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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Exposure Assessment for the Use of Cimectacarb on Turf

FROM: Charles Lewis *Charles Lewis*
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TO: Dan Hanke
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THRU: Mark I. Dow, Ph.D, Section Head *Mark I. Dow*
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Health Effects Division (H7509C)

Attached is the Occupational and Residential Exposure Branch (OREB) exposure assessment for the use of cimectacarb on turf:

DP Barcode: D180718

Pesticide Chemical Code: 112602

EPA Reg. No.: 100-TEO

PHED: Yes. Version 1.01, February 26, 1992.

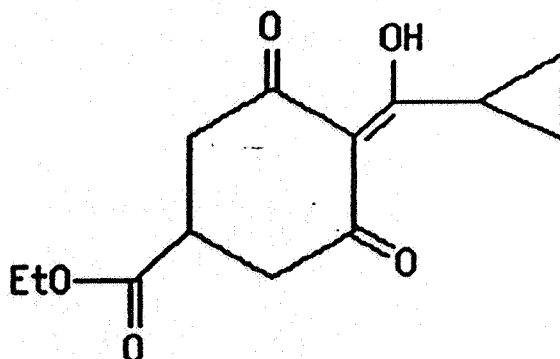
Note: This memorandum has been routed to Dan Hanke as per instructions received on September 17, 1992 from Albin Kocialski, Acting Section Head, Registration Section, Chemical Coordination Branch.

I. INTRODUCTION:

A. Background:

Cimectacarb is the common name for CGA-163935 produced by Ciba-Geigy Corporation. Proposed use is as a growth regulator for turf to reduce the frequency of mowing. Currently two labels have been submitted to the Agency; Primo™ a 1 lb ai/gal EC and [REDACTED]. Broadcast applications are made with ground equipment (excluding irrigation systems) at rates up to 0.69 lb ai/A for Primo™ and [REDACTED]. Multiple applications may be made but must not exceed 2.675 lb ai/A/yr for either product. The Primo™ label also has recommendations for use as an edger at rates of 0.024 lb ai/1000 ft², equivalent to 1.02 lb ai/A.

The chemical structure of the active ingredient is shown below:



Additional identifying characteristics of cimectacarb:

Chemical Name: 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester

Company Name: CGA-163935

CAS Registry No.: 63333-35-7

Caswell No.: 271N

Molecular Formula: C₁₃ H₁₆ O₅

Molecular Weight: 252.3

PENDING REGISTRATION INFORMATION IS NOT INCLUDED

Physical State: viscous, dark amber liquid with weak aromatic odor.

Melting Point: 36⁰C

Solubility: 2.7 g/100 ml water @ 20⁰C, pH 7

Vapor Pressure: 1.2 x 10⁻⁵ torr at 20⁰C

The registrant has provided 4 documents on the potential exposure to applicators and children during and following application of cimectacarb to turf. These include: MRID No. 422381-02, Estimate of Exposure to Children for CGA-163935 (Cimectacarb) Using Dislodgeable Residue Data from Turf Studies in NC and IL; MRID No. 41869537, CGA-163935 - Dislodgeable Residue/Reentry - Turf - North Carolina; MRID No. 41869538, Dissipation of Dislodgeable Residues on Turf for CGA-163935 2E - Illinois, and MRID No. 422381-03, Estimation of Exposure to Mixers, Loaders and Applicators Treating Turf with CGA-16395 (EC) Using Groundboom Equipment.

B. Purpose:

OREB has been requested to review the submitted documents and provide an exposure assessment for use of [REDACTED] and PrimoTM on turf.

II. DETAILED CONSIDERATIONS:

MRID No. 422381-02: Estimate of Exposure to Children for CGA-163935 (Cimectacarb) Using Dislodgeable Residue Data from Turf Studies in NC and IL.

The two studies cited in this document, MRID No. 41869537 and MRID No. 41869538, have been reviewed by OREB and do not meet requirements specified in Subdivision K of the Pesticide Assessment Guidelines (US EPA 1984/1988). The following discrepancies were noted:

MRID No. 41869537: CGA-163935 - Dislodgeable Residue/Reentry - Turf - North Carolina.

