UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MEMORANDUM

DATE: 07 June 2007

SUBJECT: **Chlormequat Chloride.** Screening-level Acute and Chronic Dietary (Drinking Water Only) Exposure and Risk Assessment for the Reregistration Eligibility Decision.

    PC Code: 018101   DP Number: D336716

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Executive Summary

A screening-level acute and chronic dietary (drinking water only) exposure and risk assessment was conducted for chlormequat chloride using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The analysis was performed to support the reregistration eligibility decision. The assessment included only the potential for exposure through drinking water, and was conducted to ensure that there are no serious risk concerns associated with all registered outdoor uses including bedding plants and containerized ornamentals in shadehouses and nurseries. This assessment is an update to a previous screening-level chronic dietary assessment for chlormequat chloride (C. Swartz, D332277, 11/20/2006) and incorporates a reduction in the maximum outdoor use rate from 49.5 to 33.3 lbs a.i./A/year.

A Tier I drinking water assessment for acute and chronic dietary exposure was provided by the Environmental Fate and Effects Division (EFED) (M. Echeverria, D336717, 03/19/2007). The highest estimated drinking water concentrations (EDWC) were found in surface water and these conservative values were used for the dietary analysis.

Acute drinking water exposure estimates were generated based on the deterministic upper bound estimates from EFED's Tier I (F)IFRA (I)ndex (R)eservoir (S)creening (T)ool (FIRST) EDWC surface water model. Therefore, because of the conservative nature of this model, it is inappropriate to assess risks based upon exposures at the 99.9th percentile. It is more appropriate to consider exposure at the 95th percentile. The acute dietary exposure estimates from drinking water are below HED's level of concern (< 100% aRfD) for the U.S. population and all population subgroups at the 95th percentile. The highest exposed population subgroup was all infants (< 1 year) at 56% of the acute RfD of 0.9 mg/kg/day. Based on the screening-level EFED assessment used to generate the drinking water estimates, HED concludes that there is no concern for potential acute dietary exposure to chlormequat chloride from drinking water.

The chronic dietary exposure estimates from drinking water are below HED's level of concern (< 100% cPAD) for the U.S. population and all population subgroups. The highest exposed population subgroup was all infants (< 1 year) at 13% of the chronic RfD of 0.05 mg/kg/day. Based on the screening-level EFED assessment used to generate the drinking water estimates, HED concludes that there is no concern for potential chronic dietary exposure to chlormequat chloride from drinking water.

I.   Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). For non-food pesticides, this dose is referred to as the reference dose (RfD). The RfD is equivalent to point of departure (POD), NOAEL, LOAEL, e.g. divided by the required uncertainty or safety factors (typically interspecies 10x and intraspecies 10x).

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the aRfD or cRfD. References which discuss acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf ; or see SOP 99.6 (08/20/1999).

The most recent chronic dietary risk (drinking water only) assessment for chlormequat chloride was conducted by C. Swartz (D332277, 11/20/2006).

II.   Residue Information

Chlormequat chloride [(2-chloroethyl)trimethylammonium chloride] is a non-food use plant growth regulator that belongs to the quaternary ammonium class of chemicals. It is used on ornamental plants grown in greenhouses, nurseries, and shadehouses. Chlormequat chloride works through inhibition of gibberellin biosynthesis in the early stages of the pathway. This early blockage prevents the synthesis of numerous gibberellins needed for normal plant growth and development.

Chlormequat chloride is a non-food use chemical, it has no existing or proposed uses (and no tolerances) that could result in exposure through food. Therefore, the requirements of FQPA do not strictly apply to this chemical. Because of this, the standard 10x FQPA uncertainty factor will not be applied to this assessment.

III. Drinking Water Data

The estimated drinking water concentration (EDWC) estimates used in the dietary risk assessment were provided by the Environmental Fate and Effects Division (EFED) in the following memorandum: "*Tier I Drinking Water Assessment for Chlormequat Chloride in Support of Reregistration Eligibility Decision*" (M. Echeverria, D336717, 03/19/2007).   EDWCs were incorporated into DEEM-FCID as the food forms "water, direct, all sources" and "water, indirect, all sources."   A summary of the EDWCs is provided in Table 1.

