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Proposed Re-evaluation Decision PRVD2016-15

Quinclorac

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Overview

What Is the Proposed Re-evaluation Decision for Quinclorac

After a re-evaluation of the herbicide quinclorac, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing quinclorac for sale and use in Canada.

An evaluation of available scientific information found that uses of quinclorac products do not present unacceptable risks to human health or the environment when used according to the proposed label directions. As a requirement of the continued registration of quinclorac, new risk-reduction measures are proposed for end-use products registered in Canada, including revised label directions.

This proposal affects the products containing quinclorac registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for quinclorac and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of quinclorac.

The PMRA will accept written comments and information up to 60 days from the date of publication of this document. Please forward all comments on this proposal to Publications (see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach, which is in line with the requirements of the *Pest Control Products Act*.

For more details on the information presented in this Overview, please refer to the Science Evaluation part of this consultation document.

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

What is Quinclorac?

Quinclorac is a herbicide registered for use on cereal and oilseed crops in the Prairie Provinces and Peace River region of British Columbia to control and/or suppress certain grassy and broadleaved weeds. Quinclorac products can be applied once per season every second year using ground equipment only. A total of eleven products containing quinclorac are currently registered under the authority of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Quinclorac Affect Human Health?

Products containing quinclorac are unlikely to affect human health when used according to label directions.

Potential exposure to quinclorac may occur through the diet (food and water) or when handling and applying end-use products containing quinclorac, or by entering treated sites. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when quinclorac products are used according to label directions.

In laboratory animals, technical grade active ingredient quinclorac was of low acute toxicity via the oral, dermal and inhalation routes. It was minimally irritating to the eyes and skin, and caused an allergic reaction.

Short and long term (lifetime) animal toxicity tests were assessed for the potential of quinclorac to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints used for risk assessment included reductions in body weight and effects on the fetuses. There was no indication that the young animal was more sensitive than the adult animal. The risk assessment protects against effects noted above by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose (ARfD) or chronic reference dose expressed as acceptable daily intake (ADI). An ADI is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Acute and chronic dietary exposures to quinclorac were estimated from residues of quinclorac (including the metabolite quinclorac methyl ester comprised in the newly proposed residue definition for oilseeds, crop subgroup 20A) in treated crops and drinking water for different subpopulations including children and women of reproductive age. All currently registered forms of quinclorac (acid and dimethylamine salt) were considered to be equivalent.

The acute dietary exposure estimate (from food and drinking water) at the 95th percentile is approximately 2% of the ARfD for females aged 13-49 years and for infants less than 1 year of age, and is less than 2% of the ARfD for all other subpopulations. The chronic dietary exposure estimate for the general population is approximately 2% of the ADI. Exposure estimates for population subgroups range from 2% of the ADI (for most population subgroups) to 6% of the ADI (for all infants less than 1 year old). Thus, acute and chronic dietary risks are not of concern.

The *Food and Drugs Act* prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the specified maximum residue limit (MRL). Pesticide MRLs are specified for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. An MRL represents the maximum amount of residues that may remain on food when a pesticide is used according to label directions, and serves as a food safety standard. The Canadian Food Inspection Agency is responsible for monitoring the Canadian food supply for pesticide residues and the determination of compliance with MRLs specified by Health Canada.

MRLs for quinclorac are currently specified for a range of commodities. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specific MRL, are regulated under Subsection B.15.002(1) of the *Food and Drugs Regulations*, which requires that residues do not exceed 0.1 ppm. A complete list of MRLs specified in Canada can be found on the PMRA's MRL database, an online query application that allows users to search for specified MRLs regulated under the *Pest Control Products Act*, both for pesticides or food commodities (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php).

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern.

Quinclorac is not registered for residential uses. Therefore, a risk assessment for this scenario is not required.

Occupational Risks from Handling Quinclorac

Occupational risks to handlers are not of concern when used according to label directions.

Risks to handlers are not of concern for all scenarios. Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation, risk estimates associated with mixing, loading, and applying activities exceeded target dermal and inhalation MOEs and are not of concern.

Post-application risks are not of concern for all uses.

Post-application occupational risk assessments consider exposures to workers performing activities in treated sites. Based on the current use pattern, postapplication risks to workers performing activities, such as scouting, exceeded target dermal MOEs and are not of concern.

Environmental Considerations

What Happens When Quinclorac Is Introduced Into the Environment?

When used according to the label directions, quinclorac is not expected to pose an unacceptable risk to the environment.

Quinclorac can enter non-target terrestrial and aquatic habitats through spray drift and can enter aquatic habitats through spray drift, run-off and leaching. Quinclorac breaks down slowly in soil where it can be persistent. Quinclorac mixes readily in water and has the potential to move through soil and may reach groundwater. Quinclorac is unlikely to enter the atmosphere and be transported long distances from where it was applied.

Quinclorac is not expected to accumulate in the tissues of organisms.

Quinclorac is not expected to pose risks of concern to birds, mammals, terrestrial and aquatic invertebrates, fish, amphibians, aquatic plants and algae. As quinclorac is an herbicide, it is toxic to terrestrial plants and may pose risks to non-target plants through spray drift. Spray buffer zones of up to 4 metres are proposed on the label in order to mitigate the potential risks posed by quinclorac to non-target terrestrial plants.

Value Considerations

What is the Value of Quinclorac?

Quinclorac provides an effective tool for western Canadian growers to manage weeds in cereals and oilseed crops.

Quinclorac offers effective control of certain grassy weeds such as green foxtail and broadleaved weeds such as cleavers in major cereal and oilseed crops grown in the Prairie Provinces. More importantly, it is an effective tool to manage the herbicide resistant green foxtail and cleavers. Quinclorac has a unique mode of action in the Group 4 herbicides which has made it a good partner for co-formulation or in tank mixture with other herbicides, resulting in broadened weed control spectrum and reduced number of applications to the crop field.

Proposed Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of quinclorac, the PMRA is proposing further risk-reduction measures outlined below.

Human Health

- Further risk reduction measures in addition to those already identified on quinclorac product labels were not required. Labels are proposed to be updated for clarification or to meet current standards.

Environment

- Standard environmental hazard and advisory label statements.
- Spray buffer zones (2 – 4 metres) to protect non-target terrestrial plants.

Next Steps

Before making a final re-evaluation decision on quinclorac, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on quinclorac. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Quinclorac is a selective systemic herbicide. It belongs to the quinoline carboxylic acid family and is classified as a Weed Science Society of America (WSSA) Group 4 herbicide. The mode of action of quinclorac is not completely understood. It is the only WSSA Group 4 herbicide that controls grassy weeds in addition to broadleaved weeds. For susceptible broadleaved weeds, the herbicidal activity of quinclorac may be due to an "auxin (IAA, indole-3-acetic acid) overload". For susceptible grasses, however, quinclorac may inhibit an enzyme associated with cell wall biosynthesis. Its effect on grasses may also be due to an increase in ethylene and cyanide production.

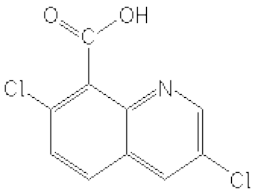
Following the re-evaluation announcement for quinclorac, the technical grade active ingredient registrants and primary data providers in Canada, BASF Canada Inc. and Productierra, indicated that they intend to continue to support all uses included on the labels of Commercial Class end-use products. There are no Domestic Class end-use products containing quinclorac in Canada.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name		Quinclorac
Function		Herbicide
Chemical Family		Quinolinecarboxylic acid
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	3,7-dichloroquinoline-8-carboxylic acid
2	**Chemical Abstracts Service (CAS)**	3,7-dichloro-8-quinolinecarboxylic acid
CAS Registry Number		84087-01-4
Molecular Formula		$C_{10}H_5Cl_2NO_2$

Structural Formula



Molecular Weight 242.1

Registration Number	**Purity of the Technical Grade Active Ingredient**
25117	98%
31364	100%

Identity of relevant impurities of human health or environmental concern:

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	**Result**
Vapour pressure at 25°C	< 0.01 mPa
Ultraviolet (UV)/visible spectrum	Does not absorb at $\lambda > 350$ nm
Solubility in water at 20°C	0.065 mg/kg at pH 7
n-Octanol/water partition coefficient (Log K_{ow})	$\log K_{ow} = -0.74$ (pH 7)
Dissociation constant	4.34 at 20°C

2.3 Description of Registered Quinclorac Uses

Appendix I lists all quinclorac products that are registered under the authority of the *Pest Control Products Act* specifically including two technical grade active ingredients, one manufacturing concentrate, and eight Commercial Class end-use products. Of the end-use products, two are formulated with quinclorac alone and the remaining is co-formulated with thifensulfuron methyl, tribenuron methyl, and/or metsulfuron methyl. Uses of quinclorac belong to the following use site categories: Industrial Oilseed and Fibre crops, Terrestrial Feed Crops and Terrestrial Food Crops.

Appendix II lists all the uses for which quinclorac is presently registered. All uses were supported by the registrant at the time of initiation of re-evaluation or subsequently and were, therefore, considered in the health and environmental risk assessments.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for quinclorac was conducted. For technical quinclorac, the majority of the available toxicity studies were conducted in the 1980s. Considered individually, some of these studies do not meet current standards although they were considered acceptable at the time of their evaluation. However, taken together, these studies provided sufficient information for risk assessment purposes. The database was supplemented with more recent studies assessing acute toxicity, neurotoxicity and immunotoxicity, and reviews from the USEPA were also consulted. Examination of the published scientific literature did not yield further relevant information.

Oral toxicokinetic studies in the rat with radio-labelled quinclorac indicated rapid absorption and excretion. Elimination of the radio-label occurred predominately in the urine and to a limited extent in the feces, with negligible amounts in expired air; the majority was eliminated within 24 h. Both absorption and excretion were comparable between sexes. Area under the curve (AUC) data showed non-linearity above 600 mg/kg bw, suggesting that excretion was saturated above this dose, which could also contribute to toxicity. The highest tissue radioactivity level occurred 30 minutes post-dosing. The GI tract contained the highest amount of radioactivity, followed by plasma and kidneys. Levels in tissues decreased rapidly and were at or below the level of detection at 72 hours and 120 hours. Based on the dosing protocol, there was no evidence of bioaccumulation.

The majority of excreted material was unchanged quinclorac. A glucuronide conjugate was the major component in the bile and also made up a small amount of urinary radioactivity; an unidentified metabolite, less polar than the glucuronide conjugate, was also detected in the urine.

Quinclorac was of low acute toxicity in mice and rats by the oral route. Clinical signs following acute oral exposure included piloerection/ruffled fur, staggering, spastic gait, apathy, dyspnea, diarrhea, and cachexia. Quinclorac was of low acute toxicity in rats by the dermal and inhalation routes. It was minimally irritating to rabbit eyes and skin, and was a dermal sensitizer in guinea pigs, when assessed by the Maximization method.

In a 21-day dermal rabbit study there were no toxicologically significant effects, and the study NOAEL was set at the highest dose, the limit dose for testing.

Repeat-dose toxicity studies, by the dietary route, were conducted in mice, rats and dogs. In these studies, the primary findings consisted of a slight reduction in body weight, clinical findings, as well as effects on the liver and kidney.

In short-term mouse, rat and dog toxicity studies, treatment resulted in body weight reduction. Food efficiency was reduced in mice and dogs, while food consumption was reduced in rats and dogs. Long-term oral exposure in mice and rats produced slight reductions in body weight, but did not affect food consumption at the highest doses tested in these studies.

Mild effects on the liver and slight changes in clinical chemistry were noted in short-term rat and dog toxicity studies were noted. In rats, elevated serum ALT and AST levels indicated liver toxicity at the limit dose. In dogs, reduced serum albumin and reduced serum ALP levels were observed at high doses in conjunction with mononuclear cell infiltration, single cell necrosis and increased liver weight. However, in long term mouse and rat studies no liver effects were noted at doses well above the limit dose in mice, and at the highest dose tested in rats.

In short-term rat and dog studies, effects on the kidneys at high doses included focal chronic interstitial nephritis, and in dogs, focal dilatation of the kidney tubules with flattening of the epithelium, hydropic degeneration and increased kidney weight. Urinalysis parameters were not affected. In mice, kidney weights were decreased in short and long term studies, although in the long term study this was due to reduced body weights. In mouse and rat short-term toxicity studies, and rat long-term toxicity studies, water intake was increased at higher dose levels.

The assessment of the oncogenic potential of quinclorac included a battery of *in vivo* and *in vitro* genotoxicity studies, as well as long-term dietary studies in rats and mice. There was no evidence of genotoxicity. The majority of the genotoxicity studies, both *in vitro* and *in vivo*, were negative. The in vitro human lymphocyte cytogenetics studies were positive only at cytotoxic levels. There was no evidence of oncogenic effects in either the mouse, or in the rat toxicity studies. In the long–term rat study there was an insufficient number of rats at the highest dose (LOAEL) to permit a valid assessment of oncogenicity at that dose, however, there was no indication of tumour induction and no dose-related trend in tumour incidence.

In the rat oral gavage developmental toxicity study, no treatment-related fetal effects were noted. Maternal effects at the high dose included an increased incidence of clinical signs such as reduced nutritional status and poor general condition with an increase in mortality. The rats that died had severe stomach ulceration, increased water intake, and reduced food consumption prior to death. In the rabbit developmental toxicity study, there was an increase in early resorptions and abortions, and a reduction in litter size and fetal body weight at the highest dose tested. Maternal toxicity also included a reduction in maternal body weight and uterine weight, an increase in the incidence of clinical signs such as reduced/absent defecation, diarrhea, and poor general condition, and an increase in mortality. There was no evidence of developmental malformations or sensitivity of the young in either study.

In a dietary two-generation rat reproduction toxicity study, toxic effects were noted only at the highest dose tested, which approached the limit dose. Parental effects included a reduction in food consumption and in body weight gain during pre-natal dosing and lactation. There was also an increased incidence of interstitial nephritis. In pups, decreases in body weight and/or body weight gain were noted throughout the lactation period; there was a slight decrease in F_{1a} and F_{2a} pup survival during the post-natal period and some developmental delays (ear unfolding in F_{1a}, ear opening in F_{1a} and F_{2a}, eye opening in F_{1a} and F_{2a} litters) possibly associated with retarded growth. No adverse effects on reproductive parameters were noted at any dose level. There was no indication of sensitivity of the young.

There was no evidence of neurotoxicity in a 90-day dietary neurotoxicity study in rats and no evidence of immunotoxicity in a 28-day dietary immunotoxicity study in mice.

Test results from studies with quinclorac on laboratory animals, along with the toxicity endpoints for use in human health risk assessment are summerized in Tables 1 and 2 of Appendix III.

