< 0.1	2.1	< 0.1	0.1	< 0.1
		Frugivore (fruit)	8.8	0.3	0.5	< 0.1	4.2	0.1	0.3	< 0.1
		Herbivore (short grass)	63.0	**2.2**	3.8	0.1	22.4	0.8	1.3	< 0.1
		Herbivore (long grass)	38.5	**1.3**	2.3	< 0.1	12.6	0.4	0.8	< 0.1
		Herbivore (broadleaf plants)	58.3	**2.0**	3.5	0.1	19.3	0.7	1.2	< 0.1
Reproduction LOAEL / 1	87.00	Insectivore	28.5	0.3	1.7	< 0.1	19.7	0.2	1.2	< 0.1
		Granivore (grain and seeds)	4.4	< 0.1	0.3	< 0.1	2.1	< 0.1	0.1	< 0.1
		Frugivore (fruit)	8.8	0.1	0.5	< 0.1	4.2	< 0.1	0.3	< 0.1
		Herbivore (short grass)	63.0	0.7	3.8	< 0.1	22.4	0.3	1.3	< 0.1
		Herbivore (long grass)	38.5	0.4	2.3	< 0.1	12.6	0.1	0.8	< 0.1
		Herbivore (broadleaf plants)	58.3	0.7	3.5	< 0.1	19.3	0.2	1.2	< 0.1
Small Mammal (0.015 kg)										
Acute LD50 / 10	221.00	Insectivore	71.9	0.3	4.3	< 0.1	49.7	0.2	3.0	< 0.1
		Granivore (grain	11.1	< 0.1	0.7	< 0.1	5.3	< 0.1	0.3	< 0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (6% drift)		On-field		Off-field (6% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		and seeds)								
		Frugivore (fruit)	22.3	0.1	1.3	< 0.1	10.6	< 0.1	0.6	< 0.1
Reproduction NOEL / 1	19.80	Insectivore	71.9	**3.6**	4.3	0.2	49.7	**2.5**	3.0	0.2
		Granivore (grain and seeds)	11.1	0.6	0.7	< 0.1	5.3	0.3	0.3	< 0.1
		Frugivore (fruit)	22.3	**1.1**	1.3	< 0.1	10.6	0.5	0.6	< 0.1
Reproduction LOAEL / 1	198.00	Insectivore	71.9	0.4	4.3	< 0.1	49.7	0.3	3.0	< 0.1
		Granivore (grain and seeds)	11.1	< 0.1	0.7	< 0.1	5.3	< 0.1	0.3	< 0.1
		Frugivore (fruit)	22.26	0.1	1.34	< 0.1	10.62	< 0.1	0.64	< 0.1
Medium-Sized Mammal (0.035 kg)										
Acute LD50 / 10	221.00	Insectivore	63.0	0.3	3.8	< 0.1	43.5	0.2	2.6	< 0.1
		Granivore (grain and seeds)	9.8	< 0.1	0.6	< 0.1	4.7	< 0.1	0.3	< 0.1
		Frugivore (fruit)	19.5	< 0.1	1.2	< 0.1	9.3	< 0.1	0.6	< 0.1
		Herbivore (short grass)	139.5	0.6	8.4	< 0.1	49.5	0.2	3.0	< 0.1
		Herbivore (long grass)	85.2	0.4	5.1	< 0.1	27.8	0.1	1.7	< 0.1
		Herbivore (forage crops)	129.0	0.6	7.7	< 0.1	42.7	0.2	2.6	< 0.1
Reproduction NOEL / 1	19.80	Insectivore	63.0	**3.2**	3.8	0.2	43.5	**2.2**	2.6	0.1
		Granivore (grain and seeds)	9.8	0.5	0.6	< 0.1	4.7	0.2	0.3	< 0.1
		Frugivore (fruit)	19.5	1.0	1.2	< 0.1	9.3	0.5	0.6	< 0.1
		Herbivore (short grass)	139.5	**7.0**	8.4	0.4	49.5	**2.5**	3.0	0.2
		Herbivore (long grass)	85.2	**4.3**	5.1	0.3	27.8	**1.4**	1.7	< 0.1
		Herbivore (broadleaf plants)	129.0	**6.5**	7.7	0.4	42.7	**2.2**	2.6	0.1
Reproduction LOAEL / 1	198.00	Insectivore	63.0	0.3	3.8	< 0.1	43.5	0.2	2.6	< 0.1
		Granivore (grain and seeds)	9.8	< 0.1	0.6	< 0.1	4.7	< 0.1	0.3	< 0.1
		Frugivore (fruit)	19.5	< 0.1	1.2	< 0.1	9.3	< 0.1	0.6	< 0.1
		Herbivore (short grass)	139.5	0.7	8.4	< 0.1	49.5	0.3	3.0	< 0.1
		Herbivore (long grass)	85.2	0.4	5.1	< 0.1	27.8	0.1	1.7	< 0.1
		Herbivore (broadleaf plants)	129.0	0.7	7.7	< 0.1	42.7	0.2	2.6	< 0.1
Large-Sized Mammal (1 kg)										

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (6% drift)		On-field		Off-field (6% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Acute LD50 / 10	221.00	Insectivore	33.7	0.2	2.0	< 0.1	23.3	0.1	1.4	< 0.1
		Granivore (grain and seeds)	5.2	< 0.1	0.3	< 0.1	2.5	< 0.1	0.1	< 0.1
		Frugivore (fruit)	10.4	< 0.1	0.6	< 0.1	5.0	< 0.1	0.3	< 0.1
		Herbivore (short grass)	74.5	0.3	4.5	< 0.1	26.5	0.1	1.6	< 0.1
		Herbivore (long grass)	45.5	0.2	2.7	< 0.1	14.9	< 0.1	0.9	< 0.1
		Herbivore (broadleaf plants)	68.9	0.3	4.1	< 0.1	22.8	0.1	1.4	< 0.1
Reproduction NOEL / 1	19.80	Insectivore	33.7	**1.7**	2.0	0.1	23.3	**1.2**	1.4	< 0.1
		Granivore (grain and seeds)	5.2	0.3	0.3	< 0.1	2.5	0.1	0.1	< 0.1
		Frugivore (fruit)	10.4	0.5	0.6	< 0.1	5.0	0.3	0.3	< 0.1
		Herbivore (short grass)	74.5	**3.8**	4.5	0.2	26.5	**1.3**	1.6	< 0.1
		Herbivore (long grass)	45.5	**2.3**	2.7	0.1	14.9	0.8	0.9	< 0.1
		Herbivore (broadleaf plants)	68.9	**3.5**	4.1	0.2	22.8	**1.2**	1.4	< 0.1

Toxicity Value / Uncertainty Factor (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (6% drift)		On-field		Off-field (6% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction LOAEL / 1	198.00	Insectivore	33.7	0.2	2.0	< 0.1	23.3	0.1	1.4	< 0.1
		Granivore (grain and seeds)	5.2	< 0.1	0.3	< 0.1	2.5	< 0.1	0.1	< 0.1
		Frugivore (fruit)	10.4	< 0.1	0.6	< 0.1	5.0	< 0.1	0.3	< 0.1
		Herbivore (short grass)	74.5	0.4	4.5	< 0.1	26.5	0.1	1.6	< 0.1
		Herbivore (long grass)	45.5	0.2	2.7	< 0.1	14.9	< 0.1	0.9	< 0.1
		Herbivore (broadleaf plants)	68.9	0.3	4.1	< 0.1	22.8	0.1	1.4	< 0.1

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 22 Maximum and Mean Residues of Ethephon from the Lowbush Blueberry and Tomato (Aerial) Scenario

Food Item	Fresh/dry weight ratios	Maximum residue concentration		Mean residue concentration	
		Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg	Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg
Ethephon on lowbush blueberry and tomato (aerial): 1 × 1536 g a.i./ha. Aerial - Agricultural Crops Medium - assuming a foliar dissipation of 5.2 days					
Short range grass	3.3	328.7 / 75.6	1084.7 / 249.5	116.7 / 26.8	385.2 / 88.6
Long grass	4.4	150.5 / 34.6	662.3 / 152.3	49.2 / 11.3	216.3 / 49.7
Broadleaf plants	5.4	185.9 / 42.7	1003.6 / 230.8	61.4 / 14.1	331.8 / 76.3
Insects	3.8	129 / 29.7	490.3 / 112.8	89.1 / 20.5	338.5 / 77.9
Grain and seeds	3.8	20 / 4.6	75.9 / 17.5	9.5 / 2.2	36.2 / 8.3

Table 23 Screening Level Risk Assessment of Birds and Mammals Exposed to Ethephon in the Lowbush Blueberry and Tomato (Aerial) Scenario

Animal/Endpoint	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (23% drift)
Birds					
Small Bird (0.02 kg)					
Acute	91.2	Insectivore	125	**1.4**	0.3
Reproduction	29	Insectivore	125	**4.3**	1.0
Medium-Sized Bird (0.1 kg)					
Acute	91.2	Insectivore	97.6	**1.1**	0.2
Reproduction	29	Insectivore	97.6	**3.4**	0.8
Large-Sized Bird (1 kg)					
Acute	91.2	Herbivore (short grass)	63.0	0.7	0.2
Reproduction	29	Herbivore (short grass)	63.0	**2.2**	0.5
Mammals					
Small Mammal (0.015 kg)					
Acute	221	Insectivore	71.9	0.3	0.1
Reproduction	19.8	Insectivore	71.9	**3.6**	0.8
Medium-Sized Mammal (0.035 kg)					
Acute	221	Herbivore (short grass)	139.5	0.6	0.1
Reproduction	19.8	Herbivore (short grass)	139.5	**7.0**	**1.6**
Large-Sized Mammal (1 kg)					
Acute	221	Herbivore (short grass)	74.5	0.3	0.1
Reproduction	19.8	Herbivore (short grass)	74.5	**3.8**	0.9

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 24 Further Characterization of the Risk of Ethephon Technical to Wild Birds and Mammals in Lowbush Blueberry and Tomato (Aerial) Scenario

