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Proposed Re-evaluation Decision

Chlormequat Chloride

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Overview

What is the Proposed Re-evaluation Decision?

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

An evaluation of available scientific information found that products containing chlormequat chloride do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of chlormequat chloride uses, new risk-reduction measures must be included on the labels of all products. No additional data are being requested at this time.

This proposal affects all end-use products containing chlormequat chloride registered in Canada. Once the final re-evaluation decision is made, the registrants 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 chlormequat chloride and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and 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 chlormequat chloride.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications.

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 DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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

Chlormequat chloride, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2007 RED, the USEPA concluded that chlormequat chloride was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

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

What is Chlormequat Chloride?

Chlormequat chloride is a plant growth regulator registered in Canada to inhibit plant elongation in ornamentals and winter wheat. Chlormequat chloride is applied by hand wand or groundboom equipment by farm workers and professional applicators.

Health Considerations

Can Approved Uses of Chlormequat Chloride Affect Human Health?

Chlormequat chloride is unlikely to affect your health when used according to the revised label directions.

People could be exposed to chlormequat chloride by consuming food and water, working as a mixer, loader or applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: 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 exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that chlormequat chloride was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and where appropriate, equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Chlormequat chloride is currently registered in Canada for use on winter wheat and could be used in other countries on crops that are imported into Canada. An MRL for chlormequat chloride is established for wheat at 1.0 ppm. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Chlormequat Chloride is Introduced into the Environment?

Chlormequat chloride is unlikely to affect non-target organisms when used according to the revised label directions.

Terrestrial and aquatic non-target organisms could be exposed to chlormequat chloride in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. In this screening level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some potential risk.

The USEPA concluded that the reregistration of chlormequat chloride was acceptable provided the risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and where appropriate, equivalent risk-reduction measures are required. Furthermore, the PMRA will require terrestrial buffer zones for chlormequat chloride to protect terrestrial plants from spray drift.

Measures to Minimize Risk

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

Human Health

- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Additional advisory label statements to reduce potential surface and groundwater contamination
- Buffer zones to protect non-target, sensitive terrestrial habitats

Data Requirements

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No other data requirements as a condition of continued registration are being requested at this time.

Next Steps

Before making a final re-evaluation decision on chlormequat chloride, the PMRA will consider all comments received from the public in response to this consultation document. 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

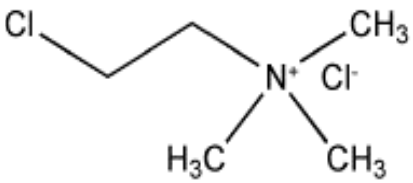
Chlormequat chloride is a plant growth regulator which acts to inhibit gibberellin biosynthesis, thereby inhibiting plant cell elongation.

Following the re-evaluation announcement for chlormequat chloride, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial end-use products in Canada.

The Pest Management Regulatory Agency (PMRA) used recent assessments of chlormequat chloride from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for chlormequat chloride, dated 27 September 2007, as well as other information on the regulatory status of chlormequat chloride in the United States can be found on the USEPA Pesticide Reregistration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	chlormequat chloride
Function	plant growth regulator
Chemical Family	Quaternary ammonium compound
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	2-chloroethyl trimethyl ammonium chloride
2 **Chemical Abstracts Service (CAS)**	2-chloro-*N*,*N*,*N*-trimethylethanaminium chloride
CAS Registry Number	999-81-5
Molecular Formula	$C_5H_{13}Cl_2N$
Structural Formula	

Molecular Weight	158.1 g/mol
Registration Number and Purity of the Technical Grade Active Ingredient	20581: 66% active ingredient (a.i.) 20582: 750 g a.i./L

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 139, No. 24, SI/2005-114 (2005-11-30), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25ºC	7.5×10^{-8} mm Hg
Solubility in water at 20ºC	1.0 kg/L
n-Octanol–water partition coefficient	log K_{ow} = -1.59 at pH 7

2.3 Comparison of Use Patterns in Canada and the United States

Chlormequat chloride is a plant growth regulator registered in Canada for use on winter wheat to produce shorter, thicker and stronger stems thereby improving resistance to lodging (leaning/bending/breaking), and on greenhouse ornamentals to enhance their aesthetic appearance by making the plants more compact with smaller, darker leaves. It acts by the inhibition of the gibberellin hormones. There are no residential uses registered in Canada. Currently registered in Canada, there are two technical products and one commercial product containing chlormequat chloride.