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 as well as potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

The toxicity database is considered complete. Data available on quinclorac includes a reproductive toxicity study in rats, and developmental toxicity studies in rats and rabbits.

The two-generation reproduction toxicity study in rats did not provide any indication of increased sensitivity of the young. The pups showed a decrease in body weight gain during the post-natal period, a slight decrease in pup survival also during the post-natal period and some developmental delays at a dose level that produced toxicity in the adult animals. In the developmental toxicity study in rats there were no treatment-related effects in the fetuses at a dose that produced maternal toxicity. In the rabbit developmental toxicity study, fetal and maternal toxicity (mortality) occurred at the highest dose tested. An increase in early resorptions and post-implantation losses, and a reduction in litter size and fetal body weight were noted in the presence of significant maternal toxicity.

Overall, the endpoints in the young were well characterized. The toxic effects to the developing fetuses in the rabbit developmental toxicity study were considered a serious endpoint. However, the concern regarding the serious nature of these effects was tempered by the presence of significant maternal toxicity at the same dose level in this study. Therefore, the *Pest Control Products Act* factor was reduced to three-fold when this endpoint was used to establish the point of departure for risk assessment. For all other scenarios, the *Pest Control Products Act* factor was reduced to one-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 quinclorac from potentially treated imported foods is also included in the assessment. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, 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 risk exceeds 100% of the reference dose. The PMRA Science Policy Note SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide*, presents detailed acute, chronic and cancer risk assessment procedures.

Residue estimates used in the dietary risk assessment (DRA) may be based conservatively (in other words upperbound 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 National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program. Theoretical and experimental processing factors as well as specific information regarding percent of crops treated may also be incorporated to the greatest extent possible.

Acute and chronic exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™; Version 4.02) program which incorporates food consumption data from the National Health and Nutrition Examination Survey/"What We Eat in America" (NHANES/WWEIA) dietary survey for the years 2005-2010. All currently registered quinclorac forms (acid and dimethylamine salt) were considered chemically and toxicologically equivalent. Therefore, the dietary exposure assessment covers both forms of quinclorac. For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendices IV and V.

3.2.1 Determination of Acute Reference Dose (ARfD)

ARfD, General Population (excluding females 13-49 years of age)

To estimate acute dietary risk (1 day), the rabbit developmental toxicity study with a NOAEL of 200 mg/kg bw/day was selected for risk assessment. At the LOAEL of 600 mg/kg bw/day, a significant reduction in maternal body weight occurred shortly after dosing began and is therefore considered relevant for acute risk assessment. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. Thus, the composite assessment factor (CAF) is 100.

The ARfD is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{200\ \text{mg/kg bw}}{100} = 2.0\ \text{mg/kg bw}$$

ARfD, Females 13-49 Years of Age

To estimate acute dietary risk (1 day) for females 13-49 years of age, the rabbit developmental toxicity study with a NOAEL of 200 mg/kg bw/day was selected for risk assessment. At the LOAEL of 600 mg/kg bw/day, there was an increase in early resorptions and a reduction in litter

size. These effects on the fetuses could result from a single dose and are therefore considered relevant for acute risk assessment. Standard uncertainty factors of 10 for interspecies extrapolation and 10 for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 3-fold for this endpoint. Thus, the composite assessment factor (CAF) is 300.

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{200 \text{ mg/kg bw}}{300} = 0.7 \text{ mg/kg bw}$$

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 quinclorac that would be likely on any one day, and using food and water consumption and food and 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 expected intake of residues is less than the ARfD, the acute dietary exposure is not of concern.

The acute exposure assessment was conducted by using Canadian MRLs or U.S. tolerances as residues for all relevant commodities, theoretical processing factors and assuming that all crops were 100% treated, including imports. Drinking water contribution to the exposure was accounted for by direct incorporation of the relevant estimated environmental concentration (EEC), obtained from water modelling (see Section 3.3), into the dietary exposure evaluation model (DEEM).

The acute dietary exposure estimate at the 95th percentile is approximately 2% of the ARfD for females aged 13-49 years and for infants less than 1 year of age, and is less than 2% of the ARfD for all other subpopulations. Thus, the acute dietary exposure to quinclorac is not of concern.

3.2.3 Determination of Acceptable Daily Intake (ADI)

To estimate the risk of repeated dietary exposure, the 1-year dog toxicity study was selected for risk assessment. A LOAEL was established for males at the lowest administered dose of 33 mg/kg bw/day, and a NOAEL was established for females at the lowest administered dose of 34 mg/kg. There was a slight reduction in body weight at 33 mg/kg bw/day in males and a slight reduction in body weight in females at the LOAEL of 133 mg/kg bw/day. Standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) were applied. An additional uncertainty factor for use of a LOAEL in male dogs was not required as effects were considered marginal. As previously discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. The CAF is 100.

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{33 \text{ mg/kg bw/day}}{100} = 0.3 \text{ mg/kg bw/day}$$

The selection of the LOAEL of 33 mg/kg bw/day in the 1-year dog study was supported by a similar endpoint in the long-term mouse toxicity study, in which a NOAEL of 42 mg/kg bw/day was established based on a reduction in body weight at the LOAEL of 170 mg/kg bw/day. The ADI (general population) of 0.3 mg/kg bw/day provides a margin of 1477 to the NOAEL (443 mg/kg bw/day) at which no evidence of carcinogenicity was detected in the rat, and a margin of 667 to the NOAEL (200 mg/kg bw/day) for developmental toxicity in the rabbit.

3.2.4 Chronic Dietary Exposure and Risk Assessment

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

The chronic exposure assessment was conducted for the general population and all population subgroups by using Canadian MRLs or U.S. tolerances as residues for all relevant commodities, theoretical processing factors and assuming that all crops were 100% treated, including imports. Drinking water contribution to the exposure was accounted for by direct incorporation of the relevant estimated environmental concentration (EEC), obtained from water modelling (see Section 3.3), into the dietary exposure evaluation model (DEEM).

The chronic dietary exposure estimate for the general population is approximately 2% of the ADI. Exposure estimates for population subgroups range from 2% of the ADI (for most population subgroups) to 6% of the ADI (for all infants less than 1 year old). Thus, the chronic dietary exposure to quinclorac is not of concern.

3.3 Exposure from Drinking Water

3.3.1 Concentrations in Drinking Water

Estimated environmental concentrations (EECs) of quinclorac in potential drinking water sources (groundwater and surface water) were calculated using the PRZM-GW model, while EECs in surface water were calculated using the Surface Water Concentration Calculator model (Appendix IX). Monitoring data available from the province of Alberta indicates that quinclorac is rarely detected in water. However, due to a lack of monitoring data, estimation of the residues of quinclorac in both surface and drinking water using monitoring data is not possible. Therefore, the EECs determined through water modelling are used in the risk assessment. The highest EEC value of 0.183 ppm (daily peak concentration was same as yearly average concentration) was found in groundwater. This EEC value was used in both acute and chronic exposure assessments.

3.3.2 Drinking Water Exposure and Risk Assessment

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

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

Short- and Intermediate-term Inhalation Risk Assessment

To estimate the risk from short- and intermediate-term inhalation exposure, the NOAEL of 200 mg/kg bw/day was selected from the rabbit developmental toxicity study. At the LOAEL of 600 mg/kg bw/day there was an increase in early resorptions and abortions, and a reduction in litter size and fetal body weight. An oral route of exposure was used for the inhalation risk assessments since an inhalation toxicity study was not available. A target MOE of 300 was established, including the standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. An additional 3-fold factor was applied, for serious effects in the young in the presence of significant maternal toxicity. The target MOE of 300 is considered protective of all populations including the unborn children of exposed pregnant workers.

Short- and Intermediate-term Dermal Risk Assessment

To estimate the risk from short- and intermediate-term dermal exposure, the NOAEL of 200 mg/kg bw/day was selected from the rabbit developmental toxicity study. At the LOAEL of 600 mg/kg bw/day there was an increase in early resorptions and abortions, and a reduction in litter size and fetal body weight. A study employing the oral route of exposure was used for the dermal risk assessments since the available dermal study did not assess the endpoint of concern in the developmental toxicity study. A target MOE of 300 was established, including the standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. An additional 3-fold factor was applied, for serious effects in the young in the presence of significant maternal toxicity. The target MOE of 300 is considered protective of all populations including the unborn children of exposed pregnant workers.

Dermal Absorption

In the absence of a dermal absorption study for quinclorac, complete (100%) dermal absorption was assumed (that is, everything applied to the skin is absorbed and available systematically). This would result in very high estimates of exposure.

3.4.2 Occupational Exposure and Risk Assessment

Workers can be exposed to quinclorac through mixing, loading, or applying the pesticide, and when entering a treated site to conduct agricultural activities.

Mixer, Loader, and Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, applicators, or other handlers. Based on typical use patterns, the major scenarios identified were:

- Mixing/loading of liquids
- Mixing/loading of dry flowables
- Mixing/loading of wettable granules
- Applying liquids by groundboom (farmer and custom scenarios) to cereal grains (wheat, barely) and large field crops (canary seed, canola varieties, and brown and oriental tame mustards)

Based on the number of applications (1 application per year) and the timing of application, workers applying quinclorac would generally have a short-term (<30 days) duration of exposure.

Handler exposure was estimated based on the following personal protective equipment (PPE)**:**

Baseline PPE:	Long-sleeved shirt, long pants and chemical-resistant gloves (unless otherwise specified). For groundboom application, this scenario does not include gloves as the data quality was better for non-gloved scenarios than gloved scenarios.

Chemical-specific handler exposure data were not available for quinclorac. Therefore, dermal and inhalation exposures were estimated using data from the *Pesticide Handlers Exposure Database* (PHED), *Version 1.1*. 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. Inhalation exposures were based on light inhalation rates (17L/min).

Occupational exposure during occasional spot treatment in field crops using handheld equipment is expected to be less than broadcast application using groundboom in the majority of situations. This is based on the comparison of PHED unit exposure values for groundboom and the handheld equipment, provided that the same level of PPE required for ground equipment is applied to handheld applicators.

Mixer/loader/applicator exposure estimates are based on the best available data at this time. Calculated dermal, inhalation, and combined (total exposure from dermal and inhalation routes) MOEs for mixer/loaders and applicators of quinclorac exceeded target MOEs for all scenarios and are not of concern. Tables 1 and 2 of Appendix VI summarize the calculated MOEs for mixer/loaders and applicators.

Post-application 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, scouting) with quinclorac residues. Based on the quinclorac use pattern, there is potential for short-term (< 30 days) postapplication exposure to quinclorac residues for workers.

Activity-specific transfer coefficients (TC) from the Agricultural Re-entry Task Force (ARTF) were used to estimate postapplication exposure resulting from contact with treated foliage at various times after application. Dislodgeable foliar residue (DFR) refers to the amount of residue that can be dislodged from a surface such as the leaves of a plant. A TC is a factor that relates worker exposure to dislodgeable residues. TCs are specific to a given crop and activity combination (for example, hand harvesting apples, scouting late season corn) and reflect standard clothing worn by adult workers. Post-application exposure activities include (but are not limited to): scouting, weeding, and transplanting. For more information about estimating worker postapplication exposure, refer to PMRA's regulatory proposal PRO2014-02 *Updated Agricultural Transfer Coefficients for Assessing Occupational Post-Application Exposure to Pesticides.*

There were no chemical specific dislodgeable foliar residue (DFR) studies submitted to the PMRA for the re-evaluation of quinclorac; therefore the following defaults were used:

- A default peak value of 25% of the application rate with a dissipation rate of 10% per day was used for DFR

PMRA's science policy note SPN2014-02, *Estimating Dislodgeable Foliar Residues and Turf Transferable Residues in Occupational and Residential Post-application Assessments* presents further details on the derivation and use of these defaults for pesticide 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. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures above the target MOE.

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 quinclorac, inhalation exposure is not likely to be of concern provided that the minimum 12-hour REI is followed.

Calculated dermal MOEs for worker postapplication exposure to quinclorac exceeded target MOEs and are not of concern. REIs were set at the standard minimum value of 12 hours for all postapplication activities in agricultural settings. The postapplication exposure assessment is outlined in Appendix VI, Table 2. For guidance on REI's please refer to the "Guidance for Federal/Provincial/Territorial Committee: Understanding Restricted Entry Intervals for Pesticides", which is available from the PMRA upon request.

Non-Occupational Exposure and Risk Assessment

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

Quinclorac is not registered for residential uses. Therefore, a risk assessment for this scenario is not required.

3.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all plausible exposure routes (oral, dermal, and inhalation). Since there are no residential uses for quinclorac, the aggregate exposure is from food and drinking water only, which are presented in Sections 3.2.2 and 3.2.4.

3.6 Cumulative Assessment

The *Pest Control Products Act* requires the Agency to consider the cumulative effects of pest control products that have a common mechanism of toxicity. A common mechanism of toxicity for quinclorac and other substances has not been identified, nor does quinclorac appear to produce a toxic metabolite in common with other substances. As such, consistent with the USEPA cumulative approach for quinclorac, no cumulative assessment is required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Quinclorac is highly soluble in water (857 mg a.i./L and 6,270 mg a.i./L at pH 5 and 7), has a very low vapour pressure ($<1 \times 10^{-9}$ mPa) and is not expected to volatilize (Table 1, Appendix A). Quinclorac does not hydrolyze. It does not phototransform in soil (half-life 162 days) unless photosensitizers, such as humic acid, natural oxidants and formulants, are present. Photosensitizers can greatly increase the phototransformation rate of quinclorac, making it a significant route of transformation (for example, half-life 7 days in presence of humic acid). Biotransformation studies indicate that quinclorac does not transform significantly in soil (shortest DT_{50} 168 days) or in aquatic environments (shortest DT_{50} 141 days). Quinclorac is a persistent chemical in aquatic and terrestrial environments unless photo-sensitizers are present.

Quinclorac is potentially very mobile in soil, with K_d values ranging from 0.05 to 0.597 and K_{oc} values ranging from 13 to 54. The Groundwater Ubiquity Score for quinclorac ranges from 4.4 to 7.4, indicating quinclorac has a high potential to leach in soils. The potential for leaching is supported by the water modelling assessment, but terrestrial field studies indicate very little quinclorac leaches below 15 cm. Quinclorac dissipates more rapidly under field conditions than results from laboratory studies suggest. Terrestrial field studies on bare soils indicate that quinclorac ranges from moderately persistent to persistent, with DT_{50} values ranging from 50 days (New Jersey loam) to 273 days (Alberta loam).

In the aquatic environment, field studies suggest quinclorac is short lived, with DT_{50} values of 2 to 5 days. Although not confirmed, the rapid dissipation of quinclorac in aquatic field studies may be due to the presence of humic acid or other photosensitizers in the water.