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (23% drift)		On-field		Off-field (23% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Acute LD50 / 10	91.2	Insectivore	125.0	**1.4**	28.8	0.3	86.3	0.9	19.9	0.2
		Granivore (grain and seeds)	19.3	0.2	4.5	< 0.1	9.2	0.1	2.1	< 0.1
		Frugivore (fruit)	38.7	0.4	8.9	< 0.1	18.5	0.2	4.2	< 0.1
Reproduction NOEL / 1	29.0	Insectivore	125.0	**4.3**	28.8	1.0	86.3	**3.0**	19.9	0.7
		Granivore (grain and seeds)	19.3	0.7	4.5	0.2	9.2	0.3	2.1	< 0.1
		Frugivore (fruit)	38.7	**1.3**	8.9	0.3	18.5	0.6	4.2	0.1
Reproduction LOAEL / 1	87.0	Insectivore	125.0	**1.4**	28.8	0.3	86.3	1.0	19.9	0.2
		Granivore (grain and seeds)	19.3	0.2	4.5	< 0.1	9.2	0.1	2.1	< 0.1
		Frugivore (fruit)	38.7	0.4	8.9	0.1	18.5	0.2	4.2	< 0.1
Medium-Sized Bird (0.1 kg)										
Acute LD50 / 10	91.2	Insectivore	97.6	**1.1**	22.4	0.2	67.4	0.7	15.5	0.2
		Granivore (grain and seeds)	15.1	0.2	3.5	< 0.1	7.2	< 0.1	1.7	< 0.1
		Frugivore (fruit)	30.2	0.3	6.9	< 0.1	14.4	0.2	3.3	< 0.1
Reproduction NOEL / 1	29.0	Insectivore	97.6	**3.4**	22.4	0.8	67.4	**2.3**	15.5	0.5
		Granivore (grain and seeds)	15.1	0.5	3.5	0.1	7.2	0.2	1.7	< 0.1
		Frugivore (fruit)	30.2	**1.0**	6.9	0.2	14.4	0.5	3.3	0.1
Reproduction LOAEL / 1	87.0	Insectivore	97.6	**1.1**	22.4	0.3	67.4	0.8	15.5	0.2
		Granivore (grain and seeds)	15.1	0.2	3.5	< 0.1	7.2	< 0.1	1.7	< 0.1
		Frugivore (fruit)	30.2	0.3	6.9	< 0.1	14.4	0.2	3.3	< 0.1
Large-Sized Bird (1 kg)										
Acute LD50 / 10	91.2	Insectivore	28.5	0.3	6.6	< 0.1	19.7	0.2	4.5	< 0.1
		Granivore (grain and seeds)	4.4	< 0.1	1.0	< 0.1	2.1	< 0.1	0.5	< 0.1
		Frugivore (fruit)	8.8	< 0.1	2.0	< 0.1	4.2	< 0.1	1.0	< 0.1
		Herbivore (short grass)	63.0	0.7	14.5	0.2	22.4	0.2	5.1	< 0.1
		Herbivore (long grass)	38.5	0.4	8.9	< 0.1	12.6	0.1	2.9	< 0.1
		Herbivore (broadleaf plants)	58.3	0.6	13.4	0.1	19.3	0.2	4.4	< 0.1

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (23% drift)		On-field		Off-field (23% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction NOEL / 1	29.0	Insectivore	28.5	1.0	6.6	0.2	19.7	0.7	4.5	0.2
		Granivore (grain and seeds)	4.4	0.2	1.0	< 0.1	2.1	< 0.1	0.5	< 0.1
		Frugivore (fruit)	8.8	0.3	2.0	< 0.1	4.2	0.1	1.0	< 0.1
		Herbivore (short grass)	63.0	**2.2**	14.5	0.5	22.4	0.8	5.1	0.2
		Herbivore (long grass)	38.5	**1.3**	8.9	0.3	12.6	0.4	2.9	< 0.1
		Herbivore (broadleaf plants)	58.3	**2.0**	13.4	0.5	19.3	0.7	4.4	0.2
Reproduction LOAEL / 1	87.0	Insectivore	28.5	0.3	6.6	< 0.1	19.7	0.2	4.5	< 0.1
		Granivore (grain and seeds)	4.4	< 0.1	1.0	< 0.1	2.1	< 0.1	0.5	< 0.1
		Frugivore (fruit)	8.8	0.1	2.0	< 0.1	4.2	< 0.1	1.0	< 0.1
		Herbivore (short grass)	63.0	0.7	14.5	0.2	22.4	0.3	5.1	< 0.1
		Herbivore (long grass)	38.5	0.4	8.9	0.1	12.6	0.1	2.9	< 0.1
		Herbivore (broadleaf plants)	58.3	0.7	13.4	0.2	19.3	0.2	4.4	< 0.1
Small Mammal (0.015 kg)										
Acute LD50 / 10	221.0	Insectivore	71.9	0.3	16.5	< 0.1	49.7	0.2	11.4	< 0.1
		Granivore (grain and seeds)	11.1	< 0.1	2.6	< 0.1	5.3	< 0.1	1.2	< 0.1
		Frugivore (fruit)	22.3	0.1	5.1	< 0.1	10.6	< 0.1	2.4	< 0.1
Reproduction NOEL / 1	19.8	Insectivore	71.9	**3.6**	16.5	0.8	49.7	**2.5**	11.4	0.6
		Granivore (grain and seeds)	11.1	0.6	2.6	0.1	5.3	0.3	1.2	< 0.1
		Frugivore (fruit)	22.3	**1.1**	5.1	0.3	10.6	0.5	2.4	0.1
Reproduction LOAEL / 1	198.0	Insectivore	71.9	0.4	16.5	< 0.1	49.7	0.3	11.4	< 0.1
		Granivore (grain and seeds)	11.1	< 0.1	2.6	< 0.1	5.3	< 0.1	1.2	< 0.1
		Frugivore (fruit)	22.3	0.1	5.1	< 0.1	10.6	< 0.1	2.4	< 0.1
Medium-Sized Mammal (0.035 kg)										
Acute LD50 / 10	221.0	Insectivore	63.0	0.3	14.5	< 0.1	43.5	0.2	10.0	< 0.1
		Granivore (grain and seeds)	9.8	< 0.1	2.2	< 0.1	4.7	< 0.1	1.1	< 0.1
		Frugivore (fruit)	19.5	< 0.1	4.5	< 0.1	9.3	< 0.1	2.1	< 0.1
		Herbivore (short grass)	139.5	0.6	32.1	0.1	49.5	0.2	11.4	< 0.1
		Herbivore (long grass)	85.2	0.4	19.6	< 0.1	27.8	0.1	6.4	< 0.1
		Herbivore (forage crops)	129.0	0.6	29.7	0.1	42.7	0.2	9.8	< 0.1

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (23% drift)		On-field		Off-field (23% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction NOEL / 1	19.8	Insectivore	63.0	**3.2**	14.5	0.7	43.5	**2.2**	10.0	0.5
		Granivore (grain and seeds)	9.8	0.5	2.2	0.1	4.7	0.2	1.1	< 0.1
		Frugivore (fruit)	19.5	1.0	4.5	0.2	9.3	0.5	2.1	0.1
		Herbivore (short grass)	139.5	**7.0**	32.1	**1.6**	49.5	**2.5**	11.4	0.6
		Herbivore (long grass)	85.2	**4.3**	19.6	1.0	27.8	**1.4**	6.4	0.3
		Herbivore (broadleaf plants)	129.0	**6.5**	29.7	**1.5**	42.7	**2.2**	9.8	0.5
Reproduction LOAEL / 1	198.0	Insectivore	63.0	0.3	14.5	< 0.1	43.5	0.2	10.0	< 0.1
		Granivore (grain and seeds)	9.8	< 0.1	2.2	< 0.1	4.7	< 0.1	1.1	< 0.1
		Frugivore (fruit)	19.5	< 0.1	4.5	< 0.1	9.3	< 0.1	2.1	< 0.1
		Herbivore (short grass)	139.5	0.7	32.1	0.2	49.5	0.3	11.4	< 0.1
		Herbivore (long grass)	85.2	0.4	19.6	< 0.1	27.8	0.1	6.4	< 0.1
		Herbivore (broadleaf plants)	129.0	0.7	29.7	0.1	42.7	0.2	9.8	< 0.1
Large-Sized Mammal (1 kg)										
Acute LD50 / 10	221.0	Insectivore	33.7	0.2	7.7	< 0.1	23.3	0.1	5.3	< 0.1
		Granivore (grain and seeds)	5.2	< 0.1	1.2	< 0.1	2.5	< 0.1	0.6	< 0.1
		Frugivore (fruit)	10.4	< 0.1	2.4	< 0.1	5.0	< 0.1	1.1	< 0.1
		Herbivore (short grass)	74.5	0.3	17.1	< 0.1	26.5	0.1	6.1	< 0.1
		Herbivore (long grass)	45.5	0.2	10.5	< 0.1	14.9	< 0.1	3.4	< 0.1
		Herbivore (broadleaf plants)	68.9	0.3	15.9	< 0.1	22.8	0.1	5.2	< 0.1
Reproduction NOEL / 1	19.8	Insectivore	33.7	**1.7**	7.7	0.4	23.3	**1.2**	5.3	0.3
		Granivore (grain and seeds)	5.2	0.3	1.2	< 0.1	2.5	0.1	0.6	< 0.1
		Frugivore (fruit)	10.4	0.5	2.4	0.1	5.0	0.3	1.1	< 0.1
		Herbivore (short grass)	74.5	**3.8**	17.1	0.9	26.5	**1.3**	6.1	0.3
		Herbivore (long grass)	45.5	**2.3**	10.5	0.5	14.9	0.8	3.4	0.2
		Herbivore (broadleaf plants)	68.9	**3.5**	15.9	0.8	22.8	**1.2**	5.2	0.3
Reproduction LOAEL / 1	198.0	Insectivore	33.7	0.2	7.7	< 0.1	23.3	0.1	5.3	< 0.1
		Granivore (grain	5.2	< 0.1	1.2	< 0.1	2.5	< 0.1	0.6	< 0.1

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (23% drift)		On-field		Off-field (23% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		and seeds)								
		Frugivore (fruit)	10.4	< 0.1	2.4	< 0.1	5.0	< 0.1	1.1	< 0.1
		Herbivore (short grass)	74.5	0.4	17.1	< 0.1	26.5	0.1	6.1	< 0.1
		Herbivore (long grass)	45.5	0.2	10.5	< 0.1	14.9	< 0.1	3.4	< 0.1
		Herbivore (broadleaf plants)	68.9	0.3	15.9	< 0.1	22.8	0.1	5.2	< 0.1