- The highest EDWC was calculated in surface water using the FIRST model and these upper bound conservative values were used for the drinking water analysis.
- Tier 1 EDWCs for surface water were generated by EFED from their Tier I (F)IFRA (I)ndex (R)eservoir (S)creening (T)ool (FIRST) EDWC surface water model
- FIRST is a screening model designed by the Environmental Fate and Effects Division (EFED, 2001a) of the Office of Pesticide Programs to estimate pesticide concentrations found in drinking water from surface water sources for use in human health risk assessment. As such, it provides upper bound values on the concentrations that might be found in drinking water due to the use of a pesticide. FIRST is a single-event model (one runoff event), but can account for spray drift from multiple applications. FIRST is hardwired to represent the Index Reservoir, a standard water body used by the Office of Pesticide Programs to assess drinking water exposure (Office of Pesticide Programs, 2002). It is

based on a real reservoir, Shipman City Lake in Illinois, which is known to be vulnerable to pesticide contamination.

- These EDWCs were obtained from modeling using the highest use rate of all labeled uses with an annual application rate of 33.3 lbs a.i./A/year.
- Since there were unidentified residues in the aquatic and soil metabolism studies that may be of risk concern, a total toxic residue approach that assumes all uncharacterized extractable residues are of equal toxicity to the parent was used to estimate exposure.
- The model and its description are available at the EPA internet site: http://www.epa.gov/oppefed1/models/water/.

Table 1 Tier I EDWC for chlormequat chloride for ground boom spray applications		
Drinking Water Source (Model)	**Use rate (lbs a.i./A/year)**	**EDWC (ppb)**
Surface water (FIRST) - **Acute (peak)** - **Chronic (annual mean)**	33.3	**2574** **91**
Groundwater (SCI-GROW)	33.3	24

Numerous conservative assumptions were used by EFED to generate the EDWCs. Based on the following, the resulting EDWCs are deterministic upper-bound estimates.

- Modeled values were used since no monitoring data are available
- Assumes 100% of watershed is treated (no percent crop area data is available, but there is a relatively low amount of chlormequat chloride applied per year on a nationwide basis, including all indoor uses)
- Assumes 100% of the product is absorbed into the ground and/or runs off (i.e.- no plants on the surface treated, all product makes ground contact)
- Ground boom applications drive the risk even though limited usage is expected

IV. DEEM-FCID™ Program and Consumption Information

Chlormequat chloride acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID™, Version 2.03 which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two nonconsecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for

the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the acute hazard value (aRfD or aPAD) on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

For chronic dietary exposure assessments, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cRfD or cPAD. This procedure is performed for each population subgroup.

V.   Toxicological Information

The toxicology database for chlormequat chloride is adequate sufficient for hazard assessment to support the proposed non-food, non-residential use. A summary of the toxicological endpoints for dietary risk assessment is shown in Table 2.

Table 2. Summary of Toxicological Doses and Endpoints for Chlormequat Chloride for Use in Dietary Exposure Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**RfD**	**Study and Toxicological Effects**
Acute Dietary (all populations)	NOAEL= 90 mg/kg/day	UF_A = 10X UF_H = 10X	aRfD=0.9 mg/kg/day	Prenatal Developmental-Rat (MRID 42246604) Single oral LOAEL 180 mg/kg/day, based on overt toxicity signs (tremors, ataxia) within an hour after a single oral dose in dams(GD6).
Acute Dietary (Females 13-49 years of age)	N/A	N/A	N/A	The risk assessment is not appropriate. Also, an acute endpoint was not selected based on the absence of an appropriate endpoint attributable to a single dose.
Chronic Dietary	NOAEL = 5 mg/kg/day	UF_A = 10X UF_H = 10X	cRfD = 0.05 mg/kg/day	Chronic Toxicity-Dog (MRID 46715201)

(all populations)				LOAEL (mg/kg/day): 10 mg/kg/day, based on salivation (both sexes), vomiting (females), diarrhea (males), and decreased body weight gain (males).
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the no carcinogenic potential was noted in the available studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures.
NOAEL = no observed adverse effect level.
LOAEL = lowest observed adverse effect level.
UF = uncertainty factor.
UF_A = extrapolation from animal to human (intraspecies).
UF_H = potential variation in sensitivity among members of the human population (interspecies).
RfD = reference dose.
N/A = not applicable

FQPA and Uncertainty Factors

As the pesticidal uses of chlormequat chloride do not involve use on food, no residues in food are expected and tolerances are not required. Therefore, chlormequat chloride uses **are not subject to the Food Quality Protection Act (1996).**

HED notes there is no evidence chlormequat causes increased susceptibility in infants and children in the submitted data. The standard UF of 100X (10X interspecies extrapolation, 10X intraspecies variability) has been applied to the hazard component of risk.

VI.   Results/Discussion

As stated above, for dietary assessments HED is concerned when dietary risk exceeds 100% of the hazard value (aRfD, aPAD, cRfD, or cPAD). The DEEM-FCID™ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The results reported in Table 3 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years.

