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PRVD2008-18

## Proposed Re-evaluation Decision

# Chlorthal

*(publié aussi en français)*

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**Canada** 

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Proposed Re-evaluation Decision - PRVD2008-18



# Overview

## What Is the Proposed Re-evaluation Decision?

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

An evaluation of available scientific information found that the product containing chlorthal does not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of chlorthal uses, new risk-reduction measures must be included on the label of this product. Additional data are being requested as a result of this re-evaluation. 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<sup>1</sup> that summarizes the science evaluation for chlorthal 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 chlorthal.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated 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 [DIR2001-03](#), *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Chlorthal, 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:

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

- 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 (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 1998 RED, the USEPA concluded that chlorthal was eligible for reregistration provided risk-reduction measures were adopted. The USEPA also conducted risk assessments for the purpose of reassessing chlorthal tolerances which were published in the United States Federal Register in 2004. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in the RED and Federal Register to represent 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 Chlorthal?**

Chlorthal is a herbicide that is used to control weeds in agricultural crops, turf and ornamentals. It is applied using ground equipment by farm workers or professional applicators.

## **Health Considerations**

### **Can Approved Uses of chlorthal Affect Human Health?**

**Chlorthal is unlikely to affect your health when used according to the revised label directions.**

People could be exposed to chlorthal by consuming food and water, working as a mixer/loader/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 (e.g. 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 chlorthal was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and 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.

Chlorthal is currently registered in Canada for use on several food commodities and the following MRLs have been established:

- 5 ppm on mustard greens and turnip greens;
- 2 ppm on beans, black-eyed peas, collards, kale, lettuce, peppers, pimentos, potatoes, soybeans, strawberries, sweet potatoes, turnips and yams; and
- 1 ppm on broccoli, Brussels sprouts, cabbage, cantaloupes, cauliflower, cucumbers, eggplants, garlic, honeydew melons, onions, summer squash, tomatoes, watermelons and winter squash.

Chlorthal could also be used in other countries on crops that are imported into Canada. 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 Chlorthal Is Introduced Into the Environment?**

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

Non-target species (birds, mammals, bees, aquatic organisms and terrestrial plants) could be exposed to chlorthal 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. 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 degree of risk.

The USEPA concluded that the reregistration of chlorthal was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

## **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 chlorthal, the PMRA is proposing further risk-reduction measures for the product label.

### **Human Health**

- Reduction of the maximum application rate on vegetables and a requirement for additional protective equipment to protect mixer/loader/applicators
- A restricted-entry interval following application on agricultural crops, ornamentals, sod farms to protect mixer/loader/applicators
- A water-in requirement following application to turf to protect mixer/loader/applicators

### **Environment**

- Reduction of the maximum application rate on vegetables to protect non-target organisms
- Additional advisory label statements to reduce potential surface and groundwater contamination to protect non-target organisms

In addition to the above, the registrant has volunteered to cancel residential uses, late fall application on turf and use on beans, potatoes and peas.

## **What Additional Scientific Information Is Required?**

Additional data is required in order for the PMRA to complete terrestrial and aquatic buffer zone calculations. An update of information related to the presence of microcontaminants is also requested from registrants to evaluate progress towards the virtual elimination of TSMP Track 1 contaminants in the technical grade active ingredient. These data are required as a condition of continued registration. The registrant of chlorthal must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists the data requirements.

## Next Steps

Before making a final re-evaluation decision on chlorthal, 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<sup>2</sup> 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.

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<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

# Science Evaluation

## 1.0 Introduction

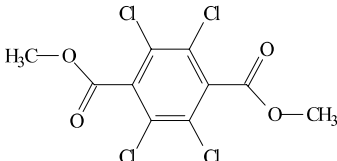
Chlorthal is a herbicide that is absorbed by young shoots of germinating weed seeds, inhibiting their growth.

Following the re-evaluation announcement for chlorthal, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for most uses currently registered in Canada.

The PMRA used recent assessments of chlorthal, called DCPA in the United States, from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) for chlorthal, dated November 1998, Federal Register documents as well as other information on the regulatory status of chlorthal in the United States can be found on the USEPA Pesticide Registration Status page at [www.epa.gov/pesticides/reregistration/status.htm](http://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

<b>Common name</b>	Chlorthal dimethyl
<b>Function</b>	Herbicide
<b>Chemical family</b>	Benzenedicarboxylic acid
<b>Chemical name</b>	
1 <b>International Union of Pure and Applied Chemistry (IUPAC)</b>	Dimethyl 2,3,5,6-tetrachloroterephthalate
2 <b>Chemical Abstracts Service (CAS)</b>	Dimethyl 2,3,5,6-tetrachloro-1,4-benzenedicarboxylate
<b>CAS Registry Number</b>	1861-32-1
<b>Molecular formula</b>	$C_{10}H_6Cl_4O_4$
<b>Structural formula</b>	

Analysis of batch samples of technical grade chlorthal previously submitted to PMRA revealed presence of hexachlorobenzene (HCB) at levels ranging from 11 to 25 ppm, pentachlorobenzene at levels ranging from 200 to 500 ppm and low levels of dioxins/furans (below the level of detection to 0.49 ppt). The registrant is required to submit analyses of recent production batches of this technical grade active ingredient using sensitive and readily available analytical methods as a condition of continued registration.