Table 25 Maximum and Mean Residues of Ethephon from the Winter Wheat (Aerial) Scenario

Food Item	Fresh/dry weight ratios	Maximum residue concentration		Mean residue concentration	
		Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg	Concentration fresh weight (On-field / Off-field) mg a.i./kg	Concentration dry weight (On-field / Off-field) mg a.i./kg
Ethephon on Winter Wheat: 1 × 600 g a.i./ha. Aerial - Agricultural Crops Coarse - assuming a foliar dissipation of 5.2 days					
Short range grass	3.3	128.4 / 21.8	423.7 / 72	45.6 / 7.8	150.5 / 25.6
Long grass	4.4	58.8 / 10	258.7 / 44	19.2 / 3.3	84.5 / 14.4
Broadleaf plants	5.4	72.6 / 12.3	392 / 66.6	24 / 4.1	129.6 / 22
Insects	3.8	50.4 / 8.6	191.5 / 32.6	34.8 / 5.9	132.2 / 22.5
Grain and seeds	3.8	7.8 / 1.3	29.6 / 5	3.7 / 0.6	14.1 / 2.4
Fruit	7.6	7.8 / 1.3	59.3 / 10.1	3.7 / 0.6	28.3 / 4.8

Table 26 Screening Level Risk Assessment of Birds and Mammals Exposed to Ethephon in the Winter Wheat (Aerial) Scenario

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (17% drift)
Birds					
Small Bird (0.02 kg)					
Acute	91.2	Insectivore	48.8	0.5	0.1
Reproduction	29	Insectivore	48.8	**1.7**	0.3
Medium-Sized Bird (0.1 kg)					
Acute	91.2	Insectivore	38.1	0.4	0.1
Reproduction	29	Insectivore	38.1	**1.3**	0.2
Large-Sized Bird (1 kg)					
Acute	91.2	Herbivore (short grass)	24.6	0.3	0.05

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE (mg a.i./kg bw)	On-field RQ	Off-field RQ (17% drift)
Reproduction	29	Herbivore (short grass)	24.6	0.8	0.1
Mammals					
Small Mammal (0.015 kg)					
Acute	221	Insectivore	28.1	0.1	0.02
Reproduction	19.8	Insectivore	28.1	**1.4**	0.2
Medium-Sized Mammal (0.035 kg)					
Acute	221	Herbivore (short grass)	54.5	0.2	0.04
Reproduction	19.8	Herbivore (short grass)	54.5	**2.8**	0.5
Large Sized Mammal (1 kg)					
Acute	221	Herbivore (short grass)	29.1	0.1	0.02
Reproduction	19.8	Herbivore (short grass)	29.1	**1.5**	0.2

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 27 Further Characterization of the Risk of Ethephon Technical to Wild Birds and Mammals in Winter Wheat (Aerial) Scenario

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (17% drift)		On-field		Off-field (17% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Acute LD50 / 10	91.2	Insectivore	48.8	0.5	8.3	< 0.1	33.7	0.4	5.7	< 0.1
		Granivore (grain and seeds)	7.6	< 0.1	1.3	< 0.1	3.6	< 0.1	0.6	< 0.1
		Frugivore (fruit)	15.1	0.2	2.6	< 0.1	7.2	< 0.1	1.2	< 0.1
Reproduction NOEL / 1	29.0	Insectivore	48.8	**1.7**	8.3	0.3	33.7	**1.2**	5.7	0.2
		Granivore (grain and seeds)	7.6	0.3	1.3	< 0.1	3.6	0.1	0.6	< 0.1
		Frugivore (fruit)	15.1	0.5	2.6	< 0.1	7.2	0.2	1.2	< 0.1
Reproduction LOAEL / 1	87.0	Insectivore	48.8	0.6	8.3	< 0.1	33.7	0.4	5.7	< 0.1
		Granivore (grain and seeds)	7.6	< 0.1	1.3	< 0.1	3.6	< 0.1	0.6	< 0.1
		Frugivore (fruit)	15.1	0.2	2.6	< 0.1	7.2	< 0.1	1.2	< 0.1
Medium-Sized Bird (0.1 kg)										
Acute LD50 / 10	91.2	Insectivore	38.1	0.4	6.5	< 0.1	26.3	0.3	4.5	< 0.1
		Granivore (grain and seeds)	5.9	< 0.1	1.0	< 0.1	2.8	< 0.1	0.5	< 0.1
		Frugivore (fruit)	11.8	0.1	2.0	< 0.1	5.6	< 0.1	1.0	< 0.1
Reproduction NOEL / 1	29.0	Insectivore	38.1	**1.3**	6.5	0.2	26.3	0.9	4.5	0.2
		Granivore (grain and seeds)	5.9	0.2	1.0	< 0.1	2.8	< 0.1	0.5	< 0.1
		Frugivore (fruit)	11.8	0.4	2.0	< 0.1	5.6	0.2	1.0	< 0.1

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (17% drift)		On-field		Off-field (17% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction LOAEL / 1	87.0	Insectivore	38.1	0.4	6.5	< 0.1	26.3	0.3	4.5	< 0.1
		Granivore (grain and seeds)	5.9	< 0.1	1.0	< 0.1	2.8	< 0.1	0.5	< 0.1
		Frugivore (fruit)	11.8	0.1	2.0	< 0.1	5.6	< 0.1	1.0	< 0.1
Large-Sized Bird (1 kg)										
Acute LD50 / 10	91.2	Insectivore	11.1	0.1	1.9	< 0.1	7.7	< 0.1	1.3	< 0.1
		Granivore (grain and seeds)	1.7	< 0.1	0.3	< 0.1	0.8	< 0.1	0.1	< 0.1
		Frugivore (fruit)	3.4	< 0.1	0.6	< 0.1	1.6	< 0.1	0.3	< 0.1
		Herbivore (short grass)	24.6	0.3	4.2	< 0.1	8.7	< 0.1	1.5	< 0.1
		Herbivore (long grass)	15.0	0.2	2.6	< 0.1	4.9	< 0.1	0.8	< 0.1
		Herbivore (broadleaf plants)	22.8	0.2	3.9	< 0.1	7.5	< 0.1	1.3	< 0.1

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (17% drift)		On-field		Off-field (17% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction NOEL / 1	29.0	Insectivore	11.1	0.4	1.9	< 0.1	7.7	0.3	1.3	< 0.1
		Granivore (grain and seeds)	1.7	< 0.1	0.3	< 0.1	0.8	< 0.1	0.1	< 0.1
		Frugivore (fruit)	3.4	0.1	0.6	< 0.1	1.6	< 0.1	0.3	< 0.1
		Herbivore (short grass)	24.6	0.8	4.2	0.1	8.7	0.3	1.5	< 0.1
		Herbivore (long grass)	15.0	0.5	2.6	< 0.1	4.9	0.2	0.8	< 0.1
		Herbivore (broadleaf plants)	22.8	0.8	3.9	0.1	7.5	0.3	1.3	< 0.1
Reproduction LOAEL / 1	87.0	Insectivore	11.1	0.1	1.9	< 0.1	7.7	< 0.1	1.3	< 0.1
		Granivore (grain and seeds)	1.7	< 0.1	0.3	< 0.1	0.8	< 0.1	0.1	< 0.1
		Frugivore (fruit)	3.4	< 0.1	0.6	< 0.1	1.6	< 0.1	0.3	< 0.1
		Herbivore (short grass)	24.6	0.3	4.2	< 0.1	8.7	0.1	1.5	< 0.1
		Herbivore (long grass)	15.0	0.2	2.6	< 0.1	4.9	< 0.1	0.8	< 0.1
		Herbivore (broadleaf	22.8	0.3	3.9	< 0.1	7.5	< 0.1	1.3	< 0.1

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (17% drift)		On-field		Off-field (17% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		plants)								
Small Mammal (0.015 kg)										
Acute LD50 / 10	221.0	Insectivore	28.1	0.1	4.8	< 0.1	19.4	< 0.1	3.3	< 0.1
		Granivore (grain and seeds)	4.3	< 0.1	0.7	< 0.1	2.1	< 0.1	0.4	< 0.1
		Frugivore (fruit)	8.7	< 0.1	1.5	< 0.1	4.1	< 0.1	0.7	< 0.1
Reproduction NOEL / 1	19.8	Insectivore	28.1	**1.4**	4.8	0.2	19.4	1.0	3.3	0.2
		Granivore (grain and seeds)	4.3	0.2	0.7	< 0.1	2.1	0.1	0.4	< 0.1
		Frugivore (fruit)	8.7	0.4	1.5	< 0.1	4.1	0.2	0.7	< 0.1
Reproduction LOAEL / 1	198.0	Insectivore	28.1	0.1	4.8	< 0.1	19.4	< 0.1	3.3	< 0.1
		Granivore (grain and seeds)	4.3	< 0.1	0.7	< 0.1	2.1	< 0.1	0.4	< 0.1
		Frugivore (fruit)	8.7	< 0.1	1.5	< 0.1	4.1	< 0.1	0.7	< 0.1
Medium-Sized Mammal (0.035 kg)										
Acute LD50 / 10	221.0	Insectivore	24.6	0.1	4.2	< 0.1	17.0	< 0.1	2.9	< 0.1
		Granivore (grain and seeds)	3.8	< 0.1	0.6	< 0.1	1.8	< 0.1	0.3	< 0.1
		Frugivore (fruit)	7.6	< 0.1	1.3	< 0.1	3.6	< 0.1	0.6	< 0.1
		Herbivore (short grass)	54.5	0.2	9.3	< 0.1	19.3	< 0.1	3.3	< 0.1
		Herbivore (long grass)	33.3	0.2	5.7	< 0.1	10.9	< 0.1	1.8	< 0.1
		Herbivore (forage crops)	50.4	0.2	8.6	< 0.1	16.7	< 0.1	2.8	< 0.1
Reproduction NOEL / 1	19.8	Insectivore	24.6	**1.2**	4.2	0.2	17.0	0.9	2.9	0.1
		Granivore (grain and seeds)	3.8	0.2	0.6	< 0.1	1.8	< 0.1	0.3	< 0.1
		Frugivore (fruit)	7.6	0.4	1.3	< 0.1	3.6	0.2	0.6	< 0.1
		Herbivore (short grass)	54.5	**2.8**	9.3	0.5	19.3	1.0	3.3	0.2
		Herbivore (long grass)	33.3	**1.7**	5.7	0.3	10.9	0.5	1.8	< 0.1
		Herbivore (broadleaf plants)	50.4	**2.5**	8.6	0.4	16.7	0.8	2.8	0.1
Reproduction LOAEL / 1	198.0	Insectivore	24.6	0.1	4.2	< 0.1	17.0	< 0.1	2.9	< 0.1
		Granivore (grain and seeds)	3.8	< 0.1	0.6	< 0.1	1.8	< 0.1	0.3	< 0.1
		Frugivore (fruit)	7.6	< 0.1	1.3	< 0.1	3.6	< 0.1	0.6	< 0.1
		Herbivore (short grass)	54.5	0.3	9.3	< 0.1	19.3	< 0.1	3.3	< 0.1
		Herbivore (long grass)	33.3	0.2	5.7	< 0.1	10.9	< 0.1	1.8	< 0.1