Acute Drinking Water Exposure Results

Acute drinking water exposure estimates were generated based on the deterministic upper bound estimates from EFED's Tier I (F)IFRA (I)ndex (R)eservoir (S)creening (T)ool (FIRST) EDWC surface water model. Therefore, because of the conservative nature of this model, it is inappropriate to assess risks based upon exposures at the 99.9[th] percentile. It is more appropriate to consider exposure at the 95th percentile. The acute dietary exposure estimates from drinking water are below HED's level of concern (< 100% aRfD) for the U.S. population and all population subgroups at the 95th percentile. A summary of the results from the acute dietary exposure analysis is shown in Table 3. The highest exposed population subgroup was all infants (< 1 year) at 56% of the acute

RfD of 0.9 mg/kg/day. Based on the screening-level EFED assessment used to generate the drinking water estimates, HED concludes that there is no concern for potential acute dietary exposure to chlormequat chloride from drinking water.

Chronic Drinking Water Exposure Results

The chronic dietary exposure estimates from drinking water are below HED's level of concern (< 100% cPAD) for the U.S. population and all population subgroups. The highest exposed population subgroup was all infants (< 1 year) at 13% of the chronic RfD of 0.05 mg/kg/day. Based on the screening-level EFED assessment used to generate the drinking water estimates, HED concludes that there is no concern for potential chronic dietary exposure to chlormequat chloride from drinking water.

Table 3. Summary of Acute and Chronic Dietary (Drinking Water Only) Exposure and Risk for Chlormequat Chloride						
Population Subgroup	Acute Drinking Water 95th Percentile			Chronic Drinking Water		
	aRfD (mg/kg/day)	Dietary Exposure (mg/kg/day)	% aRfD	cRFD (mg/kg/day)	Dietary Exposure (mg/kg/day)	% cRfD
General U.S. Population	0.9	0.134463	15	0.05	0.001918	3.8
All Infants (< 1 year old)		**0.506963**	**56**		**0.006288**	**13**
Children 1-2 years old		0.210983	23		0.002848	5.7
Children 3-5 years old		0.192735	21		0.002666	5.3
Children 6-12 years old		0.134174	15		0.001839	3.7
Youth 13-19 years old		0.109085	12		0.001386	2.8
Adults 20-49 years old		0.124579	14		0.001791	3.6
Adults 50+ years old		0.112502	13		0.001884	3.8
Females 13-49 years old		0.125285	14		0.001783	3.6

VII.   Conclusion

The acute and chronic dietary exposure analyses of conservative surface water concentrations of chlormequat chloride indicate that all population subgroups have risk estimates below HED's level of concern (< 100% of the hazard value).

VIII. List of Attachments

- Attachment 1 Acute Inputs
- Attachment 2 Acute Results
- Attachment 3 Chronic Inputs
- Attachment 4 Chronic Results

Attachment 1: Acute Inputs

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U.S. Environmental Protection Agency                        Ver. 2.02
DEEM-FCID Acute analysis for CHLORMEQUAT CHLORIDE
Residue file name: C:\Documents and Settings\dwilbur\My
Documents\DEEM\Chlormequat Chloride\CC acute.R98
Analysis Date 06-04-2007          Residue file dated: 05-17-2007/08:40:38/8
Reference dose (aRfD) = 0.9 mg/kg bw/day
Comment: Chlormequat chloride acute NOAEL=90 mg/kg/day
---------------------------------------------------------------------------
  EPA     Crop                                   Def Res    Adj.Factors
Comment
  Code   Grp  Food Name                          (ppm)      #1    #2
-------- ---- ------------------------------- ---------- ------ ------  ------
-
86010000 O    Water, direct, all sources        2.574000  1.000  1.000
86020000 O    Water, indirect, all sources      2.574000  1.000  1.000
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Attachment 2: Acute Results

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U.S. Environmental Protection Agency                        Ver. 2.02
DEEM-FCID ACUTE Analysis for CHLORMEQUAT CHLORIDE          (1994-98 data)
Residue file: CC acute.R98                  Adjustment factor #2 NOT used.
Analysis Date: 06-04-2007/11:57:32   Residue file dated: 05-17-2007/08:40:38/8
Daily totals for food and foodform consumption used.
Run Comment: "Chlormequat chloride acute NOAEL=90 mg/kg/day"
===============================================================================

Summary calculations (per capita):