1. The determination of the grass weight to surface area was not properly validated;
2. Location of the study in North Carolina may not represent worst case conditions;
3. Justification for using a research type backpack sprayer as representative application equipment for a product labelled for use on golf course turf, commercial lawns, and sod farms must be provided;

4. Only one fortification level was used to determine field recovery;

5. Tank mix was only 57% of expected value;

6. A number of other minor inadequacies or inconsistencies have been found in the report that will require clarification. Refer to the attached study evaluation for a complete explanation.

MRID No. 41869538: Dissipation of Dislodgeable Residues on Turf for CGA-163935 2E - Illinois.

1. Location of the study in Illinois may not represent worst case conditions;

2. Only one fortification level was used to determine field recovery for dislodging solution;

3. The preapplication samples and control blank sample showed detectable levels of degradate and/or parent compound;

4. Several other minor inadequacies or inconsistencies found in the report require clarification. Refer to the attached study evaluation for a complete discussion.

Even though the two studies have not had complete formal reviews, the results will be used to estimate exposure for this action.

ESTIMATED EXPOSURE TO CHILDREN

The following assumptions were used by Ciba-Geigy to estimate exposure to children using data from the two turf dislodgeable residue studies. OREB has utilized essentially the same assumptions in its exposure estimate.

✓Child weighs 35 kg, and skin surface area is 7560 cm².

✓Ratio for body surface area is the same as for body weight.

✓Transference is 100% from grass to body.

✓Dislodgeable residues are directly proportional to rate of application.

✓20% penetration of clothes.

✓The edging rate calculated by Ciba-Geigy was 1.33 lb ai/A. Based on the Primo™ label, OREB has calculated the edging rate to be 1.02 lb ai/A. Ciba-Geigy used a broadcast rate of 0.71 lb ai/A for the exposure estimate. OREB feels that the edging rate should be used to estimate potential exposure to children rather than a broadcast rate and has therefore used the higher 1.33 lb ai/A rate reported by Ciba-Geigy.

✓Dislodgeable residues will be used from the two studies dependent on which presents the highest residue at any given time point.

✓Exposure occurs over a 30 day period after application.

TABLE 1. Body surface areas for a 35 kg child wearing only short pants.

BODY SURFACE AREAS			
Exposed (cm ²)		Unexposed (cm ²) wearing short pants only.	
Face	325	Thighs	1125
Back of neck	55		
Front of neck	75		
Forearms	605		
Back	1750		
Chest and stomach	1775		
Upper arms	660		
Lower arms	1190		
Total	6435	Total	1125
Total for both exposed and unexposed = 7560 cm ²			

TABLE 2. Total dislodgeable residues (parent plus metabolite) from studies in North Carolina, MRID No. 41869537, and Illinois, MRID No. 41869538.

TOTAL DISLODGEABLE RESIDUES FROM THE NC AND IL STUDIES (parent plus acid metabolite).			
Time after application	NC ($\mu\text{g}/\text{cm}^2$)	IL ($\mu\text{g}/\text{cm}^2$)	Value used in calculations. ($\mu\text{g}/\text{cm}^2$)
0 hrs	0.23	1.4	1.4 (day 0)
4 hrs	0.40	1.1	-----
8 hrs	0.27	0.9	-----
24 hrs	0.15	0.56	0.56 (day 1)
48 hrs	0.06	0.26	0.26 (day 2)
72 hrs	0.06	0.13	0.13 (day 3-6)
168 hrs	0.007	0.0042	0.007 (day 7-20)
192 hrs	-----	0.0036	-----
336 hrs	0.007	ND	-----
504 hrs	0.003	ND	0.003 (day 21-30)
744 hrs	ND	ND	-----

TABLE 3. Sum of the dislodgeable residues for day 0 thru 30 using the North Carolina and Illinois study data.

SUM OF THE DISLODGEABLE RESIDUES FOR 30 DAYS.	
Day	Total (μg)
0	9324
1	3730
2	1732
3-6 (4 days)	3464 (866/day)
7-20 (14 days)	392 (28/day)
21-30 (10 days)	200 (20/day)
Total exposure over 30 days.	18,842 μg

Sample calculations:

$6435 \text{ cm}^2 \times 1.4 \mu\text{g}/\text{cm}^2 = 9009.0 \mu\text{g}$ on day 0 for exposed + $(1125 \text{ cm}^2 \times 1.4 \mu\text{g}/\text{cm}^2 \times 20\%) = 315.0 \mu\text{g}$ on day 0 for unexposed. Total of exposed and unexposed on day 0 = 9324.0 μg .