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (17% drift)		On-field		Off-field (17% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
		Herbivore (broadleaf plants)	50.4	0.3	8.6	< 0.1	16.7	< 0.1	2.8	< 0.1
Large-Sized Mammal (1 kg)										
Acute LD50 / 10	221.0	Insectivore	13.2	< 0.1	2.2	< 0.1	9.1	< 0.1	1.5	< 0.1
		Granivore (grain and seeds)	2.0	< 0.1	0.3	< 0.1	1.0	< 0.1	0.2	< 0.1
		Frugivore (fruit)	4.1	< 0.1	0.7	< 0.1	1.9	< 0.1	0.3	< 0.1
		Herbivore (short grass)	29.1	0.1	4.9	< 0.1	10.3	< 0.1	1.8	< 0.1
		Herbivore (long grass)	17.8	< 0.1	3.0	< 0.1	5.8	< 0.1	1.0	< 0.1
		Herbivore (broadleaf plants)	26.9	0.1	4.6	< 0.1	8.9	< 0.1	1.5	< 0.1
Reproduction NOEL / 1	19.8	Insectivore	13.2	0.7	2.2	0.1	9.1	0.5	1.5	< 0.1
		Granivore (grain and seeds)	2.0	0.1	0.3	< 0.1	1.0	< 0.1	0.2	< 0.1
		Frugivore (fruit)	4.1	0.2	0.7	< 0.1	1.9	< 0.1	0.3	< 0.1
		Herbivore (short grass)	29.1	**1.5**	4.9	0.2	10.3	0.5	1.8	< 0.1
		Herbivore (long grass)	17.8	0.9	3.0	0.2	5.8	0.3	1.0	< 0.1
		Herbivore (broadleaf plants)	26.9	**1.4**	4.6	0.2	8.9	0.4	1.5	< 0.1

Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (17% drift)		On-field		Off-field (17% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Reproduction LOAEL / 1	198.0	Insectivore	13.2	< 0.1	2.2	< 0.1	9.1	< 0.1	1.5	< 0.1
		Granivore (grain and seeds)	2.0	< 0.1	0.3	< 0.1	1.0	< 0.1	0.2	< 0.1
		Frugivore (fruit)	4.1	< 0.1	0.7	< 0.1	1.9	< 0.1	0.3	< 0.1
		Herbivore (short grass)	29.1	0.1	4.9	< 0.1	10.3	< 0.1	1.8	< 0.1
		Herbivore (long grass)	17.8	< 0.1	3.0	< 0.1	5.8	< 0.1	1.0	< 0.1
		Herbivore (broadleaf plants)	26.9	0.1	4.6	< 0.1	8.9	< 0.1	1.5	< 0.1

Shaded cells and **bold** values indicate that the level of concern is exceeded (RQ > 1)

Table 28 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value		Active Ingredient Ethephon Endpoints	Transformation Products 2-HEPA Endpoints
CEPA toxic or CEPA toxic equivalent	Yes		Ethephon can be considered toxic to birds, mammals and terrestrial vascular plants	Not enough information on 2-HEPA
Predominantly anthropogenic	Yes		-	-
Persistence	Soil	Half-life ≥ 182 days	Half-life = 56.8 days	2-HEPA + ethephon DT_{50} = 92.2 days
	Water	Half-life ≥ 182 days	Half-life = 1.97 days in water/sediment whole system	No information on 2-HEPA
	Sediment	Half-life ≥ 365 days	Half-life = Unknown	Anaerobic soil DT_{50} of 2-HEPA = 7.3 days
	Air	Half-life ≥ 2 days	Ethephon Half-life = 10.2 days (PMRA 2715174) can be considered persistent in, but vapour pressure of < 1.0×10^{-3} Pa (25°C) and Henry's Law Constant (1/H) = 1.7×10^{10}) indicate that volatilization from moist soil and water surfaces is not expected.	No information on 2-HEPA
Bioaccumulation	Log $K_{OW} \geq 5$		Log K_{OW} = -1.89 Not expected to bioaccumulate	Log K_{OW} = -1.97 based on KOWWIN v1.68. Not expected to bioaccumulate
	BCF ≥ 5000		3-5	Not available
	BAF ≥ 5000		No data available	Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No	No

[1]All pesticides will be considered CEPA-toxic or CEPA-toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).

[2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in environmental media is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) then the criterion for persistence is considered to be met.

[4]Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K_{OW}).

Appendix VIII Label Amendments for Products Containing Ethephon

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements. Please read each section carefully and make appropriate changes to your product labels.

1) Labels of Technical Products

The following information should appear on the label of technical ethephon:

> The skull and crossbones symbol enclosed in the inverted triangle border accompanied by the signal word "Poison"; the signal word and hazard statement "Danger - Corrosive to Eyes and Skin".

Add the following title "**ENVIRONMENTAL HAZARDS**": before the section entitled **STORAGE** and add the following statement:

- **TOXIC** to non-target terrestrial plants.

Remove the following statement under the "**DISPOSAL AND DECONTAMINATION**"

- Canadian formulators of this technical should dispose of unwanted active and containers in accordance with municipal or provincial regulations. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in the case of a spill, and for clean-up of spills.

and **add** the following statement:

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean-up of spills, contact the manufacturer or the provincial regulatory agency.

2) Labels for Commercial Class Products

<u>Precaution Statements (all commercial end use products)</u>

Add the following statement: "Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

Add to ENVIRONMENTAL HAZARDS:

- **TOXIC** to non-target terrestrial plants, Observe buffer zones specified under DIRECTIONS FOR USE.
- **TOXIC** to birds and mammals.
- To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil or clay.
- Avoid application when heavy rain is forecast.
- Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Personal Protective Equipment

Label statements must be amended (or added) to include the following directions to the appropriate labels, unless the current label mitigation is more restrictive:

A. Open Mixing and Loading (PCP# 30686)
"Wear chemical-resistant coveralls over a long-sleeved shirt and long pants, goggles or faceshield, chemical-resistant gloves, socks, and chemical-resistant footwear during mixing, loading, clean-up and repair. In addition, a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides MUST be worn."

B. Closed Mixing and Loading (PCP# 11580, 18685)
"Workers MUST use a closed mixing and loading system. Wear chemical-resistant coveralls over a long-sleeved shirt and long pants, goggles or faceshield, chemical-resistant gloves, socks, and chemical-resistant footwear during mixing, loading, clean-up and repair."

C. Open Mixing and Loading and Handheld Application to Greenhouse Potted Ornamentals (PCP# 29593)
"Wear chemical-resistant coveralls over a long-sleeved shirt and long pants, goggles or faceshield, chemical-resistant gloves, socks, and chemical-resistant footwear during mixing, loading, application, clean-up and repair. In addition, a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides MUST be worn. DO NOT handle more than 0.33 kg active ingredient per person in a day when using mechanically pressurized handwands."

D. Open Cab Application Equipment (Airblast & Groundboom)

"Wear chemical-resistant coveralls over a long-sleeved shirt and long pants, goggles or faceshield, chemical-resistant gloves, socks, and chemical-resistant footwear. In addition, a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides MUST be worn. When using airblast equipment or if there is overhead exposure, chemical-resistant headgear MUST also be worn. Chemical-resistant headgear includes chemical-resistant Sou'Westers, chemical-resistant rain hat or large brimmed waterproof hat, and hood with sufficient neck protection. DO NOT handle more than 46 kg active ingredient per person in a day when using airblast equipment. DO NOT handle more than 70 kg active ingredient per person in a day when using groundboom equipment."

E. Closed Cab Application Equipment (Airblast & Groundboom)

"Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks, and shoes. Chemical-resistant gloves are not required while inside an enclosed cab. DO NOT handle more than 74 kg active ingredient per person in a day when using groundboom equipment."

F. Aerial Application

"Workers MUST use a closed mixing and loading system. Wear chemical-resistant coveralls over a long-sleeved shirt and long pants, goggles or faceshield, chemical-resistant gloves, socks, and chemical-resistant footwear during mixing, loading, clean-up and repair. DO NOT handle (i.e. during mixing and loading) more than 78 kg active ingredient per person per day. Wear long-sleeved shirt and long pants during application."

Restricted Entry Interval

Table 1 lists the proposed REIs for ethephon. The minimum REI of 48 hours specified in REV2009-06, may be removed and replaced by the REIs listed in Table 1 when the REI is less than 48 hours. When the REI listed in Table 1 is greater than 48 hours it MUST be added to the label.

Table 1 Proposed REIs for Ethephon

Crop	Activity	REI (Days^)
Greenhouse Potted Ornamentals	All Activities	12 hrs
Apples	Hand Fruit Thinning	15
	Hand Harvesting, Hand Pruning, Scouting, Training	8
	All Other Activities	12 hrs
Highbush Blueberries	Hand Set Irrigation	14
	Hand Harvesting	12
	Hand Pruning, Hand Weeding, Scouting, Bird Control, Frost Control	5
	All Other Activities	12 hrs
Lowbush Blueberries	Hand Set Irrigation	14
	Scouting	10

Crop	Activity	REI (Days^)
	All Other Activities	12 hrs
Sour Cherries	All Activities	12 hrs
Sweet Cherries	Hand Fruit Thinning	15
	Hand Harvesting	8
	All Other Activities	12 hrs
Tobacco	Hand Set Irrigation	6
	All Other Activities	12 hrs
Tomatoes	Hand Set Irrigation	12
	Tying/Training	7
	All Other Activities	12 hrs
Winter Wheat, Spring Wheat, Spring Barley	All Activities	12 hrs

* As the PHI for lowbush blueberries, sour cherries, and field tomatoes are greater than the calculated REI for these crops, a REI for hand harvesting on the label is not required.
^ Unless otherwise indicated.