No other impurities of toxicological concern as identified in Regulatory Directive [DIR98-04](#), *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4, or TSMP Track1 substances as identified in Regulatory Directive [DIR99-03](#), *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II, are expected to be present in the technical product of chlorthal.

## 2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	0.21 mPa (25 °C, gas saturation method)
Henry's law constant	0.001042 atm m <sup>3</sup> mol <sup>-1</sup>
Solubility in water	0.5 mg/L at 25 °C
<i>n</i> -Octanol–water partition coefficient	log $K_{ow}$ = 4.28

## 2.3 Comparison of Use Patterns in Canada and the United States

Chlorthal is a herbicide registered in Canada to control broadleaf weeds and grasses. It is absorbed by young shoots of germinating weed seeds, inhibiting their growth. Chlorthal is used on agricultural crops, ornamentals and turf. It can be applied in the fall or spring, once or twice per year, at an application rate of up to 13.5 kg a.i./ha on field crops, 12.7 kg a.i./ha on ornamentals and 20.2 kg a.i./ha on turf. Chlorthal is formulated as a wettable powder and is applied using ground equipment.

The American and Canadian use patterns were compared and it was concluded that the USEPA assessments described in the RED and in the Federal Register represent an adequate basis for the re-evaluation of chlorthal uses in Canada.

The Canadian registrant has informed the PMRA that they will no longer be supporting the late fall use on turf (at 20.2 kg a.i./ha), in which case the maximum rate for turf treatment would be 16.8 kg a.i./ha. The registrant no longer supports residential uses of chlorthal on ornamentals or turf. Chlorthal is not currently being used on beans, potatoes, or peas, and these uses are no longer supported by the registrant. As of 23 October 2007, one end-use product containing chlorthal is registered under the authority of the *Pest Control Products Act*, as presented in Appendix II.

### **3.0 Impact on Human Health and the Environment**

The USEPA conducted a re-evaluation of chlorthal and published their conclusions in a RED for chlorthal in 1998. In this document, it was concluded that registered non-turf uses of chlorthal would not result in unreasonable adverse effects to humans and the environment if used according to the labels as amended in the RED. At the time, the USEPA was unable to make an eligibility decision for the use of chlorthal on turf and indicated they would refine risk estimates associated with turf uses pending additional data.

In 2004, the USEPA published (in the Federal Register) a final rule for establishing tolerances for combined residues of chlorthal and metabolites on a number of minor crops. This document also served the purpose of an overall reassessment of all chlorthal tolerances as required under *Food Quality Protection Act* (FQPA). It was concluded there is reasonable certainty that no harm will result to the general population, to infants and children from aggregate exposure to residues of chlorthal. The aggregate risk assessment was based on potential exposure from food, drinking water and residential use of chlorthal on turf.

#### **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 at which 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 chlorthal may occur through 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 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 (e.g. children and nursing mothers).

##### **3.1.1 Occupational Exposure and Risk Assessment**

Based on the Canadian use pattern, individuals can be exposed to chlorthal when mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as golfing or handling crops in treated fields.



### 3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

Chlorthal was classified as a Group C (possible human) carcinogen by the USEPA. When evidence of carcinogenicity is identified for the active ingredient, a cancer potency factor ( $Q_1^*$ ) is generated and used to estimate cancer risk. The product of the expected exposure and the cancer potency factor estimates the lifetime cancer risk as a probability. Cancer risk was estimated in the RED based on dermal and inhalation exposure during occupational activities for various scenarios of protective equipment, assuming a maximum application rate of 11.2 kg a.i./ha. The highest estimated risk was for the mixer/loader of wettable powder with a cancer risk estimated at  $4 \times 10^{-5}$  when wearing long pants, a long-sleeved shirt, gloves and a dust/mist respirator. This was considered acceptable by the USEPA. The USEPA's toxicological endpoints for assessing risk from occupational exposure are summarized in Appendix III, Table 1.

An assessment of short/intermediate term occupational risk was not required because no appropriate toxicological endpoint of concern was identified for that exposure duration (21-day dermal study resulted in a NOAEL greater than 1000 mg/kg bw/day).

In Canada, chlorthal is present in one registered commercial class end-use product, formulated as a wettable powder. Uses that are currently supported by the registrant include non-residential ornamentals and turf, and agricultural crops.

Based on the Canadian use pattern, potential exposure scenarios include mixer/loader of wettable powder, groundboom application and backpack sprayer for agricultural, ornamental and turf scenarios. These scenarios have been addressed in the 1998 RED. The USEPA found the risk associated with these scenarios to be acceptable provided all handlers wear long pants, a long-sleeved shirt and gloves, and mixer/loaders of the wettable powder also wear a respirator. The PMRA is proposing this protective equipment be added on the Canadian label. The label amendments are listed in Appendix IV.

The maximum rate currently registered in the United States for vegetable crops is 11.8 kg a.i./ha, and the rate used in the USEPA occupational cancer risk assessments associated with agricultural crops was 11.2 kg a.i./ha. In Canada, although most field crops are registered for treatment at a maximum of 11.6 kg a.i./ha, the maximum rate for beans, peas, soybeans, garlic, onions, potatoes, sweet potatoes and strawberries is 13.5 kg a.i./ha. It is proposed that the maximum rate be reduced to 11.6 kg a.i./ha for all registered field crops; this would be in line with the American assessments and the currently registered maximum rate for vegetable crops in the United States.