$18.8 \text{ mg}/\text{app} \div 35 \text{ kg BW} = 0.54 \text{ mg}/\text{kg BW}/\text{app}$

$0.54 \text{ mg}/\text{kg BW}/\text{app} \times 3 \text{ app}/\text{yr} \div 365 \text{ days}/\text{yr} = 0.004 \text{ mg}/\text{kg BW}/\text{day}$

$0.54 \text{ mg}/\text{kg BW}/\text{app} \times 2 \text{ app}/\text{yr} \div 365 \text{ days}/\text{yr} = 0.003 \text{ mg}/\text{kg BW}/\text{day}$

OREB has used the 1.33 lb ai/A edging rate rather than the 0.71 lb ai/A broadcast rate to estimate the exposure potential to a child playing on treated turf. The average daily dose could be 0.004 mg/kg BW/day (based on 3 applications per year). Ciba-Geigy estimated exposure to a child playing on treated turf to be 0.002 mg ai/kg BW/day.

ESTIMATED EXPOSURE TO MIXER/LOADER/APPLICATORS

MRID No. 422381-03: Estimation of Exposure to Mixers, Loaders and Applicators Treating Turf with CGA-16395 (EC) Using Groundboom Equipment.

To estimate exposure to mixer/loader/applicators treating turf with CGA-16395 (EC) using groundboom equipment, Ciba-Geigy Corporation utilized the Pesticide Users Exposure Data Base

(PUEDB). OREB has relied on a more recent version of the same data base, Pesticide Handlers Exposure Database, Version 1.01 (PHED). In addition, scenarios where clothing consisted of long-sleeved shirt, long pants, without and with gloves were also run. Ciba-Geigy did not include a long-sleeved shirt scenario.

Mixer-loaders:

Ciba-Geigy generated values for mixer-loaders handling CGA-16395 (EC) were as follows: estimated mean dermal exposure of 1.82 mg ai/kg BW/day wearing a short-sleeved shirt, long pants, without protective gloves. Addition of protective gloves reduced estimated dermal exposure to 0.16 mg ai/kg BW/day. Use of coveralls over long pants, short-sleeved shirt, with gloves reduced estimated exposure to 0.002 mg ai/kg BW/day.

Minimum personal protective equipment (PPE) required by the Worker Protection Standard for Agricultural Pesticides, requires long pants, long-sleeved shirt, shoes and socks. Consequently, OREB scenarios were not run for short-sleeved shirts. OREB values generated from PHED indicate a somewhat different estimated exposure. For long pants, long-sleeved shirt, without gloves, estimated exposure was 0.96 mg ai/kg bw/day. Use of gloves reduced estimated exposure to 0.019 mg ai/kg BW/day. Using a scenario that included protective overalls over long-sleeved shirts, long pants without and with gloves resulted in estimated exposures of 0.947 mg ai/kg BW/day and 0.0037 mg ai/kg BW/day, respectively.

Mean respiratory exposure to mixer loaders, based on PHED, was estimated to be 0.0004 mg ai/kg BW/day.

Applicators:

Ciba-Geigy generated a value of 0.014 mg ai/kg BW/day for estimated dermal exposure to groundboom applicators wearing long pants, short-sleeved shirts, without gloves. Addition of coveralls and gloves reduced estimated dermal exposure to 0.002 mg ai/kg BW/day.

The OREB values for estimated exposure were: with long pants, long-sleeved shirt, without gloves, 0.263 mg ai/kg bw/day. Use of gloves would reduce estimated exposure to 0.245 mg ai/kg BW/day. Addition of protective overalls over long-sleeved shirts, long pants without and with gloves resulted in estimated exposures of 0.036 mg ai/kg BW/day and 0.018 mg ai/kg BW/day, respectively.

Mean respiratory exposure to groundboom applicators, based on PHED, was estimated to be 0.0007 mg ai/kg BW/day.

Mixer-loader-applicators:

Ciba-Geigy did not provide exposure estimates for mixer-loader-applicators. OREB values for estimated exposure were: with long pants, long-sleeved shirt, without gloves, 33.12 mg ai/kg BW/day. Use of gloves would reduce estimated exposure to 0.696 mg ai/kg BW/day. Addition of protective overalls without and with gloves resulted in estimated exposures of 32.63 mg ai/kg BW/day and 0.215 mg ai/kg BW/day, respectively.