In Canada chlormequat chloride is used on:

- Winter wheat, applied in the spring, toward the end of tillering (the growth of side shoots) but not later than when the first node or joint can be felt at the base of the majority of tillers. Chlormequat chloride is applied to wheat as a single application (or as a split application), using groundboom foliar spray, with a total maximum application rate of up to 1380 g a.i./ha.

- Greenhouse ornamentals, applied when the plants are well-rooted and established, during the early periods of active growth. According to the current label, applications are made to geraniums and poinsettias by hand wand for drench application at a maximum rate of 3 g a.i./L. The current label is unclear on the maximum number of applications per crop cycle. The equivalent American product label indicates a maximum of two drench applications per crop cycle for poinsettias, therefore, a maximum of two applications per crop cycle is also proposed for greenhouse ornamentals for the Canadian product (see Appendix III for label amendments).

The American and Canadian use patterns were compared. The formulation, use sites, application methods and application rates registered in both countries are comparable. Based on this comparison of use patterns, it was concluded that the USEPA RED document was an adequate basis for the re-evaluation of chlormequat chloride use in Canada, with some additional PMRA assessments to evaluate the Canadian winter wheat use.

All current uses are being supported by the registrant and were, therefore, considered in the reevaluation of chlormequat chloride. Appendix I lists all chlormequat chloride products that are registered as of 7 April 2009, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2007 RED, the USEPA concluded that the end-use products formulated with chlormequat chloride would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

In Canada, exposure to chlormequat chloride may occur from the consumption of food and water, while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels where 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 populations (for example, children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

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 factors protective of the most sensitive population. 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. The USEPA's toxicological endpoints for assessing risk from occupational exposure are summarized in Appendix II.

Workers can be exposed to chlormequat chloride through mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

The USEPA did not select a toxicity endpoint for dermal exposure because no adverse systemic effect was observed up to the limit dose of 1000 mg/kg bw/day in a 21-day dermal toxicity study. However, based on acute dermal toxicity (USEPA toxicity category II) baseline personal protective equipment for all mixers, loaders, applicators and any other handlers was required. The current Canadian label states sufficient personal protective equipment (goggles or face shield; approved respirator; rubber, polyvinyl chloride, neoprene or nitrile gloves; hat, long-sleeved shirt, pants and rubber boots) to account for dermal exposure.

Exposure to chlormequat chloride for mixers, loaders and applicatiors via the inhalation route was assessed. Among the exposure scenarios identified in the RED document, the following scenarios were considered relevant to the Canadian situation:

- mixing and loading liquid concentrates for groundboom application;
- applying sprays via groundboom equipment; and
- mixing, loading or applying liquid concentrates with low-pressure handwand.

Quantitative handler exposure analyses were performed using the Pesticide Handlers Exposure Database. Exposure estimates for groundboom application assumed a maximum application rate of 4.15 kg a.i./ha and a treated area of 0.4 hectares per day. For low-pressure handwand application, exposure estimates assumed a maximum application rate of 4.07 g/L and 151.4 L applied per day.

The USEPA reported acceptable short/intermediate inhalation MOEs (in other words, >100) for all occupational exposure scenarios; therefore, no mitigation measures were required.

The RED adequately addressed potential inhalation exposure associated with the Canadian use on greenhouse ornamentals. For the Canadian use on winter wheat, the PMRA performed a short- and intermediate-term inhalation quantitative risk assessment for mixers, loaders and applicators via groundboom application, based on the Pesticide Handlers Exposure Database exposure units used in the USEPA occupational risk assessment. Exposure estimates for groundboom application assumed a maximum application rate of 1.38 kg a.i./ha and a treated area of 300 hectares per day. Using the toxicological endpoint established by the USEPA, MOEs were calculated to be 1910 for mixers and loaders and 3112 for applicators. The calculated MOEs are above the target MOE of 100 and, therefore, are not of concern. No further mitigation measures are required by the PMRA.

3.1.1.2 Postapplication Exposure and Risk

There was no dermal endpoint selected for chlormequat chloride; therefore, this route of exposure was not assessed. A quantitative risk assessment for inhalation exposure was not conducted. Due to the low vapour pressure of chlormequat chloride, inhalation exposure was not expected to be significant.

As chlormequat chloride was classified with moderate acute toxicity via the dermal route (USEPA toxicity category II), a 24-hour restricted-entry interval (REI) was required as per the USEPA Worker Protection Standard. Subsequent to the publication of the RED, the USEPA assessed additional exposure data provided by the American registrant and determined that worker re-entry at 12 hours resulted in acute dermal MOEs ranging from 25 170 to 132 600 when compared to the LD_{50} from an acute dermal toxicity study in rabbits. Based on these results, a 12-hour REI was retained for ornamental plants grown in greenhouses, nurseries and shadehouses.