Following the RED, the USEPA conducted further risk assessments in 2004 to reassess tolerances; this included an assessment of aggregate risk based on potential exposure from food, drinking water and residential use of chlorthal on turf. The risk assessment was based on the same toxicological database as in the RED, with some revisions to the short/intermediate term endpoint selection. As in the RED, the 2004 assessments did not include a short/intermediate term dermal risk assessment because the no observed adverse effect level (NOAEL) of the

dermal study was higher than 1000 mg/kg bw/day. However, an inhalation endpoint for short/intermediate-term exposure was selected.

Occupational short/intermediate term inhalation margins of exposure (MOEs) are presented in Table 1 below, using the USEPA inhalation endpoint selected in 2004 in conjunction with daily inhalation exposure estimates that had been published in the 1998 RED. Based on this, the Canadian uses of chlorthal result in acceptable occupational risk.

**Table 1 Occupational Mixer, Loader and Applicator MOEs Based on Assumptions Described in the 1998 USEPA RED and the Inhalation Short/Intermediate Term Endpoint from the USEPA 2004 Assessments**

Exposure Scenarios <sup>a</sup>	Daily Exposure (mg/kg bw/day) <sup>b, c</sup>	MOE <sup>d</sup>
Mixer/loader of wettable powder (WP), open mixing, for groundboom	0.496	100
Applicator (groundboom)	0.008	6250
Mixer/loader/applicator backpack (0.4 to 2 ha treated per day)	0.00428–0.0214	2336–11 682

<sup>a</sup> Scenarios assessed in the RED and relevant to Canada.

<sup>b</sup>  $\text{Daily area treated} \times \text{application rate} \times \text{inhalation unit exposure}$   
70 kg bw

<sup>c</sup> Assuming 100% absorption and no respirator worn.

<sup>d</sup>  $\text{MOE} = \frac{\text{NOAEL (50 mg/kg bw/day)}}{\text{Daily inhalation exposure}}$

### 3.1.1.2 Postapplication Exposure and Risk

The postapplication occupational risk assessment considers exposure to workers entering treated sites. Based on the Canadian use pattern of chlorthal, workers could be exposed to residues after the product is applied, i.e. during scouting or harvesting field crops, transplanting or maintenance work in nurseries and maintenance work on golf courses.

The RED included an assessment of risk during postapplication activities involving contact with treated crops. This was done using a dislodgeable foliar residue (DFR) study on cucumber and a transfer coefficient (TC) of 10 000 cm<sup>2</sup>/hour for cucumber harvesting to estimate potential exposure. Chemical-specific dislodgeable or turf transferable residue (TTR) and activity-specific transfer TCs can be used to characterize postapplication exposure from contact with treated foliage at various times after treatment. DFR or TTR data include the amount of residue that can be dislodged or transferred from the leaves of a plant or turf. A TC is a factor that relates worker exposure to dislodgeable residues. TCs are specific to a given crop and activity combination (e.g. hand harvesting strawberries) and reflect standard work clothing worn by adult agricultural workers.

The USEPA estimated the postapplication cancer risk to be  $1.8 \times 10^{-4}$  at day zero after treatment. This was found acceptable based on conservative assumptions and considered to be an overestimate of risk for cucumber harvesters. A restricted-entry interval (REI) of 12 hours was recommended.

A short-term risk assessment was not conducted because the dermal NOAEL was larger than 1000 mg/kg bw/day, the highest dose tested.

Based on the Canadian use pattern of chlorthal, there is potential for exposure of workers performing postapplication activities associated with field crops. However, treatment would be directed towards the soil and is expected to take place at least two months prior to harvest; furthermore, if not soil incorporated, watering in is required soon after application (within two to five days) for the products to be activated. These factors would contribute to mitigation of postapplication exposure.

The Canadian use pattern is encompassed by the American use pattern assessed in the RED. As mentioned previously, the USEPA concluded that postapplication risk from use on agricultural crops and ornamentals is acceptable.

In Canada, the residential uses of turf are no longer supported by the registrant and will be voluntarily cancelled, but commercial uses such as on golf courses and sod farms will be retained. Potential postapplication exposure resulting from these scenarios was not specifically assessed by the USEPA; however, the following is considered relevant.

In their 2004 assessments, the USEPA estimated the cancer risk from residential use of chlorthal. This was based on the assumption that potential exposure would be via the dermal route while performing heavy yard work on a lawn that had received an average rate of 14 kg a.i./ha immediately followed by irrigation. This exposure was estimated using a TTR study and a TC of 7300 cm<sup>2</sup>/hour. The cancer risk associated with residential use of chlorthal was found to be acceptable. The TC used is higher than that which would be used to assess exposure from harvesting sod or playing golf (6800 cm<sup>2</sup>/hour).

The USEPA stated that the results of their TTR study demonstrated that, on day zero, residues can be reduced by 62% with irrigation. The USEPA assessments were based on exposure to irrigated lawns. A statement requiring users to irrigate immediately after treatment of turf is being proposed to be added to the Canadian label.