Add to DIRECTIONS FOR USE (all end use products):

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

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

Add to DIRECTIONS FOR USE (all end use products except PCP#29593):

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) coarse classification. Boom height must be 60 cm or less above the crop or ground.

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

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. To reduce drift caused by turbulent wingtip vortices, the 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. Use of low-clearance hooded or shielded sprayers that prevent spray contact with crop, fruit or foliage, and soil drench or soil incorporation **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 terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of application	Crop		Buffer zone (metres) required for the protection of terrestrial habitat
Field sprayer	Lowbush blueberry and field tomato		1
	Tobacco		1
	Winter wheat, spring barley and spring wheat		1
Airblast	Apple, non-bearing type	Early growth stage	15
		Late growth stage	10
	Highbush blueberry	Early growth stage	10
		Late growth stage	5
	Sweet cherry	Early growth stage	5
		Late growth stage	3
	Sour cherry	Early growth stage	3
		Late growth stage	2
Aerial	Lowbush blueberry	Fixed wing	20
		Rotary wing	20
	Winter wheat and spring barley	Fixed wing	15
		Rotary wing	15
	Spring wheat	Fixed wing	15
		Rotary wing	10

* Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.

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.

3) Uses On Apple Fruit

Additional Label Amendments for Ethrel Liquid Plant Growth Regulator (PCP# 11580):

On the Primary Panel, revise the list of uses to read:

> Accelerates tomato ripening, accelerates blueberry coloring and fruit maturity, increases flowering of young apple trees, loosens cherries for easier harvest, promotes colour and reduces curing time of flue cured tobacco, and reduces lodging in spring and winter wheat

Under USE PRECAUTIONS, add "Do not use on apple trees when fruit are present."

Under DIRECTIONS FOR APPLES, revise to read:

> **DIRECTIONS FOR APPLES:**
>
> ETHREL Plant Growth Regulator can be used to increase flower bud development in both spur and nonspur type trees. Thorough uniform spray coverage of leaves is important. A wetting agent may improve spray coverage. Treat when air temperatures are between 16°C and 32°C. However, applications may be made at 10°C under rising temperature conditions.
>
> **TO INCREASE FLOWERING OF YOUNG APPLE TREES:**
>
> Apply a foliar spray of ETHREL Plant Growth Regulator to non-bearing apple trees, 1 to 2 weeks after peak bloom period (determined by fruit-bearing apple trees in the area). On young orchard trees just beginning to initiate a few flowers, delay applications until 3 to 5 weeks after full-bloom to avoid overthinning and misshapen fruit (calyx and pinched). Vegetative growth is reduced during the season of application, promoting flower bud development the following spring. Trees should be large enough to support a crop of apples before being treated. Consult your local Fruit Specialist for recommendations on different varieties.
>
> For spur type trees, mix 2 litres ETHREL Plant Growth Regulator in 1000 litres of water (6 litres in 3000 litres) and apply as a normal dilute spray to the point of runoff. For non-spur type trees, mix 4.25 litres of ETHREL Plant Growth Regulator in 1000 litres of water (12.75 litres in 3000 litres) and apply as a normal dilute spray to the point of runoff. For concentrate sprayers, apply 7 litres ETHREL Plant Growth Regulator per hectare for spur types or 14 litres per hectare for non-spur types, in 500 litres of water. This rate may completely defruit the current crop from trees, particularly when applied earlier than 4 weeks after full bloom.

Under Airblast Application, revise the first bullet to read:

> AIRBLAST APPLICATION:
> For application to non-bearing apple trees, sweet cherries, sour cherries and highbush blueberries.

Under Buffer Zones, remove “apples (to promote early red colouring, apple ripening, and to loosen processing apples for easier harvesting)” from the table.

4) Label Amendment for Florel Plant Growth Regulator (PCP# 29593):

“For use on potted ornamentals only. DO NOT use on cut flowers.”

5) The following label statement must appear on labels requiring a closed mixing and loading system (PCP# 18685, PCP# 11580) containing ethephon formulated as a solution:

“For use with closed mixing and loading systems only.”

References

A. Information Considered in the Chemistry Assessment

A.1 List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2728101	2015, Five batches of technical concentrate material ETHEPHON, DACO: 2.13.2, 2.13.3, 2.13.4
2737121	2015, Validation of [Methodology for the] Determination of Ethephon in Ethephon (AE F016382) Technical Concentrate Material, DACO: 2.13.1
2737122	2015, Determination of Ethephon in Ethephon (AE F016382) Technical Concentrate Material, DACO: 2.13.1
2737123	2015, Determination of [By-Products] in AE F016382 (Ethephon) Technical Concentrate Material, DACO: 2.13.1
2737124	2015, Validation of the [Methodology for the] Determination of [By-Products] in AE F016382 (Ethephon) Technical Concentrate Material, DACO: 2.13.1
2737125	2015, Determination of [Impurities] in Ethephon Technical Concentrate Material, DACO: 2.13.1
2737126	2015, Validation of [Methodology for the] Determination [Impurities] in Ethephon (AE F016382) Technical Concentrate Material, DACO: 2.13.1
2737127	2009, Determination of [Impurity] in Technical Concentrates of AE F016382 (Ethephon), DACO: 2.13.1
2737128	2009, Validation of [Methodology for the] Determination of [Impurity] in Ethephon (AE F016382) Technical Concentrates, DACO: 2.13.1
2737129	2015, Determination of [Impurities] in AE F016382 (Ethephon) Technical Concentrate Material, DACO: 2.13.1
2737130	2015, Validation of [Methodology for the] Determination of [Impurities] in AE F016382 (Ethephon) Technical Concentrate Material, DACO: 2.13.1

B. Information Considered in the Toxicological Assessment

B.1 List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
1161190 & 1583309	Ethephon Base 250 Acute Aerosol Inhalation Toxicity Test in Rats, Bushy Run Research Center, Pennsylvania, USA. Laboratory Report No. 52-580. June 27th, 1989. DACO: 4.2.3. and 4.6.3.

1161191	Ethephon base 250, Acute Peroral Toxicity Study, Bushy Run Research Center, Pennsylvania, USA. Laboratory Report No. 47-49. May 9th, 1989. DACO: 4.2.9.
1161189	Ethephon base 250, Acute Percutaneous Toxicity Study, Bushy Run Research Center, Pennsylvania, USA. Laboratory Report No. 46-122. May 9th, 1989. DACO: 4.2.2.
1583326	Dermal Sensitization Study in Guinea Pigs with Base A-250, Springborn Laboratories, Inc., Ohio, USA. Laboratory Report No. 3147.44, June 20th, 1989. DACO: 4.6.6.
1161192	One-year Oral Toxicity Study in Beagle Dogs with Ethephon, Hazleton Laboratories America, Inc., Virginia, USA. Laboratory Project Identification: HLA Study No. 400-722. May 30th, 1989. DACO: 4.3.2.
1161212	Lifetime Dietary Oncogenicity Study with Ethephon in Albino Mice, Bushy Run Research Center, Pennsylvania, USA. Laboratory Project Number: 51-502. November 14th, 1988. DACO: 4.4.2.
1198849, 1209369, 1209370, 1209371, 1209372, 1209373 & 1209375	104-week Chronic Administration of Ethrel in male and female Rats, pathology report, summary incidence tables, neoplasm summary incidence tables and histopathology incidence tables, Hazleton Laboratories America, Inc., Virginia, USA. Laboratory Project Identification: HLA Study No. 141-263. September 1st, 1983. DACO: 4.4.1.
1161213, 1161214 & 1161215	Lifetime Dietary Combined Chronic Toxicity and Oncogenicity Study with Ethephon in Albino Rats, Bushy Run Research Center, Pennsylvania, USA, Laboratory Project Number: 51-501. May 16th, 1989. DACO: 4.4.4.
1130086	Two-generation Reproduction Study in CD Albino Rats Exposed to Ethephon by Dietary Inclusion, Bushy Run Research Center, Laboratory Project ID: 51-539. May 17th, 1990. DACO: 4.5.1.
1161211	Teratology Study with Ethephon Technical Base 250 in Rats, Hazleton Laboratories America, Inc., Wisconsin, USA. Laboratory Project Identification Number: HLA 6224-125. April 6th 1989. DACO: 4.5.2.
1209377	Ethrel (Ethephon): Teratology Study in Rats, International Research and Development Corporation, Michigan, USA. Laboratory Study Number: 369-042. November 18th, 1980. DACO: 4.5.2.
1161188	Acute Oral Toxicity Study in Rabbits - Ethephon, Hazleton Laboratories America, Inc. Virginia, USA. Laboratory Project Number: 400-630. August 14th, 1980. DACO: 4.2.1.
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1161194	Teratology Study with Ethephon Technical-base 250 in Rabbits, Hazleton Laboratories America, Inc., Wisconsin, USA. Laboratory Project Identification: HLA 6224-158. June 27th, 1990. DACO: 4.5.3.