Mean respiratory exposure to mixer-loader groundboom applicators, based on PHED, was estimated to be 0.0095 mg ai/kg BW/day.

III. CONCLUSIONS:

The two studies cited in MRID No.422381-02: Estimate of Exposure to Children for CGA-163935 (Cimectacarb) Using Dislodgeable Residue Data from Turf Studies in NC and IL (MRID Nos. 41869537 and 41869538, have been reviewed by OREB and do not meet requirements specified in Subdivision K of the Pesticide Assessment Guidelines (US EPA 1984/1988). Refer to the DETAILED CONSIDERATIONS section of the review for a complete explanation of the discrepancies.

Estimated daily dermal exposure to children playing on treated turf at the 1.33 lb ai/A edging rate, wearing only short pants with 2 applications per year could be 0.003 mg ai/kg BW/day (TABLE 4).

Estimated dermal exposure to mixer-loaders wearing long-sleeved shirt, long pants, without and with gloves is 0.96 and 0.02 mg ai/kg BW/day, respectively (TABLE 4).

Estimated dermal exposure to applicators wearing long-sleeved shirt, long pants, without and with gloves is 0.26 and 0.25 mg ai/kg BW/day, respectively (TABLE 4).

Estimated dermal exposure to mixer-loader-applicators wearing long-sleeved shirt, long pants, without and with gloves is 33.12 and 0.696 mg ai/kg BW/day, respectively (TABLE 4).

Estimated inhalation exposure for mixer-loader, applicators, and mixer-loader-applicators is 0.0004, 0.0007, and 0.0095 mg ai/kg BW/day, respectively (TABLE 5).

TABLE 4: Estimated dermal exposure from cimectacarb application to turf.

Individuals Exposed	Estimated Exposure (mg ai/kg BW/day)	Clothing Worn
Children	0.003	Short pants.
Mixer/Loaders	0.96	Long sleeve shirt and long pants.
	0.02	Long sleeve shirt, long pants, and gloves.
Applicators	0.26	Long sleeve shirt and long pants.
	0.25	Long sleeve shirt, long pants, and gloves.
Mixer/Loader/Appls.	33.12	Long sleeve shirt and long pants.
	0.696	Long sleeve shirt, long pants, and gloves.

TABLE 5: Estimated inhalation exposure from cimectacarb application to turf.

Individuals Exposed	Estimated Exposure (mg ai/kg BW/day)
Mixer/Loaders	0.0004
Applicators	0.0007
Mixer/Loader/Appls.	0.0095

No statements appear on either the [redacted] or Primo™ labels concerning personal protection equipment. Based on the toxicology category for this chemical, protective eye wear and chemical resistant gloves for pesticide handlers are required. Minimum work clothing should include long-sleeved shirts, long pants, shoes and socks. The labels should be modified to reflect these requirements.

The Primo™ label provided by the Registration Division (RD) does not contain information on multiple applications when the product is intended for use as a chemical edger. According to Mr.

Tom Parshley, Ciba-Geigy Corp., the material may be used up to two times a season for this use. The exposure scenarios used by Ciba-Geigy were for 3 applications. OREB also assumed 3 applications. This contradiction on number of applications per season should be addressed.

OREB has calculated the edging rate from the Primo™ label to be 1.02 lb ai/A. Ciba-Geigy has used an edging rate of 1.33 lb ai/A. This rate difference should be clarified and if necessary, the label corrected. In addition, the maximum broadcast rates calculated by OREB for the Primo™ and [redacted] labels are slightly different. Rates up to 0.69 lb ai/A may be used with Primo™ and up to [redacted] lb ai/A may be used with [redacted]. Multiple applications may be made but must not exceed 2.68 lb ai/A/yr for both products. Since Primo™ is a 1 lb ai/gal and [redacted] is used to reduce frequency of mowing on the same species, the maximum rates should be the same.

cc. Charles Lewis, OREB
Joanne Miller, PM 23, HED/RD (H7505C)
Gary Burin, SAB/HED (H7509C)
Stephen Dapson, RS-1/TB-II/HED (H7509C)
Correspondence File
Chemical File (cimectacarb)
Circulation

PENDING REGISTRATION INFORMATION IS NOT INCLUDED