An REI of 12 hours is being proposed to be added to the Canadian label for agricultural (including sod farms) and ornamental uses. The proposed label amendments are listed in Appendix IV.

### **3.1.2 Non-Occupational Exposure and Risk Assessment**

#### **3.1.2.1 Residential Exposure**

In Canada, the residential uses on turf are no longer supported by the registrant and will be voluntarily cancelled.

#### **3.1.2.2 Exposure From Food**

No effect of concern attributable to a single exposure was identified by the USEPA; therefore, no acute dietary risk assessment was conducted.

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. The acceptable daily intake is referred to as the ADI in Canada, and, in the RED, it is expressed as the chronic population adjusted dose (cPAD). The ADI is based on a relevant endpoint from toxicology studies and on safety factors protective of the most sensitive subpopulation. The toxicological endpoints selected by the USEPA for assessment of dietary risk from food exposure to chlorthal are summarized in Appendix III, Table 1.

Chlorthal was considered by the USEPA to degrade into two major metabolites in food, tetrachloroterephthalic acid (TPA) and monomethyl-tetrachloroterephthalic acid (MTP), one of which (TPA) is also considered to be a major degradate in water. Chronic dietary risk from food was assessed for chlorthal, MTP and TPA. MTP was considered to have the same toxicity as chlorthal and was included in the chlorthal exposure assessment. TPA was found to have its own toxicological profile and unlikely to pose a cancer risk. A separate TPA assessment was conducted based on a TPA-specific endpoint (summarized in Appendix III, Table 2).

Anticipated residues and data on percent crop treated were used for most commodities to estimate food exposure. Tolerance levels and assumptions of 100% crop treated were used for a few commodities. Based on this, USEPA concluded that exposure from food alone would utilize 1.1% of the chlorthal cPAD for the most sensitive subpopulation (children 1–6 years old).

Using the same exposure assumptions as for chlorthal, TPA was found to use 0.02% of the cPAD for the American population and all subgroups.

This assessment addressed all Canadian scenarios of potential exposure through food from domestic and imported food/feed uses.

#### **3.1.2.3 Exposure Through Drinking Water**

Due to a lack of sufficient monitoring data, computer models were used to generate expected environmental concentrations (EECs) in water. Tier II estimates derived for surface water concentrations were 22 and 116 ppb for chlorthal and TPA, respectively, for chronic exposure.

A Tier I groundwater model was used to estimate groundwater concentrations, resulting in EECs of 0.17 and 192 ppb for chlorthal and TPA, respectively, for chronic exposure.

For the cancer aggregate risk assessment, EECs were based on 36-year mean concentrations (for chlorthal only, TPA was considered an unlikely carcinogen) and were as follows.

Scenario	EEC (ppb)
Surface water—turf in Pennsylvania at 16.9 kg a.i./ha	33
Surface water—Florida cabbage at 11.8 kg a.i./ha	15
Surface water—California onions at 11.8 kg a.i./ha	19
Ground water—any crop at 11.8 kg a.i./ha	0.17
Ground water—any crop at 16.9 kg a.i./ha	0.25

The USEPA estimates of drinking water concentration were based on a maximum application rate of 11.8 kg a.i./ha for field crops. This is lower than current maximum Canadian rate for some field crops. It is recommended that the Canadian maximum application rate for field crops be reduced to match with the maximum rate currently registered in the United States.

These estimates are considered to adequately address the Canadian situation and were used to estimate the aggregate risk described in the next section.

#### 3.1.2.4 Aggregate Risk Assessment

Aggregate risk combines different sources of exposure to chlorthal (from food, water and residential exposures).

The USEPA compared drinking water levels of comparison (DWLOCs) against EECs for each exposure duration, i.e. short/intermediate- and long-term (using cancer and non-cancer endpoints) to assess aggregate risk from chlorthal use.

Short-term chlorthal DWLOCs were calculated based on chronic food and water exposure plus residential handler exposure for adults and based on chronic food and drinking water exposure for toddlers. Short-term DWLOCs for TPA were calculated based on food and water alone because residential non-food exposure to TPA was not expected.

When comparing short-term DWLOCs and EEC for chlorthal or TPA, the USEPA concluded that short-term aggregate exposure would not exceed the USEPA's level of concern.

Chronic DWLOCs were estimated assuming potential sources of chronic exposure would include food and drinking water.

Chronic DWLOCs for chlorthal and TPA were higher than EECs for surface and ground water, and USEPA did not expect the chronic aggregate exposure to exceed 100% of the cPAD.

The TPA chronic DWLOCs were found to be much higher than TPA EECs.

Cancer DWLOCs were estimated for chlorthal only because TPA was considered an unlikely carcinogen. Two estimates were derived for the American population, one based on food and water alone as a source of exposure, the other based on food, water and worst-case residential exposure, i.e. the adult handler. Resulting DWLOCs were 67 and 57 ppb, respectively; these were greater than EECs, which meant that the cancer risk was expected to be less than  $3.0 \times 10^{-6}$  assuming aggregate exposure to food, water and residential uses. The risk was considered negligible by the USEPA.

The American aggregate risk assessment took into account sources of exposure that are also relevant to the current Canadian use pattern, including all commodities that could be treated with chlorthal in Canada, and was based on application rates relevant to Canada.