1209380	Ethrel: DNA Polymerase Deficient Assay, *Escherichia coli*, Pharmakon Laboratories, Pennsylvania, USA. Study Number: PH 305-UC-001-80. May 23rd, 1980. DACO: 4.5.4.
1209382 & 1209384	Ethrel: Eukaryotic Reverse Mutation and Mitotic Gene Conversion, *Saccharomyces cerevisiae*, Pharmakon Laboratories, Pennsylvania, USA. Study Numbers: PH 303-UC-001-80, PH 303-UC-001-80A. July 15th, 1980. DACO: 4.5.4.
1209383	Ethrel: Mitotic Crossing Over, *Saccharomyces cerevisiae*, Pharmakon Laboratories, Pennsylvania, USA. Study Number: PH 302-UC-001-80. July 15th, 1980. DACO: 4.5.4.
1198857	CHO/HGPRT Mammalian Cell Forward Gene Mutation Assay - Ethephon/Base 250, Pharmakon Laboratories, Pennsylvania, USA. Study Number: PH 314-UC-003-83. December 29th, 1983. DACO: 4.5.4.
1209379	Ethephon - 56375: Dominant Lethal Study, Pharmakon Laboratories, Pennsylvania, USA. Study Number: PH 307-AM-019. April 11th, 1979. DACO: 4.5.4.
1209385	Ethephon: Genetic Toxicology Micronucleus Test (MNT), Pharmakon Laboratories, Pennsylvania, USA. Study Number: PH 309A-UC-001-81. April 6th, 1981. DACO: 4.5.4.
1548712	A 28-day Cholinesterase Inhibition Study via Dietary Administration in the Beagle Dog with Ethephon Base 250, Bayer CropScience LP, Kansas, USA. Study Number: 04N-S16-VO, Report Number 201302. March 2nd, 2006. DACO: 4.3.8.
1548710	A 90-day Cholinesterase Inhibition Study via Dietary Administration in the Beagle Dog with Technical Ethephon, Bayer CropScience LP, Kansas, USA. Study Number: 04-S76-VW, Report Number 201261. August 14th, 2006. DACO: 4.3.8.
1668455	Metabolism of 14C-ethephon in the Dog - Final report, Hazleton Laboratories, Inc., Virginia, USA. Study Report Number: N/S. August 9th, 1971. DACO: 4.5.9.
1668456	Preliminary Metabolic Studies on Ethrel 2-Chloroethylphosphonic Acid-1-2-14C (Ethephon) - Final Report, Hazleton Laboratories, Inc., Virginia, USA. Study Report Number: N/S. February 4th, 1971. DACO: 4.5.9.
1198847	Addendum #1 - 42-day Neurotoxicity Study with Ethephon: Base 250 in Mature white Leghorn Chickens, Bio-Life Associates, LTD., Wisconsin, USA, Study Number: BLAL No. 83 DN 102. December 15th, 1983. DACO: 4.5.11.
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2694452 Twenty-Eight Day Dietary Toxicity Study with Ethephon in Mice - Study II, Bushy Run Research Center, Pennsylvania, USA, Project Report 49-4. February 19th, 1986. DACO 4.3.3.

2694446 Twenty-Eight Day Dietary Toxicity Study with Ethephon in Mice, Bushy Run Research Center, Pennsylvania, USA, Project Report 48-139. January 27, 1986. DACO 4.3.3.

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2694456 Mutagenicity Test on Ethephon Base 250 in the Ames Salmonella/Microsome reverse Mutation Assay, Hazleton Laboratories America Inc., Wisconsin, USA, Laboratory Project Identification: HLA Study No.: 10065-0-401. October 12th, 1987. DACO 4.5.4.

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2695175	A 2-week Range-Finding Toxicity Study of Orally Administered Ethephon Technical Grade Base 250 in Rats, ClinTrials BioResearch, Quebec, Canada, Laboratory Project ID: 97453. April 28th, 1997. DACO 4.5.9.
2694438	HEPA: Acute Oral Toxicity Study in the Rat, Covance Laboratories Ltd., North Yorkshire, England, Covance Report Number 2014/30-D6144. December 20th, 2001. DACO 4.2.1.

B.2 Additional Information Considered

Published Information

PMRA Document Number	Reference
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1669072	1999, Disruption of male sex hormones with regard to pesticides: Pathophysiological and regulatory aspects, Toxicology Letters, 107(1-3):225-231, DACO: 4.8.
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C. Information Considered in the Dietary Assessment

C.1 List of Studies/Information Submitted by Registrant

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1198806, 1198836	1982, Canadian Residue Data - Wheat And Barley - Analysis of Canadian Grain and Straw Samples for Residues of Ethephon. Data Numbering Code : 7.4.2, CBI
1198807, 2067824	1981, A Review Of The Metabolism Of 2-Chloroethylphosphonic Acid (Ethephon). Data Numbering Code : 6.1, CBI
1198812	1982, Residue Sample Reports Barley And Wheat. Data Numbering Code : 7.4.2, CBI
1198815, 2308113	1979, Residues Of Ethephon In Grapes And Related Foods And Feeds. Data Numbering Code : 7.4.2, CBI
1198823, 2067845, 2067849	1982, Residues Of Ethephon In Wheat, Barley And Oats Resulting From Application Of Ethrel As An Anti-Lodging Agent. Data Numbering Code : 7.4.2, CBI
2058300	2008, Ethephon: Magnitude of the residue on tomato. Data Numbering Code : 7.2.1, 7.4.1, CBI
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2067827, 2221752, 2242211	2006, Metabolism of [U-14C]-Ethephon in cotton. Data Numbering Code : 6.3, CBI
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2067829	1973, Decomposition of 2-Cloroethylphosphonic Acid in Stems and Leaves of Hevea Brasiliensis. Data Numbering Code : 6.3, CBI
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2067831, 2067833	2006, Metabolism of [U-14C]-Ethephon in tomatoes. Data Numbering Code : 6.3, CBI
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2067836	1984, Cerone - Detailed Methods of Analysis for Residue of (2-Chloroethyl) Phosphonic Acid (Ethephon) in Milk and Cow Liver, Muscle, Kidney and Fat Tissues. Data Numbering Code : 7.2.1, CBI
2067837	1996, 14C validation of general method for the analysis of ethephon residue in a variety of substrates for ethephon in poultry liver. Data Numbering Code : 7.2.1, CBI

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2067840	1989, Ethephon Method of Analysis for Residues of (2-Chloroethyl) Phosphonic Acid in Macadamia Nuts. Data Numbering Code : 7.2.1, 7.2.2, CBI
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2067862	1991, Storage stability of ethephon in/on walnut nutmeats. Data Numbering Code : 7.2.5, 7.3, CBI
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2067866	1992, Determination of the Storage Stability of Ethephon in Apple Fruit. Data Numbering Code : 7.2.5, 7.3, CBI
2067867	1992, Determination of the Storage Stability of Ethephon in Wheat Straw. Data Numbering Code : 7.2.5, 7.3, CBI
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2067871	1992, Determination of the Storage Stability of Ethephon in Tomato Fruit. Data Numbering Code : 7.2.5, 7.3, CBI
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2067876	1995, Storage stability of ethephon in apple juice and cottonseed oil spiked with ethephon. Data Numbering Code : 7.2.5, 7.3, CBI
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2221755, 2242214	1994, A Confined Rotational Crop Study With 14C-Ethephon Using Radishes (Raphanus sativus), Collards (Brassica oleracea), and Wheat (Triticum aestivum). Data Numbering Code : 7.4.3, CBI
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2308106, 2694467	1984, METABOLISM OF 14C-ETHEPHON IN LACTATING GOATS. Data Numbering Code : 6.2, CBI
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C.2 Additional Information Considered

C.2.1 Published Information

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C.2.2 Unpublished Information

PMRA Document Number	Reference
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2315576	USEPA (1994). Ethephon Reregistration. New Proposed Plant and Animal Enforcement Methods and Meat, Milk, and Egg Storage Stability Data and Further Evaluation of Previously Submitted Meat, Milk, Poultry, and Egg Magnitude of the Residue Data. DACO 12.5.7
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D. Information Considered in the Occupational and Non-Occupational Assessment

D.1 List of Studies/Information Submitted by Registrant

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2694466	Cage, S. 2004. [^{14}C]-Ethephon (Upgrade SL) In Vitro Dermal Penetration Study Using Human Skin. Huntingdon Life Sciences Ltd. Cambridgeshire, England. Huntingdon Life Sciences Project ID: BAG 383. Sponsored by: Bayer CropScience. August 24, 2004. Unpublished.
1112264	Kemp, L. 2004. [^{14}C]-Ethephon In Vivo Dermal Absorption in the Male Rat. Huntingdon Life Sciences Ltd. Cambridgeshire, England. Huntingdon Life Sciences Project ID: BAG 374. March 2, 2004. Unpublished.

D.1.2 Studies/Information Provided by the Task Force

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2572746	Agricultural Handler Exposure Task Force (AHETF). 2015. AHETF Scenario Monograph: Closed Cab Airblast Application of Liquid Sprays. Report Number AHE1005-1. March 31, 2015.
1913109	Agricultural Handler Exposure Task Force (AHETF). 2009. AHETF Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays. Report Number AHE1004. December 23, 2009.
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E. Information Considered in the Environmental Assessment

E.1 List of Studies/Information Submitted by Registrant

Unpublished Information

PMRA Document Number	Reference
2715165	Das, Y. T. 1990. Hydrolysis of [Ethyl(U)-14C]Ethephon in Aqueous Solutions buffered at pH 5, 7 and 9. Report No.: M-187629-01-1; Innovative Scientific Services, Inc. (ISSI), Piscataway, NJ, USA; Lab Report No.: R013276; 113 p. DACO 8.2.3.2.
2715166	Chib, J. S. 1981. Ethephon (2-Chloroethylphosphonic Acid) Hydrolytic Degradation Study. Report No.: M-187628-01-1; Union Carbide Corporation, USA; Lab Report No.: R013275; EPA MRID No.: 00124861; 10 p. DACO 8.2.3.2.
2715186	Malone, E. M. 1985. Ethephon degradation Rates of Cerone Plant Regulator at Field Use Dilution. Report No.: M-187980-01-1; Union Carbide Corporation, USA; Lab Report No.: R013456; 19 p. DACO 8.2.3.2.
2715167	Hatcher, G., Oddy, A. M. 2001. Photodegradation in soil (14C)-Ethephon. Report No.: M-199517-01-1; Aventis CropScience UK Ltd., Environmental Chemistry, Ongar, United Kingdom; Lab Report No.: C010717; DACO 8.2.3.3.1.
2715168	Das, Y. T. 1990. Photodegradation of [Ethyl(U)-14C]Ethephon on Soil under Artificial Sunlight. Report No.: M-187634-01-1; Innovative Scientific Services, Inc. (ISSI), Piscataway, NJ, USA; Lab Report No.: R013278; EPA MRID No.: 41681401; 106 p. DACO 8.2.3.3.1.
2715172	Jacob, O., Oddy, A. 2005. (14C)-ethephon: Aqueous photolysis in natural water. Report No.: M-249376-01-1; Battelle AgriFood Ltd., Ongar, Essex, United Kingdom; Lab Report No.: C047940; 100 p. DACO 8.2.3.3.2.
2715173	Das, Y. T. 1990. Photodegradation of [Ethyl(U)-14C]Ethephon in Aqueous Solution Buffered at pH 5 under artificial Sunlight. Report No.: M-187632-01-1; Innovative Scientific Services, Inc. (ISSI), Piscataway, NJ, USA; Lab Report No.: R013277; EPA MRID No.: 41545601; 95 p. DACO 8.2.3.3.2.
2715174	van der Gaauw, A. 2001. Estimation of the degradation of ethephon by photo-oxidation in air Model calculation according to Atkinson. Report No.: M-201690-01-1; RCC Ltd., Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Lab Report No.: C011869; 20 p. DACO 8.2.3.3.3.
2715175	Fitzmaurice, M. J. 2003. (14C)-Ethephon: Route and rate of degradation under aerobic conditions in one soil at 20 degrees C. Report No.: M-232779-01-2; Battelle AgriFood Ltd., Ongar, Essex, United Kingdom; Lab Report No.: CX/02/032; EPA MRID No.: 48202001; 78 p. DACO 8.2.3.4.2.
2715176	Hardy, I., Patel, M. 2006. Ethephon: Kinetic modelling analysis of data from two aerobic soil degradation studies. Report No.: M-271686-01-1; Battelle AgriFood