The RED adequately addressed potential postapplication exposure scenarios associated with the Canadian uses of chlormequat chloride, including greenhouse and field uses, and conclusions derived from the RED are considered to be applicable to the Canadian situation. Based on this, the PMRA requires a REI of 12 hours to further protect workers from postapplication exposure. The proposed label amendments are listed in Appendix III.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

No residential uses were registered in the United States at the time of the RED. Therefore, no residential exposure risk assessment was performed. Similarly, there are no residential uses registered in Canada for chlormequat chloride; therefore, no risk assessment is required.

3.1.2.2 Exposure From Food and Drinking Water

There were no food uses registered in the United States at the time of the RED. Therefore, no dietary (food) risk assessment was performed by the USEPA. However, exposure to chlormequat chloride via drinking water was assessed by the USEPA. It was concluded that both acute and chronic risks were not of concern.

In Canada, chlormequat chloride is applied to winter wheat in the spring prior to tillering and therefore, exposure to chlormequat chloride through both food and drinking water may occur.

A search was conducted for any available Canadian water monitoring data for detections of chlormequat chloride. No water monitoring data was found for the active ingredient; therefore it is unclear as to whether chlormequat chloride is present in Canadian water sources. Based on chlormequat chloride's stability and persistence, and depending on the soil, site and meteorological conditions, this active ingredient has the potential for leaching to groundwater and runoff/erosion to surface water (see Section 3.2.1 for more details).

The PMRA conducted a screening-level dietary (through food and drinking water) exposure assessment, which included a number of conservative assumptions including the use of MRLs, assuming 100% crop treated, 100% of the watershed being cropped and an annual application rate of 37.3 kg a.i./ha. The acute and chronic dietary exposure assessments of chlormequat chloride were conducted using the DEEM-FCID™, Version 2.03. The acute dietary exposure

estimate from food and drinking water was below the level of concern for infants younger than one year (most sensitive subgroup), taking up to 56% of the acute reference dose of 0.9 mg a.i./kg bw/day. The chronic dietary exposure estimate from drinking water was below the level of concern for children aged 1–2 years (the most sensitive subgroup), taking up 18% of the chronic reference dose of 0.05 mg a.i./kg bw/day.

3.1.2.3 Aggregate Risk Assessment

An aggregate risk assessment was not conducted as there were no food/feed or residential uses registered for chlormequat chloride in the United States.

As there are no residential uses for chlormequat chloride registered in Canada, an aggregate risk assessment is not required.

3.1.3 Cumulative Effects

The USEPA has not determined whether chlormequat chloride has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that chlormequat chloride does not share a common mechanism of toxicity with other substances and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

Chlormequat chloride was expected to have the potential to reach the aquatic environment via run-off or be transported off site via leaching or erosion.

To assess the ecological risk of chlormequat chloride to both terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients based on appropriate toxicity endpoints and expected environmental concentrations, comparing the resulting risk quotients to corresponding levels of concern. The USEPA determined that there were potential acute and chronic risks to non-target terrestrial animals and plants, and semi-aquatic plants. In the absence of data, potential chronic risk for freshwater and estuarine/marine fish and estuarine/marine invertebrates was assumed.

The American use pattern encompasses the Canadian uses of chlormequat chloride. However, conclusions derived by the United States are not all relevant to the Canadian situation. The rates used by the United States to calculate expected environment concentrations were considerably higher than the maximum application rate used in Canada. Furthermore, the American assessment assumed multiple applications per year, whereas chlormequat chloride is applied in Canada to winter wheat only once per year. On this basis then, risk quotients based on the maximum Canadian application rate would be much lower than those assessed by the USEPA. Additionally, terrestrial buffer zones calculated by the PMRA will minimize spray drift to non-target terrestrial plants during ground application. Therefore, concerns for acute and chronic

risks to non-target species from chlormequat chloride would be expected to be low, based on the Canadian use pattern.

To reduce the release of chlormequat chloride into the environment for the protection of non-target species and to minimize spray drift during ground application, the PMRA is proposing further risk reduction measures that include:

- additional advisory label statements concerning effluent release, drift and runoff; and
- a terrestrial buffer zone distance of one meter.