Residential uses on turf and ornamentals and several agricultural uses have been cancelled voluntarily by the American registrant. Although USEPA was unable to identify specific health risk associated with TPA, its prevalence in ground water in the United States was the basis for the request for termination of these uses. The Canadian registrant has indicated that it would voluntarily terminate residential uses on turf and ornamentals.

Overall, the USEPA aggregate risk assessment adequately addresses the Canadian aggregate exposure scenarios. The USEPA aggregate exposure conclusions are considered applicable to the uses of chlorthal in Canada.

### **3.1.3 Cumulative Effects**

The USEPA did not have available data to determine whether chlorthal has a common mechanism of toxicity with other substances and indicated that chlorthal did not appear to produce a toxic metabolite produced by other substances. For the purposes of the 2004 tolerance action published in the Federal Register, USEPA assumed that chlorthal did not have a common mechanism of toxicity with other substances.

### **3.1.4 Microcontaminants**

In the United States, HCB and dioxin/furans are recognized as manufacturing process impurities in chlorthal and were addressed in the RED and in the 2004 Federal Register. Assessments conducted for chlorthal in the RED were also conducted for HCB and TCDD, using the assumption that chlorthal would contain 3000 ppm (0.3%) of HCB and 0.1 ppb of TCDD. Cancer assessments were conducted based on  $Q_1^*$  values specific to HCB and TCDD, and the overall conclusion was that cancer or chronic risk would not exceed the level of concern from

exposure to HCB or TCDD resulting from the use of chlorthal. In the 2004 Federal Register, assessment of risk to homeowners from exposure to HCB from yard activities after chlorthal is applied was estimated and found acceptable, based on the assumption that chlorthal would contain 40 ppm of HCB.

In Canada, in the technical batch data submitted to PMRA, HCB levels ranged from 11 to 25 ppm, and for TCDD ranged from below the level of detection (LOD) to 0.49 ppt (LOD <0.44 ppt). These levels are below those reported for the American products in the USEPA RED or the 2004 Federal Register Notice.

Previously submitted batch samples of the technical grade chlorthal also revealed the presence of pentachlorobenzene at levels ranging from 200–500 ppm. Pentachlorobenzene has been identified as a contaminant of health or environmental concern (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*). The registrant is required to submit data analyses of recent production batches.

## **3.2 Environment**

### **3.2.1 Environmental Risk Assessment**

The USEPA conducted an assessment of the fate and behavior of chlorthal in the environment. It was concluded in the 1998 RED that chlorthal as the parent compound was not especially persistent or mobile (absorption coefficient [ $K_d$ ] range from 5.56–70.3 mL/g), but that substantial amounts of chlorthal could be available for runoff in the form of adsorption to eroding soil for several weeks postapplication. TPA was found to be the only significant metabolite and was unusually mobile ( $K_d$  range 0.08–0.19 mL/g) and persistent (no loss of TPA in an aerobic soil metabolism study after 300 days). Data suggested that TPA would leach to groundwater regardless of soil properties. It was reported that chlorthal could be somewhat persistent in many surface waters, particularly those with low microbiological activities and long hydrological residence times.

The USEPA reported that chlorthal is stable to hydrolysis in laboratory studies and stable to photolysis in soil and water. Chlorthal will undergo microbiological degradation which may be enhanced by warmer temperatures and elevated soil moisture (laboratory aerobic half life [ $t_{1/2}$ ] = 18–37 days; laboratory anaerobic  $t_{1/2}$  = 37–59 days). Under aerobic and anaerobic conditions, TPA was the final degradate and there was virtually no further degradation of TPA during aerobic and anaerobic soil metabolism studies. The USEPA reported that TPA exhibited low soil/water partitioning, and that substantial quantities of TPA would be available for runoff for a longer period than the parent compound.

On volatilization, the USEPA indicated chlorthal would be expected to have low volatility based on Henry's constant and soil/water partitioning. However, several published studies indicate it is volatile, especially from moist or wet soil.

The USEPA also reported that chlorthal bioaccumulates in bluegill sunfish with bioconcentration factors of 1894, 777, and 2574 in whole fish, edible tissue and viscera, respectively. Depuration was reported to appear complete after 14 days. Little metabolism or degradation of chlorthal occurred in fish, although, there was detectable amount of demethylation.

The risk to non-target organisms from exposure to chlorthal was estimated in the RED by comparing estimated risk quotients to relevant levels of concern (LOC). Exposure was calculated based on a maximum application rate of 17.0 kg a.i./ha for turf, 11.8 kg a.i./ha for vegetables and cotton (i.e. non-turf uses) and 10.0 kg a.i./ha on strawberries.

The USEPA conclusions relevant to the Canadian use pattern include the following.