PMRA Document Number	Reference
	Ltd., Ongar, Essex, United Kingdom; Lab Report No.: CX/06/025A; 59 p. DACO 8.2.3.4.2.
2715177	Burr, C. M. 2001. [14C]-ethephon - Route and rate of degradation under aerobic conditions in one soil at 20 degrees C and 10 degrees C and in three contrasting soils at 20 degrees C. Report No.: M-203033-01-2; Aventis CropScience UK Ltd., Environmental Chemistry, Ongar, United Kingdom; Lab Report No.: 17886; EPA MRID No.: 48202002; 113 p. DACO 8.2.3.4.2.
2715179	Das, Y. T. 1991. Metabolism of [Ethyl(U)-14C]Ethephon under Aerobic Soil Conditions. Report No.: M-187639-01-1; Innovative Scientific Services, Inc. (ISSI), Piscataway, NJ, USA; Lab Report No.: R013281; EPA MRID No.: 41757701; 82 p. DACO 8.2.3.4.2.
2715180	Oddy, A. M. 2001. Route and rate of degradation in soil under anaerobic conditions at 20 degrees C (14C)-Ethephon. Report No.: M-204496-01-1; Aventis CropScience UK Ltd., United Kingdom; Lab Report No.: C013378; 139 p. DACO 8.2.3.4.4.
2715181	Das, Y. T. 1991. Metabolism of [Ethyl(U)-14C]Ethephon under Anaerobic Aquatic Soil Conditions. Report No.: M-187642-01-1; Innovative Scientific Services, Inc. (ISSI), Piscataway, NJ, USA; Lab Report No.: R013283; EPA MRID No.: 41757702; 92 p. DACO 8.2.3.4.4.
2694470	Lowden, P., Simmonds, M.B., Early, E.L. 2000. (14C)-Ethephon: Degradation and retention in two water/sediment systems. Report No.: M-199017-01-2; Aventis CropScience UK Ltd, Fyfield Road, Ongar, Essex, CM5 0HW UK. Lab Report No.: 17889; EPA MRID 48202003; 160 p. DACO 8.2.3.5.4.
2694471	Hein, W. 2015. [UL-14C]ethephon - Aerobic mineralisation and metabolism in surface water - Final report. Report No.: M-532463-01-1; RLP AgroScience GmbH; Breitenweg 71; 67435 Neustadt a. d. Weinstraße; Germany; Lab Report No.: AS420; 103 p. DACO 8.2.3.5.4.
2715187	Hardy, I., Patel, M. 2008. Ethephon: Kinetic modelling analysis of data from a water/sediment study. Report No.: M-311053-01-1; Battelle UK Ltd., Ongar, Essex, United Kingdom; Lab Report No.: VC/08/032A; 29 p. DACO 8.2.3.5.4.
2715182	Huhtanen, K. L. 1986. Ethrel - Ethephon (2-Chloroethyl Phosphonic Acid) Anaerobic Aquatic Metabolism Study. Report No.: M-187641-01-1; Union Carbide Corporation, USA; Lab Report No.: R013282; EPA MRID No.: 00157158; 12 p. DACO 8.2.3.5.6.
2715183	Das, Y. T. 1991. Soil Adsorption and Desorption of [14C]Ethephon. Report No.: M-187647-01-1; Innovative Scientific Services, Inc. (ISSI), Piscataway, NJ, USA; Lab Report No.: R013285; 182 p. DACO 8.2.4.2.
2715185	Miller, N. E., Liu, A. C. 1996. 2-Hydroxyethylphosphonic Acid (Ethephon Metabolite) Adsorption/Desorption Study. Report No.: M-188164-01-1; Rhone-Poulenc Ag Company, USA; Lab Report No.: R013552; EPA MRID No.: 43991301; 232 p. DACO 8.2.4.2.

PMRA Document Number	Reference
2694473	Norris, F.A. 1991. A Terrestrial Field Soil Dissipation Study with Ethephon. Report No.: M-187653-01-1; Rhone-Poulenc Ag Company, Environmental Chemistry Department, P.O. Box 12014, 2 T. W. Alexander Drive, North Carolina, 27709; Lab Report No.: EC-89-070; 42011501; 250 p. DACO 8.3.2.
2694497	Fuchsbichler, G. 1991. Loss in Soil Ethephon. Report No.: M-188025-01-2; Bavarian Central Research, Institute for Agriculture, Department of Residue Analysis; Lab Report No.: HVA 3/91 DACO 8.3.2.
2694496	Anonymous. 1972. Studies of the behavior of (2-Chloroethyl)Phosphonic Acid (Ethephon) in Soils. M-187626-01-1; Analytical Research Laboratories; Amchem Products, Inc.; Ambler, Pa. 19002; 34 p. DACO 8.5.
2715190	Luehrs, U. 2002. Acute toxicity (14 days) of AE F020271 to the earthworm *Eisenia fetida* in artificial soil. Report No.: M-210875-01-1; IBACON GmbH, Rossdorf, Germany; Lab Report No.: C021262; 27 p. DACO 9.2.3.1.
2715191	McElligott, A. 1995. EXP 31039 - Acute toxicity (14-day) to earthworms (*Eisenia foetida*) - Artificial soil method. Report No.: M-254004-01-1; Rhone-Poulenc Agro, Sophia Antipolis, France; Lab Report No.: SA95044; 43 p. DACO 9.2.3.1.
2715206	Luehrs, U. 2001. Effects of ethephon base 250 on reproduction and growth of earthworms *Eisenia fetida* (Savigny 1826) in artificial soil. Report No.: M-200761-01-1; Aventis CropScience GmbH, Frankfurt am Main, Germany; Lab Report No.: C015579; 32 p. DACO 9.2.3.2.
2715192	Schmitzer, S. 2015. Effects of ethephon tech. (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory. Report No.: M-514214-01-1; IBACON GmbH, Rossdorf, Germany; Lab Report No.: 92031035; 33 p. DACO 9.2.4.1, 9.2.4.2.
2694474	Eckert, J. 2015. Ethephon technical concentrate - Honey bee (*Apis mellifera* L.) larval toxicity test (single exposure). Report No.: M-540682-01-1; Eurofins Agroscience Services, EcoChem GmbH, Eutinger Straße 24, D - 75223 Niefern-Öschelbronn, Germany; Lab Report No.: S15-02262; 45 p. DACO 9.2.4.3.
2715193	Pfeiffer, S. 2015. Ethephon technical: Acute oral toxicity to the bumble bee, *Bombus terrestris* L. under laboratory conditions. Report No.: M-534551-01-1; Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany; Lab Report No.: S15-00347; 31 p. DACO 9.2.4.9.
2715194	Pfeiffer, S. 2015. Ethephon technical: Acute contact toxicity to the bumble bee, *Bombus terrestris* L. under laboratory conditions. Report No.: M-525423-01-1; Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany; Lab Report No.: S14-00624; 25 p. DACO 9.2.4.9.
2694476	Knacker, T., Hilt, J. 1989. A study of the acute immobilisation to Daphnia of ethephon according to the OECD guideline for testing of chemicals no. 202, Part I "*Daphnia* sp., Acute Immobilisation Test and Reproduction Test" adopted April 4, 1984. Report No.: M-187819-01-1; Battelle Europe, Battelle-Institut e.V., Am Romerhof 35, D-6000 Frankfurt am Main; Lab Report No.: BE-ET-01-89-02-DAK-6; 26 p. DACO 9.3.2.
2694477	Riebschläger, T. 2015. Acute toxicity of ethephon (technical concentrate) to the waterflea *Daphnia magna* in a static-renewal laboratory test system - Limit test. Report No.: M-524938-01-1; Bayer CropScience AG, BCS-D-EnSa-Testing, 40789 Monheim, Germany; Lab Report No.: EBETNO25; 63 p. DACO 9.3.2.