Quinclorac is not expected to bioaccumulate based the low log ocatanol/water partition coefficient (log Kow<1 at pH values of 5, 7 and 9). Laboratory studies indicate that quinclorac does not bioconcentrate in fish significantly. Environmental fate data for quinclorac are summarized in Table 1 of Appendix VII.

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 (in other words, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk, which in the case of quinclorac is not required.

4.2.1 Effects on Terrestrial Organisms

A summary of toxicity data for quinclorac is presented in Appendix VII, Table 2. For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with quinclorac. The risk assessment for foliar spray applications was conducted for three application rates (123.75 g a.i./ha, 101.25 g a.i./ha and 50 g a.i./ha) for the various crops on which it is used (wheat, canary seed, barley, oats, canola, barley, lentils, peas, sunflower) and considers both the in-field and off-field exposure.

Since foliar dissipation DT_{50} data were not available, a default half-life of 10 days was used to calculate the foliar EDE's (estimated daily exposure) for spray applications of quinclorac. In addition, the maximum nomogram residues were used to calculate the EDE's which is considered to be a screening level risk assessment.

Quinclorac does not pose an unacceptable risk to terrestrial invertebrates. The risk assessment showed that the risk from quinclorac to bees and earthworms was negligible (Appendix VII, Tables 3 and 4).

Birds and mammals were both found to be at negligible risk from consumption of food sources sprayed with quinclorac in-field, as well as food sources exposed to quinclorac from spray drift off-field (Appendix VII, Tables 5 and 6).

Quinclorac poses potential risks to non-target terrestrial plants from spray drift (Appendix VII, Table 7). Risk quotients are less than the LOC at application rates of 50 g a.i./ha, but slightly exceed the LOC at application rates of 101.25 and 123.75 g a.i./ha. This risk can be mitigated with spray buffer zones.

4.2.2 Risks to Aquatic Organisms

A summary of aquatic toxicity data for quinclorac is presented in Table 2 (Appendix VII). Although there was no chronic toxicity data available for estuarine/marine invertebrates or fish, due to the lack of effects in marine organisms and the lack of chronic and acute effects in freshwater organisms, effects are not expected and additional data are not required. For amphibians, the toxicity data from freshwater fish was used as a surrogate for the risk assessment.

At the screening level, risk quotients for freshwater (invertebrates, fish, amphibians and algae) and estuarine/marine (invertebrates, fish and algae) species did not exceed the acute and chronic LOC for spray drift or for direct application (Tables 8 – 16, Appendix VII). Laboratory studies indicate that quinclorac does not bioconcentrate in fish significantly. Quinclorac presents a negligible risk to aquatic organisms.

5.0 Value

Quinclorac offers effective control of certain grassy weeds, especially green foxtail, and certain broadleaved weeds, especially cleavers, in cereals and oilseed crops. Cereals and oilseed crops are important commodities produced in Western Canada. However, weed infestations are one of the limiting factors for their production and cause significant yield losses. Green foxtail is one of the most common and troublesome grassy weeds in cereals and cleavers has become a problem weed in oilseed crops, especially in canola. Both green foxtail and cleavers are increasing in abundance across the Prairie Provinces. Quinclorac effectively controls green foxtail and cleavers.

Herbicide resistant green foxtail (resistant to the Weed Science Society of America (WSSA) Group 1 and 3 herbicides) and cleavers (resistant to the WSSA Group 2 herbicides) have been reported in Western Canada. The herbicide resistant green foxtail and cleavers are an increasing problem for the production of cereals and oilseed crops. Quinclorac is one of the few herbicides available to manage the resistant biotypes of green foxtail and cleavers.

Quinclorac belongs to the synthetic auxin (WSSA Group 4) herbicides. Quinclorac mode of action is unique as it controls grassy weeds in addition to broadleaved weeds while other herbicides in this group control broadleaved weeds only. In addition, it can be used in broadleaved crops as well as in cereals, while other herbicides in this group can only be used in cereals due to the phytotoxicity to broadleaved crops. This unique characteristic has made quinclorac a good partner for co-formulation or in tank mixtures with other herbicides, resulting in broadened weed control spectrum and reduced number of applications to the crop field.

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: in other words, 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, Quinclorac and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[3] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Quinclorac does not meet Track 1 criteria and is not considered a Track 1 substance. See Appendix VIII, Table 17 for comparison with Track 1 criteria.
- Quinclorac does not form any transformation products that meet all Track 1 criteria.
- Technical grade quinclorac contains the Track 1 contaminants 1,2,4,5-tetrachlorobenzene, 1,2,3,4-tetrachlorobenzene 1,2,3,5- tetrachlorobenzene, pentachlorobenzene and hexachlorobenzene, which are identified in the *Canada Gazette*. The PMRA is managing the presence of these contaminants in accordance with the Agency's strategy to prevent or minimize releases, with the ultimate goal of virtual elimination, as described in DIR99-03.

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

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical are compared against the list in the *Canada Gazette.* The list is used as described in the PMRA Notice of Intent NOI2005-01[4] and is based on existing policies and regulations including DIR99-03 and DIR2006-02[5] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol).

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Incident Reports

Since 26 April 2007, registrants have been required by law to report pesticide incidents to the PMRA that are related to their products. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA. As of 8 January 2016, five human, six domestic animal and two environmental incidents involving quinclorac have been reported to the PMRA.

It was determined that there was little to no degree of association between the symptoms reported in the human and domestic animal incidents and the reported exposure scenarios. The environment incidents involved lawn damage following the residential use of a product. No human or domestic animal health, or environmental concerns were identified from the incident reporting data.

The incident report data was incorporated into the evaluation of quinclorac.

8.0 Organisation for Economic Co-operation and Development Status

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

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member country to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Quinclorac is currently acceptable for use in other OECD member countries, including Australia and the United States. As of 8 January 2016, no decision by an OECD member country to prohibit all uses of quinclorac for health or environmental reasons has been identified.

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

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

9.0 Proposed Regulatory Re-evaluation Decision

The PMRA is proposing that products containing quinclorac are acceptable for continued registration with the implementation of the proposed risk-reduction measures. New risk-reduction measures are proposed for end-use products to further protect the environment (Appendix X).

9.1 Proposed Regulatory Actions Related to Human Health

9.1.1 Proposed Label Amendments

- The label statement for a plant back interval (10 months) for canola may be removed.
- The plant back interval for rotational crops flax and lentils may be revised to 10 months.
- Add to DIRECTIONS FOR USE (For end-use products lacking REI statements):

  "The restricted entry interval is 12 hours after application for all agricultural uses."

9.1.2 Residue Definition for Risk Assessment and Enforcement

Based on metabolism studies on cereal crops *only*, the residue definition in plant and animal commodities was previously expressed as quinclorac *per se*. The subsequently submitted canola metabolism study has demonstrated that the major route of quinclorac biotransformation in oilseeds is through the formation of quinclorac methyl ester. Based on the canola study, the joint PMRA-USEPA risk assessment team concluded that the metabolite quinclorac methyl ester should be included in the residue definition (RD) for oilseeds (crop subgroup 20A). For all other registered primary and rotational crops, the RD should remain quinclorac *per se*. Based on the difference in metabolism observed in canola, additional metabolism data may be needed if/when use on other dissimilar commodities is proposed. The methyl ester metabolite was not observed in livestock studies and was not seen in the rat metabolism study. Thus, the RD in animal commodities remains quinclorac *per se*.

9.2 Proposed Regulatory Actions Related to the Environment

Quinclorac poses negligible risks to terrestrial organisms (mammals, birds, invertebrates) from exposure to food sources contaminated by direct application as well as sites contaminated by spray drift. Quinclorac also presents negligible risks to aquatic organisms, including aquatic plants and algae, from spray drift and direct overspray. Quinclorac poses a risk to non-target terrestrial plants, which can be mitigated with spray buffer zones.

9.2.1 Proposed Label Amendments

- Standard environmental hazard and advisory label statements.
- Spray buffer zones (2 – 4 metres) to protect non-target terrestrial plants.

10.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, can be found on the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website.

List of Abbreviations

↑	increased
↓	decreased
µg	micrograms
µL	microlitre
♀	female
♂	male
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
abs	absolute
ADD	Absorbed Daily Dose
ADI	allowable daily intake level
AHETF	Agricultural Handler Exposure Task Force
ALP	alkaline phosphatase
ALT	alanine transaminase
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
AST	aspartate transaminase
atm	atmosphere
ATPD	area treated per day
BAF	bioaccumulation factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
BWG	body weight gain
^{o}C	degree Celsius
CAF	composite assessment factor
cAMP	cyclic adenosine monophosphate
CAS	chemical abstracts service
cm	centimetre(s)
d	day(s)
DA	dermal absorption
DACO	data code
DAT	days after treatment
DEEM-FCID	dietary exposure evaluation model – food consumption intake database
DER	data evaluation report
DFR	dislodgeable foliar residue
DHT	dihydrotestosterone
DNT	developmental neurotoxicity study
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
DT_{75}	dissipation time 75% (the time required to observe a 75% decline in concentration)
DT_{90}	dissipation time 90% (the time required to observe a 90% decline in concentration)
dw	dry weight

EC	emulsifiable concentrate
EC_{05}	effective concentration on 5% of the population
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
EDE	estimated daily exposure
EEC	estimated environmental exposure concentration
EP	end-use product
ER_{25}	effective rate on 25% of the population
ER_{50}	effective rate on 50% of the population
EU	European Union
EUP	end-use product
EXAMS	exposure analysis modeling system
F0	parental generation
F1	first filial generation
F2	second filial generation
FC	food consumption
FDR	Food and Drugs Regulations
FE	food efficiency
Fg	microgram(s)
FIR	food ingestion rate
Fm	micrometre(s)
FRAC	Fungicide Resistance Action Committee
FSH	follicle stimulating hormone
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GLC	gas liquid chromatography
GLP	good laboratory practices
GR	granular
GSD	geometric standard deviation
ha	hectare(s)
Hb	hemoglobin
Hb	hemoglobin
hCG	human chorionic gonadotropin
Hct	hematocrit
HDT	highest dose tested
HED	Health Evaluation Division
HPLC	high performance liquid chromatography
hr	hour
ILV	independent laboratory validation
IPM	intergrated pest management
IUPAC	International Union of Pure and Applied Chemistry
IV	intravenous
K_a	dissociation constant
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
kg	kilogram(s)
K_{oc}	organic-carbon partition coefficient

K_{ow}	octanol-water partition coefficient
L	litre(s)
LADD	lifetime average daily dose
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LDT	lowest dose tested
LEACHM	leaching estimation and chemistry model
LH	luteinising hormone
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOEC	lowest observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
M/L/A	mixer/loader/applicator
MAP	mitogen-activated protein
mg	milligram(s)
mL	millilitre(s)
MMAD	mass median aerodynamic diameter
MOA	mode of action
MOE	margin of exposure
MOR	magnitude of residue
MRL	maximum residue limit
MRM	multi-residue method
MS	mass spectrometry
MTD	maximum tolerated dose
mth(s)	month(s)
N/A	not applicable
N/R	not required
N/S	not specified
ND	not determined
NM	not measured
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OC	organic carbon content
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
ORETF	outdoor residential exposure task force database
Pa	pascal
PAM	pesticide analytical manual
PBI	plant back interval
PCP	pest control product
PCT	percent crop treated
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment

ppm	parts per million
PRVD	proposed re-evaluation decision
PRZM	pesticide root zone model
PYO	pick your own facilities
q1*	cancer unit risk
RBC	red blood cells
RD	residue definition
REI	restricted entry interval
rel	relative
RfD	reference dose
RSD	relative standard deviation
RVD	re-evaluation decision
SG	soluble granule
SN	solution
SO	solid
SU	suspension
$t_{1/2}$	half-life
TC	transfer coefficient
TGAI	technical grade active ingredient
TLC	thin layer chromatography
TRR	total radioactive residues
TSMP	Toxic Substances Management Policy
TTR	turf transferable residue
URMULE	use requested minor use label expansion
US	United States
USEPA	United States Environmental Protection Agency
USC	use site category
USDA	United States Department of Agriculture
UV	ultraviolet
v/v	volume per volume dilution
WC	water consumption
WG	wettable granules
wk	week(s)
WSP	wettable granules in water soluble package
wt	weight

Appendix I Quinclorac Products Registered in Canada as of 5 January 2016, Excluding Discontinued Products or Products with a Submission for Discontinuation

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Net Contents	Guarantee[1]
25118	Commercial	BASF Canada Inc.	Accord Dry Flowable Herbicide	Dry flowable	1.1 kg – 10 kg	75%
31539	Commercial		Facet L	Solution	0.1-1000 L Bulk	180 g ae/L
28349	Commercial	E.I. DuPont Canada Company	Triton C 75 DF Herbicide	Wettable granules	700 g	QUC-57.8% MMM-11.5% MEX-5.8%
28622	Commercial		Triton C Herbicide	Wettable granules	785 g - 6.28 kg	QUC-51.55%; MEX-5.15%; MMM-10.30%;
30121	Commercial		Pp-Q52-105 Herbicide	Wettable granules	785 g - 6.28 kg	QUC-51.55% MMM-10.3% MEX-5.15%
30583	Commercial		PP-Q50-882 Herbicide	Dry flowable	500 g-600 kg	QUC-50% MMM-7.5% MEX-7.5% MEM-1.5%
31365	Commercial	Productierra	Clever Dry Flowable Herbicide	Dry flowable	1-10 kg	75%
31753	Commercial	Univar Canada Ltd.	Masterline Quinclorac	Dry flowable	1-10 kg	75%
28962	Manufacturing	BASF Canada Inc.	Accord Dry Flowable Bulk Herbicide	Dry flowable	10 kg - Bulk	75%;
25117	Technical		Quinclorac Technical	Not applicable	Bulk	98%
31364	Technical	Productierra	Technical quinclorac	Solid	1-100 kg	100%

1. QUC = quinclorac, MMM = thifensulfuron methyl, MEX = tribenuron methyl, MEM = metsulfuron methyl

Appendix II Registered Commercial Class Uses of Quinclorac as of 29 April 2014, Excluding Discontinued Products or Products with a Submission for Discontinuation[1]