- Chlorthal presented minimal acute risks to birds; however, a confirmatory special dietary study was required at higher test levels in order to obtain a definitive lethal concentration to 50% (LC<sub>50</sub>). An avian chronic risk assessment could not be performed due to lack of data; an avian reproduction study was required.
- LOCs for acute risk to mammals were not exceeded. LOCs for chronic risk to mammals were exceeded for all use scenarios assessed. For the crop scenarios, risk quotient values were overestimates because the ground would usually be free of vegetation when chlorthal is applied to these crops or, if the crop had emerged, chlorthal sprays would be directed past the foliage to treat the bare ground. Therefore, no substantial mammalian exposure would be expected through grazing on or near treated crops. For turf use, the USEPA concluded the risk quotients exceeded the chronic LOC and chronic effects to mammals could occur based on an application rate of 17.0 kg a.i./ha and higher.
- Chlorthal is practically non-toxic to bees, and the risk to insects is expected to be minimal.
- For non-target aquatic animals, application of chlorthal would not result in unacceptable acute risk for freshwater fish, invertebrates or for most estuarine species. Chronic risk was not assessed.
- LOCs for terrestrial and semi-aquatic non target plants were not exceeded; however, they recommended a vegetative vigour study and a seedling emergence study be conducted on sensitive species. LOCs for aquatic non-target plant were not exceeded.

The application rates of 10–17 kg a.i./ha used by the USEPA in the ecological risk assessment encompass current Canadian maximum application rates. The mitigation measures the USEPA recommended will also apply to Canadian products as follows.

- The USEPA had concerns with mammal and mollusk species exposure to chlorthal when used on turf. The Canadian registrant has agreed to cancel the fall application on turf at 20.2 kg a.i./ha and to cancel the residential uses of chlorthal on turf and ornamentals. In addition, the statement “Toxic to small mammals” is proposed to be added to the Canadian label to address the concern regarding effects to mammals.



- The USEPA required label precautionary statements to reduce spray drift potential. At this time, the PMRA can not determine buffer zones for chlorthal as the terrestrial plant data are incomplete and no aquatic plant data are available. As chlorthal is a herbicide and the buffer zones are based on the most sensitive species, it is likely that the endpoints of concern will originate from the terrestrial and aquatic plant data. Therefore, the PMRA requires Tier II data for terrestrial and aquatic plants.
- The USEPA required groundwater advisory statements. The PMRA is also proposing to include such statements on the label of the Canadian end-use product.

Proposed label amendments are listed in Appendix IV. Data requirements are described in Appendix I.

### 3.2.2 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 Track 1 substances.

The federal TSMP and the PMRA Regulatory Directive [DIR99-03](#), *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of chlorthal which lead to the following conclusions.

- The *n*-octanol–water partition coefficient ( $\log K_{ow}$ ) of chlorthal is 4.28, which is below the TSMP threshold value of 5, and chlorthal does not meet the Track 1 criteria for bioaccumulation; a bioconcentration factor of 1894 for whole fish was reported by the USEPA, which also supports the conclusion that chlorthal is not a candidate for Track 1 classification.
- Analysis of batch samples of technical grade chlorthal previously submitted to PMRA revealed presence of HCB at levels ranging from 11 to 25 ppm, pentachlorobenzene at levels ranging from 200 to 500 pm and low levels of dioxins/furans (below the level of detection to 0.49 ppt). Dioxins/furans and chlorinated benzenes have been identified in the federal government's TSMP as Track 1 substances. Analyses of recent production batches of the technical grade of chlorthal using sensitive and readily available analytical methods are required from the registrant.
- No other impurities of toxicological concern as identified in Regulatory Directive DIR98-04, Section 2.13.4, or TSMP Track1 substances as identified in Regulatory Directive DIR99-03, Appendix II, are expected to be present in the technical product of chlorthal.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive [DIR2006-02](#), *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

#### **4.0 OECD Status of Chlorthal**

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 policy. 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 currently available information on the status of chlorthal in other OECD member countries, all uses as a pesticide have been prohibited in Norway since 1990. This regulatory action was taken by Norway based on their assessment that chlorthal is persistent and its main metabolite is very water soluble. Notification of this action was published in Prior Informed Consent (PIC) Circular X in 1999<sup>3</sup>.

The United States, also an OECD member, concluded in the USEPA 1998 and 2004 assessments described previously that use of chlorthal as a pesticide does not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the Reregistration Eligibility Decision are implemented. Part of this evaluation included an environmental risk assessment. The USEPA found chlorthal was not especially persistent or mobile, but TPA, the only significant metabolite, was unusually mobile and persistent. In response to the USEPA concerns regarding contamination of groundwater, American registrants voluntarily cancelled all residential uses and several agricultural uses of chlorthal. The USEPA also identified concerns with non-target species (i.e. mammal and mollusk species) exposure to chlorthal when used on turf.

The Canadian re-evaluation of chlorthal is largely based on the 1998 and 2004 USEPA assessments. As described above, the PMRA has found the USEPA environmental risk conclusions to be relevant to the Canadian use of chlorthal and requires measures to mitigate contamination of water and risk to non-target species. The Canadian registrant has agreed to cancel the fall application on turf at 20.2 kg a.i./ha and cancel all residential uses of chlorthal. The registrant no longer supports uses of chlorthal on peas, potatoes and beans. The PMRA is also requiring a reduction of maximum application rate on field crops from 13.5 to 11.6 kg a.i./ha.

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<sup>3</sup> PIC circulars are published by the Rotterdam Convention Secretariat; under this Convention, parties to the Convention have committed to inform other parties about legislative bans or severe restrictions on the use of chemicals, and to notifying recipient countries of any exports of regulated substances. This procedure is called Prior Informed Consent (PIC). When a party has adopted a final regulatory action to ban or severely restrict a chemical, the party notifies the Rotterdam Convention Secretariat; notifications are published in PIC circulars.