                 95th Percentile     99th Percentile     99.9th Percentile
                 Exposure  % aRfD    Exposure  % aRfD    Exposure  % aRfD
                 --------- --------  --------- --------  --------- --------
U.S. Population:
                 0.134463   14.94    0.252560   28.06    0.505316   56.15
All infants:
                 0.506963   56.33    0.726768   80.75    1.301874  144.65
Children 1-2 yrs:
                 0.210983   23.44    0.352343   39.15    0.512433   56.94
Children 3-5 yrs:
                 0.192735   21.42    0.302097   33.57    0.493062   54.78
Children 6-12 yrs:
                 0.134174   14.91    0.223095   24.79    0.304673   33.85
Youth 13-19 yrs:
                 0.109085   12.12    0.183531   20.39    0.330092   36.68
Adults 20-49 yrs:
                 0.124579   13.84    0.208625   23.18    0.377378   41.93
Adults 50+ yrs:
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                          0.112502   12.50    0.160887   17.88    0.260907   28.99
Females 13-49 yrs:
                          0.125285   13.92    0.201640   22.40    0.357586   39.73
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Attachment 3: Chronic Inputs

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U.S. Environmental Protection Agency                              Ver. 2.00
DEEM-FCID Chronic analysis for CHLORMEQUAT CHLORIDE               1994-98 data
Residue file: C:\Documents and Settings\dwilbur\My Documents\DEEM\Chlormequat
Chloride\Chlormequat Chloride.R98
                                                            Adjust. #2 used
Analysis Date 04-17-2007          Residue file dated: 04-17-2007/10:05:37/8
Reference dose (RfD) = 0.05 mg/kg bw/day
-----------------------------------------------------------------------------
Food Crop                                    Residue     Adj.Factors
Comment
EPA Code  Grp  Food Name                     (ppm)
                                                        #1        #2
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86010000 O    Water, direct, all sources     0.091000  1.000      1.000
86020000 O    Water, indirect, all sources   0.091000  1.000      1.000
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Attachment 4: Chronic Results

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U.S. Environmental Protection Agency                              Ver. 2.00
DEEM-FCID Chronic analysis for CHLORMEQUAT CHLORIDE              (1994-98 data)
Residue file name: C:\Documents and Settings\dwilbur\My
Documents\DEEM\Chlormequat Chloride\Chlormequat Chloride.R98
                                              Adjustment factor #2 used.
Analysis Date 04-17-2007/10:06:36    Residue file dated: 04-17-2007/10:05:37/8
Reference dose (RfD, Chronic) = .05 mg/kg bw/day
=============================================================================
                   Total exposure by population subgroup
-----------------------------------------------------------------------------
                                               Total Exposure
                                      ------------------------------------
           Population                    mg/kg               Percent of
            Subgroup                   body wt/day              Rfd
-------------------------------------  ------------         ---------------
U.S. Population (total)                  0.001918                 3.8%

U.S. Population (spring season)          0.001901                 3.8%
U.S. Population (summer season)          0.002060                 4.1%
U.S. Population (autumn season)          0.001854                 3.7%
U.S. Population (winter season)          0.001854                 3.7%

Northeast region                         0.001750                 3.5%
Midwest region                           0.001939                 3.9%
Southern region                          0.001823                 3.6%
Western region                           0.002198                 4.4%

Hispanics                                0.002177                 4.4%
Non-hispanic whites                      0.001871                 3.7%
Non-hispanic blacks                      0.001821                 3.6%
Non-hisp/non-white/non-black             0.002351                 4.7%

All infants (< 1 year)                   0.006288                12.6%
Nursing infants                          0.002332                 4.7%
Non-nursing infants                      0.007790                15.6%
Children 1-6  yrs                        0.002680                 5.4%
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Children 7-12 yrs                        0.001742              3.5%

Females 13-19 (not preg or nursing)      0.001350              2.7%
Females 20+ (not preg or nursing)        0.001915              3.8%
Females 13-50 yrs                        0.001856              3.7%
Females 13+ (preg/not nursing)           0.001865              3.7%
Females 13+ (nursing)                    0.002657              5.3%

Males 13-19 yrs                          0.001411              2.8%
Males 20+ yrs                            0.001719              3.4%
Seniors 55+                              0.001883              3.8%

Children 1-2 yrs                         0.002848              5.7%
Children 3-5 yrs                         0.002666              5.3%
Children 6-12 yrs                        0.001839              3.7%
Youth 13-19 yrs                          0.001386              2.8%
Adults 20-49 yrs                         0.001791              3.6%
Adults 50+ yrs                           0.001884              3.8%
Females 13-49 yrs                        0.001783              3.6%

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