Use Site Category[2]	Sites[3]	Weeds[4]	Maximum Application Rate (g a.e./ha)[5]	
			Single	Cumulative per year
13 - Terrestrial Feed crops 14 - Terrestrial food crops	Wheat (spring, durum) Prairie Provinces and Peace River Region of British Columbia only	Note[4]	124	124
13 - Terrestrial Feed crops 14 - Terrestrial food crops	Barley (spring) Prairie Provinces and Peace River Region of British Columbia only		101	101
13 - Terrestrial Feed crops	Canary seed Prairie Provinces and Peace River Region of British Columbia only	Green foxtail (including Group 1 and Group 3 resistant biotypes), volunteer flax, cleavers, barnyard grass, annual sow-thistle (suppression), perennial sow-thistle (suppression)	124	124
7 - industrial oilseed and fibre crops 13 - Terrestrial Feed crops 14 - Terrestrial food crops	Canola (*Brassica napus* – all varieties, including conventional, Clearfield, LibertyLink and Roundup Ready) Prairie Provinces and Peace River Region of British Columbia only		101	101
7 - industrial oilseed and fibre crops 13 - Terrestrial Feed crops 14 - Terrestrial food crops	Clearfield canola quality *Brassica juncea* (for example, canola quality *Brussica juncea* varieties with Clearfield trait) Prairie Provinces and Peace River Region of British Columbia only		101	101
14 - Terrestrial food crops	Brown and oriental tame mustard Prairie Provinces and Peace River Region of British Columbia only		101	101

1. All uses are supported by the registrants. Formulation types include solution, wettable granules or dry flowable. Ground application only and no aerial application is allowed. The maximum number of applications is one per season every second year. Note that the maximum number of applications per year was not stated on registered end-use product labels but was interpreted as such by PMRA based on the label instructions for each end-use product.
2. Use Site Category 1 to 14 belongs to the use sector AGRICULTURE AND FORESTRY.
3. Sites are listed either as stated on the label or as interpreted by the PMRA so as to achieve consistency in timing.
4. **When formulated as quinclorac alone:**
   Weeds controlled include: green foxtail (including Group 1 and Group 3 resistant biotypes), volunteer flax, cleavers, barnyard grass, annual sow-thistle (suppression), perennial sow-thistle (suppression).
   When co-formulated with thifensulfuron + tribenuron methyl:
   (1) weeds controlled include: annual smartweed (green smartweed, lady's thumb), annual sowthistle (1-4 leaf), ball mustard, chickweed (small (1-6 leaf) and actively growing but before crop canopy prevents thorough coverage of weeds), cleavers (1-4 whorls), groundsel (common), corn spurry, cow cockle, flixweed, hemp-nettle, kochia, lamb's-quarters, narrow-leaved hawk's-beard, redroot pigweed, Russian thistle, shepherd's purse, stinkweed, tartary buckwheat, volunteer rapeseed (will not control imazethapyr tolerant canola varieties, (e.g. canola varieties with the PURSUIT SMART™) trait), volunteer sunflower, wild buckwheat (cotyledon 1-3 leaf stage), wild mustard and (2) weeds suppressed including Canada thistle, round-leaved mallow, scentless chamomile, sow thistle and toadflax
   When co-formulated with thifensulfuron + tribenuron methyl + metsulfuron methyl:
   (1) weeds controlled include: annual smartweed (green smartweed, lady's thumb), cleavers (1-4 whorls), cow cockle, hempnettle, kochia, lamb's-quarters, narrow-leaved hawk's beard (up to 20 cm), redroot pigweed, Russian thistle, scentless chamomile, stinkweed, stork's-bill, white cockle, volunteer canola (will not control imazethapyr tolerant canola varieties (for example, Clearfield* varieties or other varieties with the Pursuit Smart* trait)), wild buckwheat, wild mustard and (2) weeds suppressed including Canada thistle Russian thistle and dandelion.
5. Rates of active ingredient were calculated by the PMRA.

Appendix III Toxicology Profile and Endpoints for Health Risk Assessment of Quinclorac

Table 1 Toxicity Profile of Quinclorac

Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to body weight ratios unless otherwise noted.

Study Type/Animal /PMRA #	Study Results
Toxicokinetic Studies	
Absorption, Distribution, Metabolism and Excretion Single or multiple doses, gavage or diet CD rats PMRA #1125145	**Absorption:** Almost completely absorbed following gavage administration (low or high single doses, or multiple doses). Peak plasma concentration was 0.5 h after a single dose (15 or 100 mg/kg bw); and 0.5/3.0 h (♂/♀) at 600 mg/kg bw. Quinclorac AUCs increased in an approximately linear fashion with dose level (single doses) from 15 mg/kg to 600 mg/kg; above 600 mg/kg the relationship was non-linear. The lack of linearity at doses above 600 mg/kg bw suggests that the mechanism for elimination was saturated. **Distribution:** Distributed widely. Highest tissue levels were noted at 30 minutes, which was greatest in the GI tract (129/115 µg/g, ♂/♀), followed by plasma (35.4/62.4 µg/g, ♂/♀) and kidneys (24.2/42.2 µg/g, ♂/♀). Levels in tissues decreased rapidly and were at or below the limit of measurement (<0.1 µg/g) at 72 and 120 h. **Metabolism:** The majority of excreted material (70-80%) was unchanged quinclorac. A glucuronide conjugate was the major component in the bile and also made up 2-5% of urinary radioactivity; an unidentified metabolite, less polar than the glucuronide conjugate, was also detected in the urine (1-4% of the administered dose). **Excretion:** >90% of the administered dose was excreted in urine over 5 days, mostly within 24 h (89.3% at 15 mg/kg bw, and 81.5% at 600 mg/kg bw, in 24 h), with 0.7 to 3.7% in faeces. The T½ of plasma elimination was approximately 3 and 12.5 h, at 15 and 600 mg/kg bw respectively. There were negligible amounts of ^{14}C in expired air. Both absorption and excretion were comparable between sexes.
Acute Toxicity Studies	
Acute oral toxicity $B_6C_3F_1$ mice PMRA #1126926	LD_{50} > 5000 mg/kg bw (♂&♀) Clinical signs included staggering, piloerection, apathy, and dyspnea. Animals that died had general congestive hyperemia; no abnormalities were noted in mice killed at scheduled sacrifice. **Low Toxicity**

Study Type/Animal /PMRA #	Study Results
Acute oral toxicity Wistar rats PMRA #1126924	LD_{50} > 2610 mg/kg bw (♂&♀) Clinical signs included dyspnea, apathy, staggering, spastic gait, ruffled fur, diarrhea, and cachexia. Animals that died had general congested lungs; no abnormalities were noted in rats killed at scheduled sacrifice. **Low Toxicity**
Acute oral toxicity Wistar rats PMRA #1126925	LD_{50} = 2680 mg/kg bw (♂&♀) LD_{50} = 3060 mg/kg bw (♂) LD_{50} = 2190 mg/kg bw (♀) Clinical signs were limited to dyspnea, excitation, piloerection, staggered gait and spastic gait. In animals that died, pathology findings included isolated bloody ulcerations in the glandular stomach, and bloody intestinal contents; no abnormalities were noted in rats killed at scheduled sacrifice. **Low Toxicity**
Acute oral toxicity ♀ Wistar rats PMRA #2313372	LD_{50} > 2000 mg/kg bw (♀) Clinical signs included an impaired general state, dyspnea, and piloerection. In animals that died, pathology findings included black erosions/ulcers in the glandular stomach, and red discoloration of the small intestine. **Low toxicity (♀)**
Acute dermal toxicity Wistar rats PMRA #1126927	LD_{50} > 2000 mg/kg bw (♂&♀) No clinical signs or local irritation were observed. **Low Toxicity**
Acute dermal toxicity Wistar rats PMRA #2313373	LD_{50} > 2000 mg/kg bw (♂&♀) No systemic clinical signs or local irritation were observed. No macroscopic pathological abnormalities were noted. **Low Toxicity**
Acute inhalation toxicity (nose-only exposure) Wistar rats PMRA #1126928	LC_{50} > 5.2 mg/L (♂&♀) No clinical signs, mortality or effects on bw. **Low Toxicity**

Study Type/Animal /PMRA #	Study Results
Acute inhalation toxicity (nose-only exposure) Wistar rats PMRA #2313374	LC_{50} > 5.5 mg/L (♂&♀) Clinical signs included accelerated respiration; other symptoms included red nasal discharge, squatting posture, and stained fur **Low Toxicity**
Primary skin irritation White Vienna rabbits PMRA #1126930	No mortalities or dermal reactions. **Non-irritating**
Primary skin irritation New Zealand White rabbits PMRA #2313377	MAS = 0.1, all scores zero by 48 h Moderate erythema was observed in all animals up to 1 h after removing dressings; slight erythema in one animal after 24h. **Minimally Irritating**
Primary eye irritation White Vienna rabbits PMRA #1126929	MIS (1 h) = 10/110 Irritation was limited to the conjunctivae, clearing by day 8: slight redness of conjunctivae, chemosis (clear by 72 h) and discharge (1 h only). **Minimally Irritating**
Primary eye irritation New Zealand White rabbits PMRA #2313375	MIS (1 h) = 10/110 Slight or moderate conjunctival redness, slight or moderate conjunctival chemosis and slight discharge were observed in all animals within 48 h after application, reversible within 72 h. **Minimally Irritating**
Dermal sensitization (Maximization method) Guinea pigs PMRA #1126910	**Dermal Sensitizer**
Dermal sensitization (Maximization method) Guinea pigs PMRA #2313379	**Negative (not a dermal sensitizer)**

Study Type/Animal /PMRA #	Study Results
Short-Term Toxicity Studies	
3-month toxicity study Diet $B_6C_3F_1$ mice PMRA #1126918	**NOAEL = 1000 mg/kg bw/day (♂&♀)** **LOAEL = 2202/2735 mg/kg bw/day (♂/♀),** based on ↓ bw, ↓ food efficiency, ↑ water intake (slight at this dose) **4555/5953 mg/kg bw/day (♂/♀):** ↓ kidney wt., slight ↑ fc No effects on clinical signs, mortality, haematology, or clinical chemistry
3-month toxicity study Diet $B_6C_3F_1$ mice PMRA #1126919	**85/129 mg/kg bw/day**: no adverse effects No adverse effects were observed on fc, water intake, bw, bwg, feed efficiency, incidence of clinical signs, mortality, organ absolute or relative weights, hematology, clinical chemistry parameters or gross pathology. Histopathology was not assessed. **Supplementary – single dose**
6-month toxicity study (sub-report to 78-week carcinogenicity study) Diet $B_6C_3F_1$ mice PMRA #1126936	**NOAEL not established (♂)** **LOAEL = 209 mg/kg bw/day (♂)**, based on ↓ bw (♂) **NOAEL = 1018 mg/kg bw/day (♀)** **LOAEL = 1929 mg/kg bw/day (♀)**, based on ↓ kidney wt.; ↓ bw (♀)
3-month toxicity study Diet Wistar rats PMRA #1126917	**NOAEL = 302/360 mg/kg bw/day (♂/♀)** **LOAEL = 930/1035 mg/kg bw/day (♂/♀)**, based on slight ↓ fc, ↑ water consumption, slight ↓ bw, ↓ Hct; ↑ ALT, ↑ AST, focal chronic interstitial nephritis in 4/10 (♂); ↓ Hgb (♀)
4-week toxicity study Range-finding Diet Beagle dogs PMRA #1125104	**912/906 mg/kg bw/day (♂/♀)**: clinical signs (vomiting), ↓ bw, ↓ fc, focal dilatation of the tubules of the kidneys with flattening of the epithelium & focal chronic interstitial nephritis (1♂ & 2♀), ↓ ALP; ↓ testes wt **NOAEL and LOAEL not established as study was considered supplementary – range-finding study**

Study Type/Animal /PMRA #	Study Results
12-month oral toxicity study Diet Beagle dogs PMRA #1126921	**NOAEL not established (♂)** **LOAEL = 33 mg/kg bw/day (♂)**, based on clinical signs (vomiting: ↑ number of dogs affected); ↓ bw (♂) **NOAEL = 34 mg/kg bw/day (♀)** **LOAEL = 133 mg/kg bw/day (♀)**, based on clinical signs (vomiting: ↑ number of dogs affected); ↓ bw (♀) **462/445 mg/kg bw/day**: ↓ food efficiency, ↓ bilirubin, ↓ creatinine, ↓ Ca, ↓ albumin, ↑ liver wt. (rel.), ↑ kidney wt. (rel.), mononuclear infiltration and single cell necrosis in liver, hydropic degeneration in kidney
21-day dermal toxicity study New Zealand White rabbits PMRA #1125101	**NOAEL ≥ 1000 mg/kg bw/day (♂&♀)** **LOAEL > 1000 mg/kg bw/day (♂&♀)**
Chronic Toxicity/Oncogenicity Studies	
78-week dietary chronic toxicity/carcinogenicity study $B_6C_3F_1$ mice PMRA #1126933 PMRA #1126935	**NOAEL not determined (♂/♀)** **LOAEL = 170/266 mg/kg bw/day (♂/♀)**, based on ↓ bw, ↓ kidney wt. (absol.) **1745/2272 mg/kg bw/day**: ↓ liver wt. (absol.) No effects on food consumption, mortality, clinical signs, haematology, gross pathology or histopathology. **No evidence of carcinogenicity**
78-week dietary chronic toxicity/carcinogenicity study Sub-report to 78-week carcinogenicity study (PMRA# 1126933/35) $B_6C_3F_1$ mice PMRA #1126936	**NOAEL = 42/60 mg/kg bw/day (♂/♀)** **LOAEL > 42/60 mg/kg bw/day (♂/♀),** based on the lack of toxicologically significant effects at the dose tested. No histopathology was performed, however, in the previous study no histopathological effects of toxicological importance were noted at 170/266 mg/kg bw/day (♂/♀). This study was carried out as a follow-up to the main 78-week study noted previously, using the same conditions but at a lower dose.