See Appendix III for the proposed label amendments and Appendix IV for buffer zone model inputs.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the re-evaluation, chlormequat chloride was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, chlormequat chloride was evaluated against the following Track 1 criteria: Persistence in soil $\geq$182 days; persistence in water $\geq$182 days, persistence in sediment $\geq$365 days; persistence in air $\geq$2 days; bioaccumulation log $K_{ow} \geq 5$ or BCF $\geq$5000 (or Bioaccumulation Factor (BAF) $\geq$5000). In order for chlormequat chloride or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one medium) must be met. The technical product was assessed against contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3 Contaminants of Health or Environmental Concern*.

The PMRA concluded that chlormequat chloride does not meet the Track 1 criterion for bioaccumulation, as its *n*-octanol–water partition coefficient (log K_{ow} = -1.59 at pH 7) is below the TSMP Track 1 cut-off criterion. Since the half-life values in aerobic soil (32–132 days) of chlormequat chloride are below the TSMP Track 1 criterion, chlormequat chloride does not meet the Track 1 criterion for persistence. Therefore, chlormequat chloride is not considered a Track 1 substance.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the review process, contaminants in the technical are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[3] The list is used as described in the PMRA Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act* and is based on existing policies and regulations including: Regulatory Directives DIR99-03 and DIR2006-02, *Formulants Policy and Implementation Guidance Document*, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol).

The PMRA concluded that the technical grade chlormequat chloride does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

4.0 Incidence Report

As of 26 April 2007, the law requires registrants to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Incidents are classified into six major categories including effects on humans, effects on domestic animals and packaging failure. Incidents are further classified by severity, in the case of humans for instance, from minor effects such as skin rash, headache, etc., to major effects such as reproductive or developmental effects, life-threatening conditions or death.

The PMRA will examine incident reports and, where there are reasonable grounds to suggest that the health and environmental risks of the pesticide are no longer acceptable, appropriate measures will be taken, ranging from minor label changes to discontinuation of the product.

There were no incident reports submitted for chlormequat chloride as of 9 August 2009.

[3] *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

5.0 Organisation for Economic Co-operation and Development Status of Chlormequat Chloride

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the current available information on the status of chlormequat chloride, the European Food Safety Authority (EFSA) has recently released their conclusion on the peer review of chlormequat chloride (29 September 2008) wherein additional risk mitigation measures were proposed.

As described earlier in this document, the United States, an OECD member, assessed the registration of all uses of chlormequat chloride in 2007 and concluded that using chlormequat chloride as a pesticide would not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the RED document were implemented.

The Canadian re-evaluation of chlormequat chloride is largely based on the 2007 USEPA assessments. As described in Section 3.1 and Section 3.2, the PMRA has found the USEPA environmental and human health risk conclusions to be relevant to the use of chlormequat chloride in Canada and requires measures to mitigate risk to human health and the environment (see Appendix III).

Therefore, the issues identified in the OECD relating to the health and environmental properties of the active ingredient were taken into consideration in the re-evaluation of chlormequat chloride in Canada and have been addressed in the proposed Canadian re-evaluation decision.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that chlormequat chloride is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use product must be amended to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No other data requirements as a condition of continued registration under section 12 of the *Pest Control Products Act* are being requested at this time.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and data code (DACO) tables can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for Chlormequat Chloride is available on the USEPA Pesticide Reregistration Status page at www.epa.gov/pesticides/reregistration/status.htm.

The EFSA pesticide risk assessment peer review for Chlormequat Chloride is available at the EFSA website at www.efsa.europa.eu.

List of Abbreviations

a.i.	active ingredient
ARfD	acute reference dose
BAF	bioaccumulation factor
BCF	bioconcentration factor
CAS	Chemical Abstracts Service
cRfD	chronic reference dose
CSFII	Continuing Survey of Food Intakes by Individuals
DACO	data code
DEEM-FCID™	Dietary Exposure Evaluation Model software with the Food Commodity Intake Database
EC_{25}	effect concentration to 25% of the population
EDWC	estimated drinking water concentration
EFSA	European Food Safety Authority
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FIRST	*Food Quality Protection Act* Index Reservoir Screening Tool
g	gram(s)
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	n-octanol-water partition coefficient
L	Litre(s)
LD_{50}	lethal dose to 50% of the population
LOAEC	lowest observed adverse effect concentration
mg	milligram
MOE	margin of exposure
MRL	maximum residue limit
NOAEC	no observed adverse effect concentration
NOI	notice of intent
OECD	Organisation for Economic Co-operation and Development
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
SCI-GROW	screening concentration in ground water
TGAI	technical grade active ingredient
T-REX	terrestrial residue exposure
TSMP	Toxic Substances Management Policy
µg	microgram
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
WHO	World Health Organization