Concerns identified in Norway, a member of the OECD relating to the environmental properties of the active ingredient chlorthal and its metabolite were taken into consideration in the Canadian re-evaluation and have been addressed in the proposed Canadian re-evaluation decision.

## **5.0 Proposed Re-evaluation Decision**

The PMRA has determined that chlorthal 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 label of the Canadian end-use product must be amended to include the label statements listed in Appendix IV. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. The registrant of the technical grade active ingredient is required to submit data as a condition of continued registration under section 12 of the *Pest Control Products Act*. Appendix I lists the data requirements.

## **6.0 Data Required as a Condition of Continued Registration**

Additional data is required in order for the PMRA to complete terrestrial and aquatic buffer zone calculations. An update of information related to the presence of microcontaminants is also requested. Appendix I lists the data requirements.

## **7.0 Supporting Documentation**

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at [www.pmra-arla.gc.ca](http://www.pmra-arla.gc.ca). 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](mailto:pmra_infoserv@hc-sc.gc.ca).

The federal TSMP is available through Environment Canada's website at [www.ec.gc.ca/toxics](http://www.ec.gc.ca/toxics).

The USEPA RED document for chlorthal is available on the USEPA Pesticide Registration Status page at [www.epa.gov/pesticides/reregistration/status.htm](http://www.epa.gov/pesticides/reregistration/status.htm). Federal Register Notices are available at [www.gpoaccess.gov/fr/](http://www.gpoaccess.gov/fr/).

## List of Abbreviations

°C	degree(s) Celsius
ADI	acceptable daily intake
a.i.	active ingredient
atm	atmosphere(s)
bw	body weight
CAS	Chemical Abstracts Service
cm <sup>2</sup>	centimetre(s) cubed
cPAD	chronic population adjusted dose
DACO	data code
DFR	dislodgeable foliar residue
DWLOC	drinking water level of comparison
EEC	expected environmental concentration
FQPA	<i>Food Quality Protection Act</i>
g	gram(s)
ha	hectare
HCB	hexachlorobenzene
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
k <sub>d</sub>	absorption coefficient
K <sub>ow</sub>	<i>n</i> -octanol–water partition coefficient
L	litre(s)
LC <sub>50</sub>	lethal concentration to 50%
LOC	level of concern
LOD	limit of detection
LOQ	limit of quantitation
m	metre(s)
m <sup>3</sup>	metre(s) cubed
mg	milligram(s)
ml	millilitre(s)
mPa	millipascal(s)
MOE	margin of exposure
mol	mole
MRL	maximum residue limit
MTP	monomethyl-tetrachloroterephthalic acid
NIOSH	National Institute of Occupational Safety and Health
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
OPPTS	Office of Prevention, Pesticide and Toxic Substances
PCPA	<i>Pest Control Products Act</i>
PIC	Prior Informed Consent
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppt	parts per trillion
ppm	parts per million

PRVD	Proposed Re-evaluation Decision
PSL	Priority Substance List
$Q_1^*$	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
TC	transfer coefficient
$t_{1/2}$	half life
TPA	tetrachloroterephthalic acid
TTR	turf transferable residue
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
WP	wettable powder

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## Appendix I Additional Data Requirements

In order for the PMRA to complete terrestrial and aquatic buffer zone calculations and to evaluate the registrants progress towards the virtual elimination of TSMP Track 1 contaminants, the following data are required as a condition of continued registration.

### Buffer Zones

- DACO 9.8.2: Fresh Water Algae (USEPA OPPTS 850.5400 guideline)
- DACO 9.8.3: Marine Algae (USEPA OPPTS 850.5400 guideline)
- DACO 9.8.4: Terrestrial Vascular Plants - Seedling Emergence (USEPA OPPTS 850.4225 guideline) and Vegetative Vigour (USEPA OPPTS 850.4250 guideline)].
- DACO 9.8.5: Aquatic Vascular Plants (USEPA OPPTS 850.4400 guideline)

These studies must be conducted according to the appropriate OPPTS guidelines indicated.

### Impurities of Human Health or Environmental Concern

- DACO 2.13.4: Impurities of Human Health or Environmental Concern  
Deficiency: The registrant is required to provide recent analytical data for all identifiable dioxins and furans (including the 17 substances listed in Table 4 of the Priority Substances List Assessment Report Number 1, [\*Polychlorinated dibenzodioxins and polychlorinated dibenzofurans\*](#) from at least five batches of technical grade active ingredient manufactured at each of the registered sites. The data must be obtained under good laboratory practice and must utilize the lowest practical limits of quantitation (LOQs). The analytical method(s) used should also be specified, either by reference to a standard method or by inclusion of a detailed description together with validation data.