Study Type/Animal /PMRA #	Study Results
24-month dietary chronic toxicity/carcinogenicity study Wistar rats PMRA #1126923 PMRA #1126931 PMRA #1126932	**NOAEL = 443/549 mg/kg bw/day (♂/♀)** **LOAEL = 676/856 mg/kg bw/day (♂/♀)**, based on ↑ water intake, ↓ urinary protein levels, ↓ bw/bwg No compound-related effects on fc, food efficiency, mortality, clinical signs, ophthalmology, haematology, clinical chemistry, gross pathology or histopathology. **No evidence of carcinogenicity up to 443/549 mg/kg bw/day (♂/♀)(8000 ppm)** The data at 676/856 mg/kg bw/day (12000 ppm) was insufficient (too few rats) to permit a valid assessment of carcinogenicity; however, there were no indications of tumour induction, and individual organ tumour incidence did not show any dose-related trends.
Developmental/Reproductive Toxicity Studies	
2-generation dietary reproductive toxicity study Diet Wistar rats PMRA #1125092	**Parental Toxicity:** **NOAEL = 307 mg/kg bw/day (♂/♀)** **LOAEL = 914 mg/kg bw/day (♂/♀)**, based on ↓ fc, ↓ bwg during pre-natal period (♂&♀); ↓ bwg during lactation, ↑ incidence of interstitial nephritis (♀) **Offspring Toxicity:** **NOAEL = 307 mg/kg bw/day (♂/♀)** **LOAEL = 914 mg/kg bw/day(♂/♀)**, based on ↓ bwg in pups during post-natal period, slight decrease in F_{1a} & F_{2a} pup survival during post-natal period; delays in morphological development (ear unfolding in F_{1a}, ear opening in F_{1a} and F_{2a} and eye opening in F_{1a} and F_{2a} litters), likely associated with retarded growth. **Reproductive Toxicity:** **NOAEL ≥ 914 mg/kg bw/day (♂/♀) (HDT)** No adverse effects were noted **No evidence of sensitivity of the young**

Study Type/Animal /PMRA #	Study Results
Developmental toxicity study Gavage Wistar rats PMRA #1126937	**Maternal Toxicity:** **NOAEL = 146 mg/kg bw/day** **LOAEL = 438 mg/kg bw/day**, based on ↑ incidence of clinical signs (reduced nutritional status, poor general condition), ↑ mortality (deceased rats showed severe stomach ulceration), ↓ fc, ↑ water intake **Developmental Toxicity:** **NOAEL ≥ 438 mg/kg bw/day (HDT)** No adverse effects were noted. **No evidence of malformations** **No evidence of sensitivity of the young**
Developmental toxicity study Gavage Himalayan rabbits PMRA #1126938	**Maternal Toxicity:** **NOAEL = 200 mg/kg bw/day** **LOAEL = 600 mg/kg bw/day**, based on ↓ bw, ↓ bwg, ↓ fc, ↑ incidence of clinical signs of toxicity (reduced/absent defecation, diarrhea, poor general condition), mortality (5/15), ↑ early resorptions, ↓ litter size, ↑ incidence of post-implantation loss (resorption, abortion), ↓ uterine wt **Developmental Toxicity:** **NOAEL = 200 mg/kg bw/day** **LOAEL = 600 mg/kg bw/day**, based on ↑early resorptions, ↓ litter size, ↑ incidence of post-implantation loss (resorption, abortion), ↓ fetal bw **No evidence of malformations** **No evidence of sensitivity of the young**
Genotoxicity Studies	
Ames reverse mutation test S. typhimurium TA1535, TA100, TA1537, TA98 PMRA #1125103	**Negative**
Ames reverse mutation test S. typhimurium TA1535, TA100, TA1537, TA98 Escherichia coli WP2 uvrA PMRA #1125105 PMRA #1125099	**Negative**

Study Type/Animal /PMRA #	Study Results
Bacterial DNA repair (rec assay) Bacillus subtilis strains H17 (rec+) & M45 (rec-) PMRA #1125110	**Negative**
In vitro mammalian cell gene mutation test: CHO cells (HGPRT locus) Sub-strain K1 of Chinese Hamster Ovary cells PMRA #1125106	**Negative**
In vitro mammalian cell gene mutation test: CHO cells (HGPRT locus) Sub-strain K1 of Chinese Hamster Ovary cells PMRA #1125098	**Negative**
In vitro unscheduled DNA synthesis Hepatocytes prepared from a ♂Fischer 344 rat PMRA #1125112	**Negative**
In vivo/in vitro unscheduled DNA synthesis Wistar/WV ♂ rats PMRA #1125100	**Negative**
In vivo cytogenetic micronucleus test NMRI mice PMRA #1125108	**Negative**

Study Type/Animal /PMRA #	Study Results
In vivo mammalian bone marrow chromosome aberration test Chinese hamsters PMRA #1125109	**Negative**
In vivo mammalian bone marrow chromosome aberration test Chinese hamsters PMRA #2313381	**Negative**
In vitro cytogenetics Human lymphocytes PMRA #1125107	**Positive at cytotoxic doses** Quinclorac is clastogenic at cytotoxic levels, producing a slight elevation in the incidence of chromosome aberration.
In vitro cytogenetics Human lymphocytes PMRA #1125096	**Positive at cytotoxic doses** In this study a different batch of quinclorac was compared directly with the batch that had been used in the previous study. Both batches of quinclorac caused a significant increase in chromosome aberrations in the cultured human lymphocytes.
Neurotoxicity Studies	
90-day neurotoxicity study Diet Wistar rats PMRA #2313384	**NOAEL = 301/368 mg/kg bw/day (♂/♀)** **LOAEL = 976/1142 mg/kg bw/day** (♂/♀), based on slight ↓ bw (~5%) **No evidence of neurotoxicity**

Study Type/Animal /PMRA #	Study Results
Immunotoxicity Studies	
28-day immunotoxicity study Diet ♀ C57BL mice PMRA #2313383	**NOAEL ≥ 1760 mg/kg bw/day (♀)(HDT)** **No evidence of immunotoxicity**

Table 2 Toxicology Endpoints for Use in Health Risk Assessment for Quinclorac

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary study - general population (excluding females aged 13 – 49 years)	Developmental toxicity in the rabbit	Maternal NOAEL = 200 mg/kg bw/day Reduced body weight	100 PCPA factor = 1
	ARfD = 2.0 mg/kg bw		
Acute dietary study - females aged 13-49 years	Developmental toxicity in the rabbit	Maternal NOAEL = 200 mg/kg bw/day Increased early resorptions/abortions	300 PCPA factor = 3
	ARfD = 0.7 mg/kg bw		
Chronic dietary study	1-year dietary study in the dog	LOAEL[2] = 33 mg/kg bw/day Reduced body weight NOAEL/LOAEL is further supported by the NOAEL of 42 mg/kg bw/day in the 18-month mouse study	100 PCPA factor = 1
	ADI = 0.3 mg/kg bw/day		
Short/intermediate-term dermal/inhalation[3]	Developmental toxicity in the rabbit	Maternal NOAEL = 200 mg/kg bw/day Increased early resorptions/abortions	300
Cancer	Not considered oncogenic		

[1] CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* (PCPA) factors for dietary assessments; MOE refers to a target MOE for occupational assessments.
[2] An additional uncertainty factor for use of a LOAEL in male dogs was not required as effects were considered marginal.
[3] Since an oral NOAEL was selected, a dermal and inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Appendix IV Dietary Exposure and Risk Estimates for Quinclorac

Table 1 Dietary Exposure and Risk Estimates for Quinclorac

Population Subgroup	Acute Dietary (95th percentile)[1]		Chronic Dietary[2]	
	Food + Water		Food + Water	
	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw/day)	%ADI
Geneneral Population	--	--	0.00690	2
All Infants <1 year	0.04524	2	0.01947	6
Children 1-2 years	0.03003	1.5	0.01349	4
Children 3-5 years	0.02451	1	0.01073	3
Children 6-12 years	0.01780	<1	0.00731	2
Males 13-19 years	0.01370	<1	--	--
Youths 13-19 years	--	--	0.00520	2
Males 20-49 years	0.01847	<1	--	--
Adults 20-49 years	--	--	0.00679	2
Adults 50+ years	0.01280	<1	0.00573	2
Females 13-49 years	0.01460	2	0.00601	2

[1]Acute Reference Dose (ARfD) of 0.7 mg/kg bw applies to females aged 13-49 years; ARfD of 2 mg/kg bw applies to subpopulations other than females aged 13-49 years.
[2]Acceptable Daily Intake (ADI) of 0.3 mg/kg bw/day applies to the general population and all population subgroups.

Appendix V Food Residue Chemistry Summary

Metabolism in Livestock and Plants – The nature of the residue of quinclorac in plants and livestock was investigated in rice, sorghum, wheat, canola, lactating goat and laying hen. Based on metabolism studies in cereals (rice, sorghum and wheat), quinclorac undergoes hydroxylation of its quinoline ring, followed by conjugation (at the hydroxylated site) with glucose and other biologically available compounds. In each of these studies, the major radioactive residue in/on various matrices was identified as parent compound. Some radioactivity originated from minor amounts of the metabolite quinclorac methyl ester or was found to be incorporated into high molecular weight natural products. In canola (oilseeds), the metabolic pathway of quinclorac was different comparatively to the one found in cereal crops. The major route of quinclorac biotransformation in canola was through the formation of the metabolite quinclorac methyl ester. Based on the observed difference in the canola study, additional metabolism data may be needed if/when use on other dissimilar commodities is proposed. The methyl ester metabolite was not observed in livestock metabolism studies and was not seen in the rat metabolism study. Submitted studies showed that the two registered forms of quinclorac (acid and dimethylamine salt) are chemically and toxicologically equivalent.

Residue Definition – Based on metabolism studies on cereal crops *only*, the residue definition in plant and animal commodities was previously expressed as quinclorac *per se* for both enforcement and dietary risk assessment purposes. Based on the canola study, the joint PMRA-USEPA risk assessment team concluded that the quinclorac methyl ester metabolite should be included in the residue definition (RD) for oilseeds (crop subgroup 20A) for both risk assessment and enforcement purposes. For all other registered primary and rotational crops, the RD for risk assessment should include the methyl ester as well but the RD for enforcement should remain quinclorac *per se*. The RD in animal commodities is quinclorac *per se* for both enforcement and risk assessment purposes. The RD in drinking water (for risk assessment) is quinclorac *per se*.

Analytical Methodology – Adequate analytical methods have been developed for the determination of quinclorac and its methyl ester metabolite in plant and animal commodities. Previously submitted plant and livestock magnitude of the residue data were generated with data collection methods which included a methylation step, as do the currently accepted enforcement methods. These are GC-ECD methods which use methylation with diazomethane. Hence, although the RD for enforcement in crops other than oilseeds and in livestock commodities is expressed as quinclorac only, all previously established MRLs included both quinclorac and its methyl ester metabolite. However, new data collection methods have been submitted in connection with the petition for use on canola, which determined quinclorac and its methyl ester separately. These are LC-MS/MS methods with a validated LOQ of 0.05 ppm. In addition, the USEPA reported that there are USFDA multiresidue method (MRM) testing data which indicate that quinclorac is completely recovered using Protocol B. Quinclorac is currently not included in the scope of the Canadian Food Inspection Agency multiresidue method.

Magnitude of Residues – Field trial data on file, conducted at the registered label rates and preharvest intervals (PHIs), support the established MRLs for quinclorac. Quinclorac acid and quinclorac dimethylamine (DMA) salt were deemed chemically and toxicologically equivalent and are registered on the same crops. Thus, the two chemicals are covered by the same MRLs. Established MRLs are accessible through Health Canada's MRL Database. Canola is the representative crop for the crop subgroup 20A (rapeseed), which includes both brown and oriental tame mustards. Therefore, canola residue data were used to support the registration of brown and oriental tame mustards.

Crop Rotation Studies – Confined crop rotation and field crop rotation trials on file support plant back intervals (PBIs) specified on quinclorac labels, in other words, 10-12 months PBI for canola, field peas, sunflowers and oats except for flax and lentils (22 months). With regard to flax and lentils, a registrant's petition to amend the recropping interval from 22 to 10 months was granted by the PMRA. This revision should be implemented on product labels. With regard to canola, a registrant's petition for registration of quinclorac use on canola and brown and oriental tame mustards (as primary crops) was granted by the PMRA. From a residue standpoint, this registration waives the necessity for plank back restrictions on canola and brown and oriental tame mustards.

Processing Studies – Processing studies on file were reviewed in past petitions and deemed adequate. The studies support the fact that residues in all processed commodities are covered by the respective MRL of the raw agricultural commodity (RAC) except for barley bran, for which a separate MRL (3.5 ppm) has been established.

Animal Derived Commodities Residue Data (from feeding of treated crops) – Feeding studies conducted with dairy cows and laying hens have been reviewed in past petitions and deemed adequate to support the MRL of 0.05 ppm (at the limit of quantitation) for residues of quinclorac in any livestock or dairy commodity. Grazing treated wheat or barley or cutting for hay is not allowed within 77 days of application. As the residue definition in canola feedstuff (canola meal) comprises an additional metabolite, the quinclorac methyl ester, a feeding study with this metabolite was required. A waiver request submitted by the registrant in this regard was granted by the PMRA on the basis that the quinclorac methyl ester residue level and the contribution of canola meal to livestock diet are negligible. An updated dietary burden calculation resulted in no modification of the currently established quinclorac MRL of 0.05 ppm in any livestock or dairy commodity. It was concluded that canola seed/grain and meal can be fed to livestock. However, grazing or feeding other portions of treated canola is prohibited. No data is available to support such use.

Data Gaps – No deficiencies were identified in the residue chemistry database with regard to currently registered uses of quinclorac (acid and DMA salt). No further data are required for continued registration.