PMRA Document Number	Reference
2694478	Bentley, R.E. 1974. Acute Toxicity of Technical Ethrel to Grass Shrimp (*Palaemonetes vulgaris*), MUD Crab (*Neopanope texana*), Water Flea (*Daphnia magna*) Midge Larvae (*Chironomus tentans*), and Scud (*Gammarus fasciatus*). Report No.: M-187821-01-1; Bionomics, E G & G, Inc., 790 Main Street, Wareham, Massachusetts; Lab Report No.: ETH/T44; 9 p. DACO 9.3.2, 9.3.4, 9.4.2, 9.9.
2694479	Knacker, T., Reifenberg, P., Schallnap, H. 1989. A Study of the Chronic Toxicity to *Daphnia* of Ethephon accordding to the OECD Guidlines for Testing of Chemicals No. 202, Part II "*Daphnia* sp., Acute Immobilisation Test and Reproduction Test" adopted April 4, 1984. Report No.: M-187831-01-1; Battelle Europe, Battelle-Institute.V., Am Romerhof 35, D-6000 Frankfurt am Main; Lab Report No.: BE-ET-01-89-02-DCH-6; 48 p. DACO 9.3.3.
2694481	Putt, A.E. 1992. (Ethephon technical) - The chronic toxicity to *Daphnia magna* under flow-through conditions. Report No.: M-187833-01-1; Springborn Laboratories, Inc., Environmental Sciences Division, 790 Main Street, Wareham, Massachusetts 02571; Lab Report No.: 92-1-4074; 98 p. DACO 9.3.3.
2694483	Bentley, R.E. 1974. Acute Toxicity of Ethrel to Atlantic Oyster (*Crassostrea virginica*). Report No.: M-187817-01-1; Bionomics, E G & G, Inc., Environmental Consultants, 790 Main Street, Wareham, Massachusetts; Lab Report No.: ETH/T70; 6 p. DACO 9.4.2.
2694484	Dionne, E. 1989. (Ethephon) - Acute toxicity to Eastern Oyster (*Crassostrea virginica*) under flow-through conditions. Report No.: M-187969-01-1; Springborn Laboratories, Inc., 790 Main Street, Wareham, Massachusetts 02571; Lab Report No.: 89-10-3121; 37 p. DACO 9.4.2.
2715195	Douglas, M. T., Handley, J. W. 1988. The Acute Toxicity of Ethephon Base 250 to Rainbow Trout (*Salmo gairdneri*). Report No.: M-187805-01-1; Huntingdon Research Centre Ltd., Huntingdon, United Kingdom; Lab Report No.: R013361; 33 p. DACO 9.5.2.1.
2715196	Sleight, B. H., Hutchinson, C. 1971. The acute Toxicity of Ethrel to Bluegill (*Lepomis macrochirus*) and Rainbow Trout (*Salmo gairdneri*). Report No.: M-187807-01-1; Bionomics Laboratories, USA; Lab Report No.: R013362; EPA MRID No.: 00054010; 5 p. DACO 9.5.2.2, 9.5.2.1.
2694500	Banman, C.S., Howerton, J.H., Moore, S. 2013. Acute Toxicity of Ethephon to the Sheepshead minnow (*Cyprinodon variegatus*) Under Flow-Through Conditions. Report No.: M-44829-01-1; SynTech Research Laboratory Services LLC, Ecotoxicology, 17745 South Metcalf Avenue, Stilwell, Kansas 66085-9104; Lab Report No.: EBETL014; 59 p. DACO 9.5.2.4.
2694487	Sousa, J.V. 2001. The toxicity to fathead minnow (*Pimephales promelas*) during an early life-stage exposure Ethephon. Report No.: M-205148-01-2; Springborn Laboratories, Inc., 790 Main Street, Wareham, Massachusetts 02571-1075; Lab Report No.: 13726.6143; 68 p. DACO 9.5.3.1.
2715197	Sleight, B. H., Macek, K. J. 1972. Exposure of fish to 14C-labeled ethephon: accumulation, distribution and elimination of residues. Report No.: M-187651-01-1; Bionomics Laboratories, USA; Lab Report No.: R013287; EPA MRID No.: 00136290; 15 p. DACO 9.5.6.

PMRA Document Number	Reference
2715198	Rodgers, M. H. 1995. EXP 31039 - Acute oral toxicity (LD50) to bobwhite quail. Report No.: M-253500-01-1; Huntingdon Research Centre Ltd., Huntingdon, United Kingdom; Lab Report No.: RNP470/951678; 41 DACO 9.6.2.1.
2715199	Beavers, J. B., Fink, R. 1979. Acute Oral LD50 - Bobwhite Quail Technical Ethephon Final Report. Report No.: M-187798-01-1; Wildlife International, Ltd., Easton, MD, USA; Lab Report No.: R013357; EPA MRID No.: 00026041; 18 p. DACO 9.6.2.1.
2715200	Gabriel, K. L. 1969. Acute Oral Toxicity - Bobwhite Quail. Report No.: M-187803-01-1; Union Carbide Corporation, USA; Lab Report No.: R013360; EPA MRID No.: 00054012; 2 p. DACO 9.6.2.1.
2715201	Fink, R. 1977. Eight-day dietary LC50 - Bobwhite Quail Ethrel Final Report. Report No.: M-187815-01-1; Wildlife International, Ltd., Easton, MD, USA; Lab Report No.: R013366; EPA MRID No.: 00085446; 11 p. DACO 9.6.2.4.
2715202	Fink, R. 1972. Eight-day dietary LC50 - Mallard Ducks - Ethephon - Final Report. Report No.: M-187811-01-1; Hazleton Virginia, Inc., USA; Lab Report No.: R013364; EPA MRID No.: 00072983; 5 p. DACO 9.6.2.5.
2715203	Fink, R. 1972. Eight day dietary LC50 - Mallard ducks - Ethephon - Final report. Report No.: M-166196-01-1; Hazleton Virginia, Inc., USA; Lab Report No.: R004444; EPA MRID No.: 00073622; 5 p. DACO 9.6.2.5.
2694489	Stafford, J.M. 2014. Ethephon: Reproductive toxicity test with the northern bobwhite (*Colinus virginianus*) - Ethephon technical (Base 250). Report No.: M-478412-01-1; Smithers Viscient, 2900 Quakenbush Rd., Snow Camp, NC 27349 USA; Lab Report No.: XY4711; 83 p. DACO 9.6.3.1.
2694491	Christ, M.T., Sheperd, J., Moore, S. 2014. Toxicity of ethephon (Base 250) on the reproduction of the mallard duck (*Anas platyrhynchos*). Report No.: M-474649-01-1; SynTech Research Laboratory Services, LLC, Ecotoxicology, 17745 South Metcalf Avenue, Stilwell, Kansas 66085-9104; Lab Report No. EBETL012; 73 p. DACO 9.6.3.2.
2694492	Douglas, M. T., Handley, J. W. 1988. The algistatic activity of ethephon Base 250. Report No.: M-187835-01-1; F. Barciet, Rhône-Poulenc Agrochimie, Department de Toxicologie, 14-20 rue Pierre Baizet, BP 9163, 69263 Lyon Cedex 09, France; Lab Report No.: RNP 289/88604; 24 p. DACO 9.8.2, 9.8.3, 9.9.
2715204	Matlock, D., Banman, C., Moore, S. 2015. Toxicity of ethephon technical to the freshwater diatom *Navicula pelliculosa* during a 96 hour exposure. Report No.: M-534339-01-1; SynTech Research Laboratory Services, LLC, Stilwell, KS, USA; Lab Report No.: 007SRUS15C110; 93 p DACO 9.8.2.
2694493	Giddings, J.M. 1990. Ethephon - Toxicity to the marine diatom Skeletonema costatum. Report No.: M-187843-01-1; Springborn Laboratories, Inc. Environmental Sciences Division, 790 Main Street, Wareham, Massachusetts 02571; Lab Report No.: 90-1-3207; 36 p. DACO 9.8.3.
2694494	Hoberg, J.R. 1990. (Ethephon) - Determination of Effects on Seedling Germination, Shoot Emergence and Seedling Vigor of ten Plant Species. Report No.: M-187847-01-1; Springborn Laboratories, Inc., Environmental Sciences Division, 790 Main Street, Wareham, Massachusetts 02571; Lab Report No.: 90-2-3220; 310 p. DACO 9.8.4.

PMRA Document Number	Reference
2694495	Hoberg, J.R. 1990. (Ethephon) - Supplemental Report determination of Effects on Carrot and Ryegrass Emergence and Carrot Seedling Vegetative Vigor. Report No.: M-187849-01-1; Springborn Laboratories, Inc., Environmental Sciences Division, 790 Main Street, Wareham, Massachusetts 02571; Lab Report No.: 90-3-3244; 107 p. DACO 9.8.4.
2715205	Kuhl, K. 2015. Toxicity of ethephon (technical concentrate) to the aquatic plant *Myriophyllum spicatum* in a semi-static growth inhibition test. Report No.: M-537257-01-1; Bayer CropScience AG, Monheim, Germany; Lab Report No.: EBETN042; 140 p. DACO 9.8.5.

E.2 Additional Information Considered

E.2.1 Published Information

PMRA#	DACO 8.0	Published Studies
2805267		Klein, I, Lavee, S. and Ben-Tal, Y. 1979. Effect of Water Vapor Pressure on the Thermal Decomposition of 2-chloroethylphosphonic Acid. Plant Physiology, Vol. 63: 474-477 DACO 8.5.
2805268		Woolf, A.B., Clemens, J., Plummer, J.A. 1995. Leaf Maturity and Temperature Affect Removal of Floral Buds from Camellia Ethephon. J. Amer. Soc. Hort. Sci. Vol 120 (4): 614-621 DACO 8.5.
2805269		Dong, J.-N., Ma, Y.-Q., Liu, F.-M., Jiang, N.-W. and Jian, Q. 2015. Dissipation and Residue od Ethephon in Maize Field. Journal of Integrative Agriculture, Vol 14 (1): 106-113 DACO 8.3.2.
2805270		Shaver, T.N. 1984. Fate of Ethephon and N-methyl-2-pyrrolidone in Soil and Cotton Plants. Arch. Environ. Contam. Toxicol. Vol 13: 335-340 DACO 8.5 .
2805271		Wang, K.-S., Lu, C.-Y., Chang, S.-H. 2011. Evaluation of Acute Toxicity and Teratogenic Effects of Plant Growth Regulators by Daphnia magna Embryo Assay. Journal of Hazardous Materials; Vol 190: 520-528 DACO 9.3.2.
1618452		USEPA RED. 1995. Reregistration Eligibility Decision (RED) Ethephon - List A, Case 0382. . United States Environmental Protection Agency; Prevention, Pesticides and Toxic Substances (7508W); Office of Pesticide Programs, Special Review and Reregistration Division, EPA 738-R-95-003; 257 p. http://www.epa.gov/oppsrrd1/REDs/0382.pdf DACO 12.5.4.
1618457		EFSA. 2006. Conclusion Regarding the Peer Review of the Pesticide Risk Assessment of the Active Substance Ethephon. EFSA Scientific Report (2006) 67, 1-61, Conclusion on the peer review of ethephon; http://www.efsa.europa.eu/EFSA/PRAPER_Conclusion/praper_concl_sr67_ethephon_en_rev11,0.pdf DACO 12.5.4.