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**Appendix II      Registered Products Containing Chlorthal as of  
January 2008**

<b>Registrant</b>	<b>Registration Number</b>	<b>Guarantee</b>	<b>Product Name</b>	<b>Formulation</b>	<b>Class</b>	<b>First Registered</b>
AMVAC Chemical Corp.	8963	75%	Dacthal W-75 Herbicide	Wettable Powder	Commercial	1964/07/01
	20850	98.8%	Dacthal Technical Herbicide (Chlorthal Dimethyl)	Solid	Technical	1988/08/31
	22602	90%	90% Dimethyl-T Manufacturing Concentrate	Dust or Powder	Manufacturing concentrate	1992/10/07

## Appendix III Toxicological Endpoints for Chlorthal and TPA Health Risk Assessments

**Table 1 Toxicological Endpoints Selected by the USEPA for Chlorthal Health Risk Assessments**

Exposure Scenario	Dose (mg/kg bw/day)	Study
Short/intermediate dermal	NOAEL >1000 (highest dose tested)	21/28 dermal study
Short/intermediate inhalation	NOAEL = 50	90-day feeding study in rat
Acute dietary	An endpoint of concern attributable to a single dose was not identified, no dietary acute endpoint selected.	
Chronic dietary	NOAEL = 1 (all populations) cPAD = 0.01	Combined chronic/carcinogenicity study in rats
Cancer	Group C, possible human carcinogen. $Q_1^* = 0.0015 \text{ (mg/kg bw/day)}^{-1}$ based on 3 combined types of liver tumours in female rats.	

**Table 2 Toxicological Endpoints Selected by the USEPA for Risk Assessments with TPA, a Major Metabolite of Chlorthal**

Exposure Scenario	Dose (mg/kg bw/day)	Study
Acute dietary	An endpoint of concern attributable to a single dose was not identified, no dietary acute endpoint selected.	
Chronic dietary	NOAEL = 500 (all populations) cPAD = 0.5	90-day feeding study in rats
Cancer	TPA is not likely to be carcinogen to humans.	



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## Appendix IV      Label Amendments for the Product Containing Chlorthal

The label of the end-use product in Canada must be amended as follows to further protect workers and the environment.

1)      The following uses are no longer supported.

- Late fall application on turf (at 27 kg/ha of Dacthal-75, or 20.2 kg a.i./ha)
- Residential uses on turf and ornamentals
- Use on beans, potatoes and peas

All references to these uses must be removed.

2)      The end-use product label must be amended to indicate a maximum application rate of 11.6 kg a.i./ha for all field crops.

3)      On the secondary display panel, the following statements must appear under the **PRECAUTIONS** section.

Wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves during mixing/loading, clean-up and repair activities and when using handheld equipment. In addition, wear a NIOSH-approved dust/mist respirator during mixing/loading.

Do not use in residential areas. Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, on school grounds, in parks, in playgrounds, on playing fields, around public buildings or any other areas where the general public including children could be exposed.

4)      On the secondary display panel, the following statements must appear in the **DIRECTIONS FOR USE** section.

In areas of the label associated with ornamentals, agricultural crops and sod farms:

Do not enter or allow entry into treated areas during the restricted-entry interval (REI) of 12 hours.

In the “Turf” section:

This product must be watered in immediately following application.

- 5) On the secondary display panel the following statements must appear under the **ENVIRONMENTAL HAZARD** section.

Toxic to small mammals.

Chlorthal demonstrates the properties and characteristics associated with chemicals detected in groundwater. 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 water table is shallow. Tetrachloroterephthalic acid, a breakdown product of chlorthal, is known to leach through soil as a result of agricultural and turf uses and has been found in groundwater which may be used for drinking water. Users are advised not to apply chlorthal to sand or loamy sand soils where the water table (groundwater) is close to the surface and where those soils are very permeable, i.e. well drained. Your local agricultural agencies can provide further information on the type of soil in your area and the location of groundwater used for drinking water.

To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted silt or clay.

Avoid application of this product 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.

The label amendments presented above 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.

## References

### Studies/Information Provided by Applicant/Registrant

PMRA Number	Reference
1436664	Note to Reviewer: Dissociation Constant - N/A, DACO: 2.14.10
1436671	Note to Reviewer: Boiling Point- N/A, PC89RPB, DACO: 2.14.5
1436658	2000, Production Process for Technical Chlorthal Dimethyl., PROC-082-1A, DACO: 2.11.1,2.11.3
1436659	2000, Materials Used for the Production of Technical Chlorthal Dimethyl., RAW-082-1, DACO: 2.11.2
1436662	2000, Dacthal- Five Batch Analysis, 012381-1, DACO: 2.13.1,2.13.2,2.13.3,2.13.4
1436676	1999, Product Samples. Alta Batch ID: 6879, DACO: 2.15 , DACO 2.13.4
1436664	Note to Reviewer: Dissociation Constant - N/A, DACO: 2.14.10

## References

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PMRA Number	Reference
1436664	Note to Reviewer: Dissociation Constant - N/A, DACO: 2.14.10
1436671	Note to Reviewer: Boiling Point- N/A, PC89RPB, DACO: 2.14.5
1436658	2000, Production Process for Technical Chlorthal Dimethyl., PROC-082-1A, DACO: 2.11.1,2.11.3
1436659	2000, Materials Used for the Production of Technical Chlorthal Dimethyl., RAW-082-1, DACO: 2.11.2
1436662	2000, Dacthal- Five Batch Analysis, 012381-1, DACO: 2.13.1,2.13.2,2.13.3,2.13.4
1436676	1999, Product Samples. Alta Batch ID: 6879, DACO: 2.15 , DACO 2.13.4
1436664	Note to Reviewer: Dissociation Constant - N/A, DACO: 2.14.10