Appendix VI Agricultural Mixer/Loader/Applicator and Post-Application Risk Assessment

Table 1 Commercial Mixer/Loader/Applicator Exposure and Risk Assessment

Crop	Formulation	Application Equipment	Max Rate (kg a.i./ha)	ATPD (ha/day)	Dermal Exposure[a] (mg/kg bw/day)	Inhalation Exposure[b] (mg/kg bw/day)	Dermal MOE[c]	Inhalation MOE[c]	Combined MOE[d]
Baseline PPE: single layer, no gloves, open M/L, open cab Application									
All (wheat, barley, canary seed, canola varieties, and brown and oriental tame mustard)	Liquid	Groundboom - custom	0.124	360	0.0469	0.001428	4300	140000	4100
	Dry flowable			360	0.1098	0.001105	1800	180000	1800
	Wettable granules			360	0.1098	0.001105	1800	180000	1800

M/L = mix/load, A = apply, ATPD = area treated per day, MOE = margin of exposure
[a] Dermal exposure (mg/kg bw/day) = (dermal unit exposure × ATPD × maximum application rate × 100% default dermal absorption)/80 kg body weight
[b] Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/80 kg body weight
[c] MOE = NOAEL (mg/kg bw/day) / Exposure (mg/kg bw/day), based on a NOAEL of 200 mg/kg bw/day, target MOE = 300
[d] Combined MOE = NOAEL / dermal exposure + Inhalation Exposure

Table 2 Commercial Post-application Exposure and Risk Assessment

Crop[a]	Activity	TC[b] (cm^2/hr)	Max application rate (kg a.i./ha)	DFR[c] (ug/cm^2)	Number of applications per year	Dermal Exposure[d] (mg/kg bw/day)	Dermal MOE[e]	REI[f] (hours)
All (large field crops: wheat, barley, canary seed, canola varieties, and brown and oriental tame mustard	Weeding (hand)[g]	70	0.124	0.31	1	0.00217	92000	12
	Scouting	1100	0.124	0.31	1	0.0341	5900	

[a] Based on application timing at the 1-6 leaf stage for crops
[b] TC = Transfer coefficient. The TC values are from the PMRA Transfer Coefficient Memo (PMRA, 2012a)

[c] DFR = Dislodgeable Foliar Residue. Since no DFR studies were submitted, a peak default DFR value of 25% of the application rate and a dissipation rate value of 10%/day were used.
[e] Dermal exposure (mg/kg bw/day) = DFR (ug/cm²) × TC (cm²/hr) × work duration (8 hr) × DA (default 100%) / BW (80kg)
[e] MOE = NOAEL (mg/kg bw/day) / Exposure (mg/kg bw/day), based on an oral NOAEL of 200 mg/kg bw/day and a target MOE of 300
[f] If the target MOE is met, the minimum REI is set at 12 hours.
[g] The TC value for maximum foliage density was considered as a worst case scenario for the risk assessment

Appendix VII Fate, Toxicity and Risks to the Environment

Table 1 Fate and Behaviour in the Environment

Study type	Test material	Study Conditions	Value or Endpoint	Interpretation	Transformation products*	Reference
Hydrolysis	Quinclorac	pH 5, 7 and 9. 25^{0}C.	$T_{1/2}$ pH 5: stable $T_{1/2}$ pH 7: stable $T_{1/2}$ pH 9: stable	Does not hydrolyze.	Not relevant.	PMRA
Phototransformation – soil	Quinclorac	25^{0}C, 30 day study	$T_{1/2}$ 162 days extrapolated 529 days dark control 7 days with humic acid 24 hours with H_2O_2sensitized	Not a route of transformation unless photo-sensitizers present.	None identified.	PMRA
Phototransformation – water		25^{0}C , 35 day study	$T_{1/2}$ 100 days nonsensitized 45 days acetone sensitized	Not a route of transformation unless photo-sensitizers present	None identified.	PMRA
		25^{0}C	$T_{1/2}$ 100 days nonsensitized 7 days humic acid sensitized. 24 hours H_2O_2 sensitized	Not a route of transformation unless photo-sensitizers present	None identified.	PMRA
		25^{0}C, 30 day study	$T_{1/2}$ 15.7 days technical active 5.3 days formulated product contains photo sensitizers.	Can be an important route of transformation if photo-sensitizers present	20% CO_2	PMRA
Biotransformation						
Soil- aerobic	Quinclorac	Silt loam. 23^{0}C pH 6.4. 2.5% O.M. 12 month study	DT_{50} >12 months	Persistent. Not a route of transformation	No CO_2 formed over 240 days. 84% applied radioactivity remained as parent at day 360.	PMRA
		Silt loam. 23^{0}C pH 6.4. 0.6% O.M. 12 month study	DT_{50} >12 months	Persistent. Not a route of transformation	No CO_2 formed over 240 days. 84% applied radioactivity remained as parent at day 360.	PMRA
		Clay. 25^{0}C pH 6.9. 1.7% O.M.12 month study	DT_{50} 168 days	Persistent. Not an important route of transformation	2-OH-quinclorac 12.4% and quinclorac methyl ester 3% at day 364. Parent 58.1% at day 364.	PMRA
		Loamy sand. 25^{0}C pH 6.8. 1.2% O.M.12 month study	DT_{50} 391 days	Persistent. Not a route of transformation	2-OH-quinclorac 8.1 % and quinclorac methyl ester 7.8% at day 364. Parent 58.1% at day 364.	PMRA

Study type	Test material	Study Conditions	Value or Endpoint	Interpretation	Transformation products*	Reference
		Silt. 25^{0}C. 1.1% O.M. 138 day study	DT_{50} > 138 days	Not an important route of transformation	5.4% CO_2 at day 138.	PMRA
Soil – anaerobic	Quinclorac		No data			
Water/sediment - aerobic	Quinclorac	23^{0}C. Rice field water-sediment system. 12 month study in dark.	DT_{50} >12 months	Persistent. Not a route of transformation	CO_2 5.4% day 360	PMRA
		23^{0}C. Rice field water-sediment system. 12 month study in dark.	DT_{50} 141 days	Moderately persistent. Not an important route of transformation	CO_2 8.8%, parent 61% applied at 6 moths.	PMRA
		Clay. Well water. 30 day study in dark.	DT_{50} > 30 days 339 days extrapolated	Persistent. Not a route of transformation	CO_2 0.67%, parent 95% applied at day 30	PMRA
		Loam. Well water. 30 day study in dark.	DT_{50} >30 days 1229 days extrapolated	Persistent. Not a route of transformation	CO_2 8.8%, parent 94% applied at day 30	PMRA
Water/sediment-anaerobic	Quinclorac	23^{0}C. Rice field water-sediment system. 12 month study in dark.	DT_{50} >12 months	Persistent. Not a route of transformation	None identified.	PMRA
		23^{0}C. Rice field water-sediment system. 12 month study in dark.	DT_{50} >12 months	Persistent. Not a route of transformation	None identified.	PMRA
		25^{0}C. Loam sediment-well water system. 180 day study.	DT_{50} 1691 days extrapolated	Persistent. Not a route of transformation	None identified. Parent 90% applied at 6 months.	PMRA
		25^{0}C. Clay sediment-well water system. 180 day study.	DT_{50} 2263 days extrapolated	Persistent. Not a route of transformation	None identified. Parent 84% applied at 6 months.	PMRA
Mobility						
Adsorption/ desorption	Quinclorac	OC =0.2%, pH 6.6, sand	K_d = 0.05 K_{oc}= Not reported	Very high mobility	Not reported	PMRA
		OC = 0.9%, pH 6.8, sandy loam	K_d = 0.67 K_{oc}= 13	Very high mobility	Not reported	PMRA
		OC = 1.1%, pH 6.3, loam	K_d = 0.258 K_{oc}= 40	Very high mobility	Not reported	PMRA
		OC = 1.9%, pH 6.6, clay	K_d = 0.597 K_{oc}= 54	High mobility	Not reported	PMRA
		OC = 2.5%, pH 7.1, silty clay	K_d = 0.516 K_{oc}= 36	High mobility	Not reported	PMRA
		OC = 0.2%, pH 6.6, sand	K_d = 1.56 K_{oc}= 1300	High mobility	3-chloro-8-quinilinecarboxylic acid reported	PMRA
		OC = 0.9%, pH 6.8, sandy loam	K_d = 1.97 K_{oc}= 860	Moderate mobility	3-chloro-8-quinilinecarboxylic acid reported	PMRA
		OC = 1.1%, pH 6.3, loam	K_d = 11.4 K_{oc}= 1780	Low mobility	3-chloro-8-quinilinecarboxylic acid reported	PMRA

Study type	Test material	Study Conditions	Value or Endpoint	Interpretation	Transformation products*	Reference
		OC = 1.9%, pH 6.6, clay	K_d = 13.3 K_{oc}= 1210	Low mobility	3-chloro-8-quinilinecarboxylic acid reported	PMRA
		OC = 2.5%, pH 7.1, silty clay	K_d = 30.2 K_{oc}= 2080	Low mobility	3-chloro-8-quinilinecarboxylic acid reported	PMRA
Soil column leaching	Quinclorac		No studies available			
Field Studies						
Field dissipation	Quinclorac	Multiyear study of 3 bare loam soils in Manitoba, Alberta and Saskachewan. Irrigated with 110% normal precipitation.	DT_{50} 217 days Manitoba DT_{50} 273 days Alberta DT_{50} 15 days Saskatchewan	Persistent Manitoba and Alberta. Saskachewan site possibly due to photosensitizers present soil but not confirmed. No leaching below 15 cm depth.	Not identified.	PMRA
		655 day study in bare sandy clay loam North Dakota, pH 7.1, 2.5% OM. 2 applications 99 days apart.	DT_{50} 128 days 1st application DT_{50} 145 days 2nd application	Moderately persistent. 98% applied radioactivity recovered from 0-15 cm depth and 2% from 15-30 cm depth.	Not identified.	PMRA
		Quinclorac applied to turf (Silt loam) in Oregon and New Jersey sites.	DT_{50} 66 days Oregon DT_{50} 50 days New Jersey	Persistent and moderately persistent, respectively. 76-100% applied radioactivity recovered from top 15 cm depth and remainder from 15-30 cm depth.	Not identified.	PMRA

Table 2 Toxicity to Non-Target Species

Organism	Study type	Species	Test material	Endpoint	Value* (effect)	Effect of concern	Reference
Terrestrial Species							
Invertebrate	Acute contact. Since control populations had 11.3% and 8.6% mortality it was not possible to derive a valid LD_{50}	Honey bee (*Apis mellifera*)	Quinclorac	Max. Conc.	24.1 % mortality	Conc. Tested = 181.3 µg a.i. /bee	PMRA
				Max. conc.	21% mortality	Conc. Tested = 357 µg a.i. /bee	PMRA
				48 h LD_{50}	µg a.i. /bee	Mortality	PMRA
	Acute contact	Earthworm (*Eisenia foetida*)	Quinclorac	14 d LC_{50}	>4000 mg a.i./kg soil	Mortality	PMRA
				NOEC	4000 mg a.i./kg soil	Mortality	PMRA
Birds	Acute oral	Mallard (*Anas platyrhynchos*)	Quinclorac	LD_{50}	2000 mg a.i./kg bw	Mortality	PMRA

Organism	Study type	Species	Test material	Endpoint	Value* (effect)	Effect of concern	Reference
Terrestrial Species							
		Bobwhite Quail (*Coturnix virginianus*).		LD_{50}	2000 mg a.i./kg bw	Mortality	PMRA
	Dietary	Bobwhite Quail (*Coturnix virginianus*).	Quinclorac	LC_{50}	>5000 mg a.i./kg diet	Mortality	PMRA
		Mallard (*Anas platyrhynchos*)		LC_{50}	>5000 mg a.i./kg diet	Mortality	PMRA
	Reproduction	Bobwhite Quail (*Coturnix virginianus*).	Quinclorac	NOEL	106 mg a.i./kg bw	Embryonic Mortality, hatchling success, body wt.	PMRA
		Mallard (*Anas platyrhynchos*)		NOEC	56.6 mg a.i./kg bw	Embryonic Mortality, hatchling success, body wt.	PMRA
Mammals	Acute oral	Rat	Quinclorac	LD_{50}	3060 mg a.i./kg bw male 2190 mg a.i./kg bw female	Mortality	PMRA
				LD_{50}	>2000 mg a.i./kg bw	Mortality	PMRA
	Reproduction	Rat	Quinclorac	NOEL	>438 mg a.i./kg bw /day	Developmental	PMRA
				NOEL	160 mg a.i./kg bw /day	Reproduction 2 generation. Reduced pup viability.	PMRA
		Rabbit		NOEL	200 mg a.i./kg bw /day	Developmental. Fetal resorption	PMRA
Freshwater Invertebrates	Acute	*Daphnia magna*	Quinclorac	48-h LC_{50}	113.4 mg a.i./L	Immobility	PMRA
	Acute	*Daphnia magna*		48-h EC_{50}	28.9 mg a.i./L	Immobility	PMRA
	Acute	*Daphnia magna*		48-h EC_{50}	>100 mg a.i./L	Immobility	PMRA
	Acute	*Daphnia magna*	Quinclorac + BAS 864 01S 1:12 ratio.	48-h EC_{50}	33.1 mg a.i./L	Immobility	PMRA

Organism	Study type	Species	Test material	Endpoint	Value* (effect)	Effect of concern	Reference
Terrestrial Species							
	Chronic	*Daphnia magna*	Quinclorac	21 d NOEC	110 mg a.i. /L	Growth and reproduction	PMRA
Estuarine/ marine Invertebrates	Acute	Blue crab *(Callinectes sapidus)*	Quinclorac	48-h LC_{50}	>100 mg a.i./L	Mortality	PMRA
		Quahog clam (*Mercenaria mercenaria*)		48-h EC_{50}	>100 mg a.i./L	Mortality	PMRA
		Mysid (*Americamysis bahia*)		96-h EC_{50}	67 mg a.i./L	Mortality	PMRA
	Chronic		Quinclorac		No data		PMRA
Freshwater Fish	Acute	Rainbow trout (*Oncorhynchus mykiss*)	Quinclorac	96-h LC_{50}	>100 mg a.i./L	Mortality	PMRA
				96-h LC_{50}	>100 mg a.i./L	Mortality	PMRA
		Bluegill sunfish (*Lepomis macrochirus*)	Quinclorac	96-h LC_{50}	>100 mg a.i./L	Mortality	PMRA
			Quinclorac + BAS 864 01S 1:12 ratio.	96-h LC_{50}	33.3 mg a.i./L	Mortality BAS 864 01S 1:12 ratio.	PMRA
	Chronic (Early Life Stage)	Fathead Minnow	Quinclorac	NOEC	16 mg a.i./L	Larval growth	PMRA
Estuarine/ marine Fish	Acute	Sheepshead minnows (*Cyprinodon variegatus*)	Quinclorac	96-h LC_{50}	>100 mg a.i./L	Mortality	PMRA
	Chronic		Quinclorac		No data		PMRA
Freshwater Plants & Algae	Acute	Marine diatom *(Skeletonema costatum)*	Quinclorac	EC_{50}	>500 mg a.i./L	Biomass	PMRA
		Freshwater diatom *(Navicula pelliculosa)*		EC_{50}	>500 mg a.i./L	Biomass	PMRA
		Blue-green alga *(Anabena flos-aquae)*		EC_{50}	>500 mg a.i./L	Biomass	PMRA

Organism	Study type	Species	Test material	Endpoint	Value* (effect)	Effect of concern	Reference
Terrestrial Species							
		Green alga (*Selenastrum capricornutum*)		EC_{50}	>500 mg a.i./L	Biomass	PMRA
		Duckweed (*Lemna gibba)*		EC_{50}	>500 mg a.i./L	Biomass	PMRA
* Values Used In Risk Assessment Highlighted In Bold Font							

Screening Level Risk Assessment for Terrestrial Invertebrates

Table 3 Risk Assessment for Honey Bees from Direct Applications and Off-Site Spray Drift of Quinclorac

Crop	Quinclorac Appl. Rate* g a.i./ha	Quinclorac EEC* Direct Overspray µg a.i./bee	Direct Overspray Acute RQ = EEC/Tox Endpoint **	Quinclorac EEC Spray Drift*** mg a.i./kg soil	Spray Drift Acute RQ = Spray Drift / Tox Endpoint
Wheat, canary seed	123.75	0.297	0.002	0.033	0.000
Canola, barley, wheat, canary seed	101.25	0.243	0.001	0.027	0.000
Wheat, barley, canola, lentils, peas, sunflower , oats, lentils	50.0	0.120	0.001	0.013	0.000