Appendix I Registered Products Containing Chlormequat Chloride as of 15 April 2009

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
20581	Technical	BASF Canada Inc.	Technical Chlormequat Chloride (Cycocel)	Solution	66%
20582	Manufacturing concentrate	BASF Canada Inc.	BASF Chlormequat Chloride 750	Solution	750 g/L
17001	Commercial	BASF Canada Inc.	Cycocel Extra Liquid Plant Growth Regulator	Solution	460 g/L

Appendix II Toxicological Endpoints for Chlormequat Chloride Health Risk Assessments

Exposure Scenario	NOAEL] (mg/kg bw/day)	Study	Target MOE[a]
Acute Dietary (all populations)	90	Prenatal developmental study in rat (oral)	100 ARfD = 0.9 mg a.i./kg bw/day
Chronic dietary (all populations)	5	Chronic toxicity in dog (oral)	100 cRfD = 0.05 mg a.i./kg bw/day
Short/Intermediate-term Inhalation	30 [b]	Prenatal developmental toxicity study in rat (oral)	100
Short/intermediate-term Dermal	not applicable; no systemic effect up to the limit dose.	21-day dermal toxicity study in rabbit	not applicable

[a] Desired margin of exposure for occupational or residential assessments.

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

Appendix III Label Amendments for Commercial Products Containing Chlormequat Chloride

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers, bystanders, and the environment.

I) The following statements must be included in a section entitled **PRECAUTIONS**:

> Do not enter or allow worker entry into treated areas for 12 hours following application.

II) The following statements must be included in a section entitled **DIRECTIONS FOR USE**:

> **DO NOT** exceed 2 applications per crop cycle for greenhouse ornamentals.
>
> **DO NOT** allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.
>
> As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.
>
> **DO NOT** contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
>
> **DO NOT** apply by air.
>
> 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) medium classification. Boom height must be 60 cm or less above the crop or ground.
>
> Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.
> **Buffer zones:**

The buffer zone specified in the table below is required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of application	Crop	Buffer Zones (metres) Required for the Protection of Terrestrial habitat
Field sprayer	winter wheat	1

If this pest control product is to be used on a commodity that may be exported to the U.S. and you require information on acceptable residue levels in the U.S. contact 1-866-375-4648 or www.cropro.org/.

III) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**:

Observe buffer zones specified under DIRECTIONS FOR USE.

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

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 area and the edge of the water.

Appendix IV Inputs to Buffer Zone Models

Ground Use Data (from Canadian labels)				
Crop	**Formulation Type**	**Method of Application**	**Number of Application**	**Maximum Application Rate (g a.i./ha)**
Winter wheat	Solution	Groundboom	1	1380
Winter wheat	Solution	Groundboom	2 (split)	1380

Model Input Data for Aquatic Buffer Zones (from 2007 RED)		
Half-life for aquatic buffer zones	Aerobic water	12.6 days
Most sensitive freshwater species	*Lemna gibba*	1.4 mg a.i./L
Most sensitive estuarine/marine species	*Lemna gibba*	1.4 mg a.i./L

Model Input Data for Terrestrial Buffer Zones (from 2007 RED)		
Half-life for terrestrial buffer zones	Aerobic soil	100 days
Most sensitive terrestrial plant species EC_{25} for vegetative vigour	*Brassica napus*	1000 g a.i./ha

References

Studies considered in the Chemistry Assessment

A. List of Studies/Information Submitted by Registrant

PMRA Document Number 1462949
Reference Information migrated from TGAI Chemistry paper files CCC-ALX-1, DACO: 2.99, DACO 2.11

PMRA Document Number 742297
Reference 1999, Characterization of Five Batches of Technical Chlormequat-chloride, Report No. PCP05239, MRID: N/S, DACO: 2.13.3 CBI

PMRA Document Number 742293
Reference 1991, Determination of 1,2-Dichloroethane (1,2 DCE)) in "Chlormequat-chloride" by Gas Chromatography, Report No. M 91/29e, MRID: N/S, DACO: 2.13.1 CBI

PMRA Document Number 742292
Reference 1991, Determination of Vinylchloride (VC) in "Chlormequat chloride**"** by Gas Chromatography, Report No. M 91/30e, MRID: N/S, DACO: 2.13.1 CBI