* EEC = Application rate (0.123 kg a.i./ha × 2.4 µg a.i./be per kg a.i./ha.
** Toxicity endpoint for quinclorac is NOEL = 181.3 µg a.i./bee
***Spray drift 11% ground boom applications

Table 4 Risk Assessment for Earthworms from Direct Applications and Off-Site Spray Drift of Quinclorac

Crop	Quinclorac Appl. Rate* g a.i./ha	Quinclorac EEC in soil Direct Overspray mg a.i./kg soil	Direct Overspray Acute RQ = EEC/Tox Endpoint *	Quinclorac EEC in soil Spray Drift** mg a.i./kg soil	Spray Drift Acute RQ = Spray Drift in Soil / Tox Endpoint
Wheat, canary seed	123.75	0.055	0.0	0.00605	<0.1
Canola, barley, wheat, canary seed	101.25	0.045	0.0	0.00495	<0.1
Wheat, barley, canola, lentils, peas, sunflower , oats, lentils	50.0	0.022	0.0	0.00242	<0.1

* Tox Endpoint for quinclorac = 0.5 × 4000 mg a.i./kg soil (LC_{50} = 2000 mg a.i./kg soil)
**Spray drift 11% ground boom applications

Screening Level Risk Assessment for Birds and Mammals

Table 5 Screening Level Risk Quotients for Birds

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)				
Acute	200	Insectivore	10.07	0.05
Reproduction	56.6	Insectivore	10.07	0.18
Medium Sized Bird (0.1 kg)				
Acute	200	Insectivore	7.86	0.04
Reproduction	56.6	Insectivore	7.86	0.14
Large Sized Bird (1 kg)				
Acute	200	Herbivore (short grass)	5.08	0.03
Reproduction	56.6	Herbivore (short grass)	5.08	0.09

Table 6 Screening Level Risk Quotients for Mammals

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
Small Mammal (0.015 kg)				
Acute	219.00	Insectivore	24.72	0.1
Reproduction	160.00	Insectivore	24.72	0.15
Medium Sized Mammal (0.035 kg)				
Acute	219.00	Insectivore	21.67	0.1
Reproduction	160.00	Insectivore	21.67	0.13
Large Sized Mammal (1 kg)				
Acute	219.00	Herbivore (short grass)	41.38	0.19
Reproduction	160.00	Herbivore (short grass)	41.38	0.26

Risk Assessment for Non-Target Terrestrial Plants

Table 7 Risk Assessment for Non-target Terrestrial Plants from Direct Applications and Off-Site Spray Drift of Quinclorac

Crop	Quinclorac Appl. Rate* g a.i./ha	Tox. Endpoint EC_{25} g ae/ha	Quinclorac Appl. Rate* g a.i./ha	Direct Overspray Acute RQ = Appl. Rate EEC/ Tox Endpoint	Spray Drift* EEC g a.i./ha	Spray Drift Acute RQ = Spray Drift EEC/ Tox Endpoint
Wheat, canary seed	123.75	6.7	Seedling mergence	18.5	13.61	**2.0**
Canola, barley, wheat, canary seed	101.25	6.7	Seedling emergence	15.1	11.14	**1.7**
Wheat, barley, canola, lentils, peas, sunflower , oats, lentils	50.0	6.7	Seedling emergence	7.5	5.5	0.8
Wheat, canary seed	123.75	7.8	Vegetative Vigour	15.9	13.61	**1.7**

Crop	Quinclorac Appl. Rate* g a.i./ha	Tox. Endpoint EC_{25} g ae/ha	Quinclorac Appl. Rate* g a.i./ha	Direct Overspray Acute RQ = Appl. Rate EEC/ Tox Endpoint	Spray Drift* EEC g a.i./ha	Spray Drift Acute RQ = Spray Drift EEC/ Tox Endpoint
Canola, barley, wheat, canary seed	101.25	7.8	Vegetative Vigour	13.0	11.14	**1.4**
Wheat, barley, canola, lentils, peas, sunflower , oats, lentils	50.0	7.8	Vegetative Vigour	6.4	5.5	0.7
*Spray drift 11% ground boom applications, fine droplet size						

Screening Level and Refined Risk Assessment for Non-Target Aquatic Species

Table 8 Screening Level Acute Risk to Freshwater Invertebrates from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	Toxicity Endpoint mg a.i./L	Water Depth m	Quinclorac EEC Direct Application mg a.i./L	Acute RQ EEC/(0.5 × LC_{50})	Quinclorac EEC Spray Drift mg a.i./L	Acute RQ 11% Spray Drift
123.75	56.6	80	0.0155	<0.1	0.001705	<0.1
123.75	16.6	80	0.0155	<0.1	0.001705	<0.1
101.25	56.6	80	0.0127	<0.1	0.001397	<0.1
101.25	16.6	80	0.0127	<0.1	0.001397	<0.1
50.0	56.6	80	0.0063	<0.1	0.000693	<0.1
50.0	16.6	80	0.0063	<0.1	0.000693	<0.1

Table 9 Screening Level Risk to the Life Cycle of Freshwater Invertebrates from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	Toxicity Endpoint mg a.i./L	Water Depth m	Quinclorac EEC Direct Application mg a.i./L	Acute RQ EEC/NOEC	Quinclorac EEC Spray Drift mg a.i./L	Acute RQ 11% Spray Drift
123.75	110.0	80	0.0155	<0.1	0.001705	<0.1
123.75	110.0	80	0.0155	<0.1	0.001705	<0.1
101.25	110.0	80	0.0127	<0.1	0.001397	<0.1
101.25	110.0	80	0.0127	<0.1	0.001397	<0.1
50.0	110.0	80	0.0063	<0.1	0.000693	<0.1
50.0	110.0	80	0.0063	<0.1	0.000693	<0.1

Table 10 Screening Level Acute Risk to Freshwater Fish from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	Toxicity Endpoint mg a.i./L	Water Depth m	Quinclorac EEC Direct Application mg a.i./L	Acute RQ EEC/(0.5 × LC_{50})	Quinclorac EEC Spray Drift mg a.i./L	Acute RQ 11% Spray Drift
123.75	10.0	80	0.0155	<0.1	0.001705	<0.1
123.75	3.33	80	0.0155	<0.1	0.001705	<0.1
101.25	10.0	80	0.0127	<0.1	0.001397	<0.1
101.25	3.33	80	0.0127	<0.1	0.001397	<0.1
50.0	10.0	80	0.0063	<0.1	0.000693	<0.1
50.0	3.33	80	0.0063	<0.1	0.000693	<0.1

Table 11 Screening Level Chronic Risk to Freshwater Fish from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	Toxicity Endpoint **mg a.i./L**	**Water Depth m**	**Quinclorac EEC Direct Application mg a.i./L**	**Acute RQ EEC/NOEC**	**Quinclorac EEC Spray Drift mg a.i./L**	**Acute RQ 11% Spray Drift**
123.75	16.0	80	0.0155	<0.1	0.001705	<0.1
123.75	16.0	80	0.0155	<0.1	0.001705	<0.1
101.25	16.0	80	0.0127	<0.1	0.001397	<0.1
101.25	16.0	80	0.0127	<0.1	0.001397	<0.1
50.0	16.0	80	0.0063	<0.1	0.000693	<0.1
50.0	16.0	80	0.0063	<0.1	0.000693	<0.1

Table 12 Screening Level Acute Risk to Amphibians from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	Toxicity Endpoint **mg a.i./L**	**Water Depth m**	**Quinclorac EEC Direct Application mg a.i./L**	**Acute RQ EEC/(0.5 × LC_{50})**	**Quinclorac EEC Spray Drift mg a.i./L**	**Acute RQ 11% Spray Drift**
123.75	10.0	15	0.0825	<0.1	0.009075	<0.1
123.75	3.33	15	0.0825	<0.1	0.009075	<0.1
101.25	10.0	15	0.0675	<0.1	0.007425	<0.1
101.25	3.33	15	0.0675	<0.1	0.007425	<0.1
50.0	10.0	15	0.0333	<0.1	0.003663	<0.1
50.0	3.33	15	0.0333	<0.1	0.003663	<0.1

Table 13 Screening Level Chronic Risk to Amphibians from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	Toxicity Endpoint **mg a.i./L**	**Water Depth m**	**Quinclorac EEC Direct Application mg a.i./L**	**Acute RQ EEC/(0.5 × LC_{50})**	**Quinclorac EEC Spray Drift mg a.i./L**	**Acute RQ 11% Spray Drift**
123.75	16.0	15	0.0825	<0.1	0.009075	<0.1
123.75	16.0	15	0.0825	<0.1	0.009075	<0.1
101.25	16.0	15	0.0675	<0.1	0.007425	<0.1
101.25	16.0	15	0.0675	<0.1	0.007425	<0.1
50.0	16.0	15	0.0333	<0.1	0.003663	<0.1
50.0	16.0	15	0.0333	<0.1	0.003663	<0.1

Table 14 Screening Level Acute Risk to Estuarine/Marine Invertebrates from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	**Toxicity Endpoint mg a.i./L**	**Water Depth m**	**Quinclorac EEC Direct Application mg a.i./L**	**Acute RQ EEC/(0.5 × LC_{50})**	**Quinclorac EEC Spray Drift mg a.i./L**	**Acute RQ 11% Spray Drift**
123.75	33.5	80	0.0155	<0.1	0.001705	<0.1
101.25	33.5	80	0.0127	<0.1	0.001397	<0.1
50.0	33.5	80	0.0063	<0.1	0.000693	<0.1

Table 15 Screening Level Acute Risk to Estuarine/Marine Fish from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	Toxicity Endpoint **mg a.i./L**	**Water Depth m**	**Quinclorac EEC Direct Application mg a.i./L**	**Acute RQ EEC/(0.5 × LC_{50})**	**Quinclorac EEC Spray Drift mg a.i./L**	**Acute RQ 11% Spray Drift**
123.75	10.0	80	0.0155	<0.1	0.001705	<0.1
101.25	10.0	80	0.0127	<0.1	0.001397	<0.1
50.0	10.0	80	0.0063	<0.1	0.000693	<0.1

Table 16 Screening Level Acute Risk to Freshwater Algae from Exposure to Direct Overspray and Spray Drift of Quinclorac

Application Rate g a.i./ha	Toxicity Endpoint **mg a.i./L**	**Water Depth m**	**Quinclorac EEC Direct Application mg a.i./L**	**Acute RQ EEC/(0.5 × LC_{50})**	**Quinclorac EEC Spray Drift mg a.i./L**	**Acute RQ 11% Spray Drift**
123.75	250.0	80	0.0155	<0.1	0.001705	<0.1
101.25	250.0	80	0.0127	<0.1	0.001397	<0.1
50.0	250.0	80	0.0063	<0.1	0.000693	<0.1

Appendix VIII Toxic Substances Management Policy

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

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
Toxic or toxic equivalent according to the *Canadian Environmental Protection* Act[1]	Yes		Yes	-
Predominantly anthropogenic[2]	Yes		Yes	-
Persistence[3]	Soil	Half-life ≥ 182 days	Yes - Half-life 168 d to >365 d	Not available
	Water	Half-life ≥ 182 days	Yes - Half-life 141 d to > 365 d	Not available
	Sediment	Half-life ≥ 365 days	Yes - Half-life 141 d to >365 d	Not available
	Air	Half-life ≥ 2 days or evidence of long range transport	No - Volatilization is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the Quinclorac vapour pressure (< 1×10^{-9} mPa 20°C) and Henry's Law Constant (5.15×10^{-7} Pa m^3mole^{-1} pH 7).	-
Bioaccumulation[4]	Log $K_{OW} \geq 5$		No - Log K_{OW} <1	-
	Bioconcentration factor ≥ 5000		No - Bioconcentration factor < 1	-
	Bioaccumulation factor ≥ 5000		Not available	-
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	Not available

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

Appendix IX Water Modelling Data

Estimated environmental concentrations (EECs) of quinclorac in potential drinking water sources (groundwater and surface water) were estimated using computer simulation models. An overview of how the EECs are estimated is provided in the PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*. EECs of quinclorac in groundwater were calculated using the PRZMGW model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using PRZMGW are based on the flux, or movement, of pesticide into shallow groundwater with time. EECs of quinclorac in surface water were calculated using the Surface Water Concentration Calculator model, which simulates pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in two types of vulnerable drinking water sources, a small reservoir and a prairie dugout.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. The Level 1 EEC estimate is expected to allow for future use expansion into other crops at this application rate. Table 2 lists the application information and main environmental fate characteristics used in the simulations. Thirteen initial application dates between April and June were modelled for surface water modelling. Four initial dates were modelled in groundwater modelling. The model was run for 50 years for all scenarios. The largest EECs of all selected runs are reported in Table 1.

Table 1 Level 1 Estimated Environmental Concentrations of Quinclorac in Potential Drinking Water Sources

Compound	Groundwater EEC (µg a.i./L)		Surface Water EEC (µg a.i./L)	
			Reservoir	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
quinclorac	183	183	3.3	1.1

Notes:
1 90th percentile of daily average concentrations
2 90th percentile of 365-day moving average concentrations
3 90th percentile of the peak concentrations from each year
4 90th percentile of yearly average concentrations

Table 2 Water Modelling Inputs for Drinking Water Assessment of Quinclorac

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	wheat, barley, canary seed, canola and mustard
	Maximum allowable application rate per year (g a.i./ha)	124.2
	Maximum rate each application (g a.i./ha)	124.2
	Maximum number of applications per year	1
	Minimum interval between applications (days)	-
	Method of application	Ground, foliar
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	Stable
	Photolysis half-life in water (days)	200
	Adsorption K_{OC} (mL/g)	14 (20th percentile of five K_{OC} values for quinclorac)
	Aerobic soil biotransformation half-life (days)	920 000 (longer of two half-life values at 25ºC)
	Aerobic aquatic biotransformation half-life (days)	stable
	Anaerobic aquatic biotransformation half-life (days)	stable

Appendix X Label Amendments for Commercial Class Products Containing Quinclorac

The label amendments presented below do not include all label requirements for individual 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.

1. ENVIRONMENTAL HAZARDS

Add the following statements:

TOXIC *to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.*

LEACHING
This product demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of quinclorac in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

RUN-OFF
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.

2. DIRECTIONS FOR USE

Plant back interval (PBI):

- The label statement for a 10 month PBI for canola may be removed.
- The PBI for rotational crops flax and lentils may be reduced to 10 months (from 22 months).

For the end-use products lacking REI statements (i.e. Registration Number 25118):

The restricted entry interval is 12 hours after application for all agricultural uses.

The following statement is required for all agricultural and commercial pesticide 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.

DO NOT apply by air.

For field applications using conventional boom sprayers (agricultural or commercial products), the following statements are required:

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

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.

Buffer Zones for the Protection of Terrestrial Habitats from Spray Drift of Quinclorac

Method of application	***Crop***	***Application Rate g product/ha***	***Buffer Zones (metres) Required for the Protection of Terrestrial Habitats***
Field sprayer	*Wheat, canary seed*	*165*	*4*
	Canola, barley, wheat, canary seed	*135*	*3*
	Wheat, barley, canola, lentils, peas, sunflower , oats, lentils, flax	*87 - 99.5*	*2*

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.

References

Chemistry

Studies/Information submitted by the registrant

Registration Number 25117

PMRA Document Number	Reference
1364527	Data on the Physical and Chemical Characteristics of Quinclorac, the Technical Grade Active Ingredient Used in the Formulated End Use Product Facet Herbicide, DACO: 2.14.1,2.14.10,2.14.11,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9, 3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.7,3.5.8,3.5.9,3.6 CBI
1911534	2010, Physical properties of Quinclorac Technical Grade Active Ingredient (TC/TGAI) manufactured at [Privacy Info Removed], DACO: 2.14.1,2.14.2,2.14.3,2.14.4,2.14.9
1911536	2010, Determination of the solubility in water and the n-octanol / water partition coefficient for Technical Quinclorac (TGAI), DACO: 2.14.11,2.14.7
1364558	Spectra of Quinclorac Reg No. 150732 (PAI), DACO: 2.14.12
2310304	2001, Physical and Chemical Properties of Quinclorac (TC), DACO: 2.14.6
2310305	2010, Determination of the solubility in water and the n-octanol / water partition coefficient for Technical Quinclorac (TGAI), DACO: 2.14.11,2.14.7 CBI
2456672	2005, Determination of the OctanolNVater Partition Coefficient of Quinclorac (BAS 514H, RegNo 150732) TGAl at 20Â¿Â¿C, DACO: 2.14.11
2310306	2005, Determination of the solubility in organic solvents at 20Â°C of Quinclorac (BAS 514 H, Reg.No. 150 732) TGAI, DACO: 2.14.8 CBI
1364524	1988, Determination of the pKa-value of quinclorac in water, DACO: 2.14.10 CBI
2456668	2014, Response to PMRAÂ¿Â¿Â¿s Request to Clarify the Discrepancy Between the Provided and Literature Values for Water Solubility and Kow, DACO: 2.14.11,2.14.7
2310294	2013, Description of Starting Materials and Specifications, Quinclorac Technical, DACO: 2.11.2 CBI
2322970	2013, 3,7-dichloro-8-quinolinecarboxylic acid, Product Identification and Disclosure of Ingredients, Description of Manufacturing Process, DACO: 2.11.1,2.11.2,2.11.3 CBI

2310300	2010, Quali-Quantitative Analysis of five batches of Technical Quinclorac (TGAI) Manufactured at OCI Company Ltd., South Korea, DACO: 2.13.2,2.13.3 CBI
2310301	2011, Final Report: Determination of [CBI Removed], [CBI Removed] and the Total [CBI Removed] content in "BAS 514 H Quinclorac", DACO: 2.13.1,2.13.4 CBI
2412735	2014, Letter re: Ref: Ref. No. 2012-1632 – Chemistry Clarification, Quinclorac Technical
2412744	2014, TEA signal after exposure to light, DACO: 2.13.4 CBI
2412748	2014, HPLC [CBI Removed], DACO: 2.13.4 CBI
2412750	2014, HPLC [CBI Removed] spike experiments, DACO: 2.13.4 CBI
2456663	2014, Method Validation: Quinclorac Quantitative Determination of Tetra-, Penta- and Hexachlorobenzenes, DACO: 2.13.1 CBI
2456665	2014, Quinclorac: 5-Batch-Analysis Quantitative Determination of Tetra-, Penta- and Hexachlorobenzenes, DACO: 2.13.4 CBI

Registration Number 31364

PMRA Document Number	Reference
2260766	2012, Product Chemistry Testing of Quinclorac Technical, DACO: 2.14.1,2.14.2,2.14.3,2.14.4,2.14.6,2.16 CBI
2260772	2012, Preliminary Analysis Testing and Determination of the Ultraviolet-Visible Absorption Spectrum of Quinclorac Technical, DACO: 2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3 CBI
2260770	2012, Combined Storage Stability/Corrosion Characteristics Testing of Quinclorac 75% DF (WDG), DACO: 2.14.14 CBI
2260775	2012, QUINCLORAC TECHNICAL Source B Product Identity and Composition, Description of Beginning Materials, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4 CBI
2260773	2012, Preliminary Analysis Testing of Quinclorac Technical for Chlorobenzenes and [CBI Removed], DACO: 2.13.4 CBI
2260774	2012, Expert Statement Request for Test Exemption: [CBI Removed] during Quinclorac Synthesis, DACO: 2.13.4 CBI
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Toxicology

A. Studies/Information submitted by the registrant

PMRA Document Number	Reference
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1125094	1983, Report on the acute intraperitoneal toxicity in rats of Reg. No. 150 732 (BAS 514 H) (BCI #83-0117; 83/0242), DACO: 4.2.9
1125095 1126910	1986, 1987, Report on the maximization test for the sensitizing potential of Reg. No. 150 732 (BAS 514 H) in guinea pigs (BCI #86-0207/#91-0028; 86/117; 85/282; 30 H282/85), DACO: 4.2.6
1125096	1987, Comparative “in vitro” cytogenetics investigations in human lymphocytes with Reg. No. 150 732, batch CH 384 121 and Reg. No. 150 732, batch N32 (BCI #87-0112; 87/0555), DACO: 4.5.4
1125097	1986, Amendments 1988, Report on the study of the subchronic toxicity of Reg. No. 150 732 in rats after 3-months administration in the diet – Vol. I & II (BCI #91-0035; 86/057; 31 SO150/8413); (Amendment I, 88/0163); Amendment II, 88/0229)
1125098	1990, Report on the study on a point mutation test carried out on CHO cells (HGPRT locus) of Reg. No. 150 732 (BAS 514) (BCI #90-0008), DACO: 4.5.4
1125099 1125105	1988, Addendum 1990, Report on the study of Reg. No. 150-732 in the Ames Salmonella/mammalian microsome mutagenicity test and reverse mutation assay – E. coli WP2 uvrA (standard plate test and pre-incubation test) (BCI #91-0047; 88/0358; 85/2821; 40 MO282/854179) (Addendum BCI #91-0113; 88/5520), DACO: 4.5.4
1125100	1991, In vivo/in vitro unscheduled DNA synthesis in rat hepatocytes with Reg. No. 150 732 (BAS 514H) (BCI #91-0114; 91/10965), DACO: 4.5.4
1125101 1126922	1990, Report on the study of subacute 21-day repeated dose dermal toxicity with Reg. No. 150 732 (Quinclorac) in rabbits (BCI #89-0361 & 91-0039; 90/0021; 85/282; 245878; 41 H0282/859017), DACO: 4.3.4
1125103	1984, Report on the study of Reg. No. 150-732 in the Ames test (standard plate test with Salmonella typhimurium) (BCI #91-0046; 84/156), DACO: 4.5.4
1125104	1985, Report on the study of the toxicity of Reg. No. 150 732 (Quinclorac) in beagle dogs following 4-week administration in the diet (BCI #91-0057; 85/234; 30 DO117/8320), DACO: 4.3.1

1125106 1986, Report on a point mutation test carried out on CHO cells (HGPRT locus) with the test substance Reg. No. 150 732 (BAS 514.H) (BCI #91-0048; 86/214), DACO: 4.5.4

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1125108 1986, Report on a cytogenetic investigations in NMRI mice after a single oral administration of Reg. No. 150 732 – Micronucleus test (BCI #91-0050; 86/018; 26 MO150/8452), DACO: 4.5.4

1125109 1988, Report on the cytogenetic study in vivo of Reg. No. 150 732 in Chinese hamsters, bone marrow chromosome analysis, single oral administration (BCI #91-0051; 88/0186; 10 MO448/85100), DACO: 4.5.4

1125110 1987, Report on the mutagenicity evaluation of BAS 514.H in the rec-assay with Bacillus subtilis, (BCI #91-0052; 87/025; E-9533) final report, DACO: 4.5.4

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1125145 1986, The biokinetics and metabolism of ^{14}C-BAS 514H in the rat (BCI #92-0086; 86/431; 86/5013; BSF 425/86684), DACO: 6.4

1126917 1988, Report on the study of the subchronic toxicity of Reg. No. 150 732 in rats after 3-months administration in the diet (BCI #91-0035; 86/057; 84/150; 31 SO150/8413)(Amendment I: 88/0163)(Amendment II: 88/0229), DACO: 4.3.1

1126918 1988, Report on the study of the oral toxicity of Reg. No. 150 732 in mice after 3-months administration in the diet (BCI #91-0036; 88/0337; 85/282; 53 SO282/8566), DACO: 4.3.1

1126919 1988, Report on the study of oral toxicity of Reg. No. 150 732 in mice; administration in the diet over 3 months. Supplementary study (BCI #91-0037; 88/0338; 85/282; 53 SO282/85123), DACO: 4.3.1

1126921 1988, Report on the study of the toxicity of Reg. No. 150 732 in beagle dogs after 12 months administration in the diet (BCI #91-0038; 88/0029; 84/150; 33 DO150/8445), DACO: 4.4.1

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1126924 1988, Report on the study of the acute oral toxicity in rats of Reg. No. 150 732 (BCI #91-0021; 88/0171), DACO: 4.2.1

1126925 1983, Report on the study of the acute oral toxicity in rats of Reg. No. 150 732 – BAS 514.H, (BCI #91-0022; 83/240), DACO: 4.2.1

1126926	1986, Report on the study of the acute oral toxicity on the mouse based on OECD and USEPA (FIFRA) of Reg. No. 150 732 (BCI #91-0023; 86/401; 85/282-1), DACO: 4.2.1
1126927	1983, Report on the acute dermal toxicity in rats of Reg. No. 150 732 – BAS 514.H (BCI #91-0024; 83/244; 83-117), DACO: 4.2.2
1126928	1984, Report on the study of acute inhalation toxicity LC_{50} 4 hours (rat) of Reg. No. 150 732 – Dust/Aerosol Study (BCI #91-0025; 85/271), DACO: 4.2.3
1126929	1983, Report on the study of the irritation to the eye of the white rabbit based on Draize of Reg. No. 150 732 – BAS 514.H (BCI #91-0026; 83-171), DACO: 4.2.4
1126930	1983, Report on the study of the irritation to the intact and abraded dorsal skin of the white rabbit based on Draize of Reg. No. 150 732 – BAS 514.H (BCI #91-0027; 83-169), DACO: 4.2.5
1126933 1126935	1988, Report on the study of the potential carcinogenic effect of Reg. No.150 732 in mice; dietary administration for 78 weeks (BCI #91-0041; 88/0411b; 85/282; 80 SO282/8520), DACO: 4.4.1, 4.4.2
1126936	1988, Report on the study of the potential carcinogenic effect of Reg. No. 150 732 in mice; dietary administration for 78 weeks, supplementary study (BCI #91-0042; 88/0412; 85/282; 80 SO282/85107), DACO: 4.4.1, 4.4.2
	1988, Sub-report on satellite groups in the study of the toxicity of Reg. No. 150 732 in mice after 6 months administration in the diet (BCI #91-0042; 80 SO282/8520), DACO: 4.3.1
1126937	1987, Report on the study to determine the prenatal toxicity of Reg. No. 150-732 in rats after oral administration (gavage) (BCI #91-0043; 87/0167; 84/150; 34 R0150/8453), DACO 4.5.2
1126938	1988, Report on the study of the prenatal toxicity of Reg. No. 150-732 in rabbits after oral administration (gavage) (BCI #91-0044; 88/0099; 38 RO282/85111), DACO: 4.5.2
2313372	2005, BAS 514 H (Quinclorac) – Acute oral toxicity study in rats (10A0608/041085), DACO: 4.2.1
2313373	2005, BAS 514 H (Quinclorac) – Acute dermal toxicity study in rats (11A0608/041086), DACO: 4.2.2
2313374	2005, BAS 514 H (Quinclorac) – Acute inhalation toxicity study in Wistar rats, 4-hour dust exposure (13I0608/047015), DACO: 4.2.3
2313375	2005, BAS 514 H (Quinclorac) – Acute eye irritation in rabbits (11H0608/042245), DACO: 4.2.4
2313377	2005, BAS 514 H (Quinclorac) – Acute dermal irritation/corrosion in rabbits (18H0608/042244), DACO: 4.2.5

2313379	2005, BAS 514 H (Quinclorac) – Maximization test in Guinea pigs (30H0608/042246), DACO: 4.2.6
2313381	1993, Chromosome aberration test in the bone marrow of the Chinese hamster with test article Reg. No. 150 732, batch No. N 146 (ZST No.92/232) after single oral dosing (10M0232/929030; MPF/WT 9335), DACO: 4.5.7
2313383	2010, BAS 514 H (Quinclorac) – Immunotoxicity study in female C57BL/6 J Rj mice – Administration via the diet for 4 weeks (43C0081/01S005; ID 386032; #2010/1208709), DACO: 4.8(B)
2313384	2012, BAS 514 H (Quinclorac) – Repeated dose 90-day oral neurotoxicity study in Wistar rats – Administration via the diet (63C0081/01S016; ID 419473; #2012/1257671), DACO: 4.8

B. Additional Information Considered

Published Information

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2475657	2009, Quinclorac. Human health risk assessment for the proposed food/feed use of the herbicide (associated with section 18 registration) on cranberries in Massachusetts. USEPA Memorandum. PC Code: 128974, DP Number: 363604, June 2, 2009, DACO 12.5
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Dietary

A. Studies/Information submitted by the registrant

PMRA Document Number	Reference
1125115	Wood N.F. (1988) Metabolism of BAS 514 H in rice, BASF Corporation, BASF Report# M8702A, BASF Reg.# 88/5059, BCI# 92-0089, 40 pages, unpublished.

1125116 Ellenson J.L. (1993) Metabolism and Distribution of BAS 514 H in Sorghum Forage, Fodder and Grain, BASF Corporation, BASF Report# M9213, BCI# 93-0130, 95 pages, unpublished.

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1125145 Hawkins D.R., Kirkpatrick D., Dean G.M., Whitby B.R. and Biggs S.R. (1986) The biokinetics and metabolism of 14C-BAS 514H in the rat, Huntingdon Research Centre Ltd, HRC Report# BSF 425/86634, BASF Reg.# 86/5013, BCI# 92-0086, 195 pages, unpublished.

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