Shaugh. No. 121301

EAB Log Out Date SEP 25 1985

Init. _____

To: Tim Gardner
Product Manager (17)
Registration Division (TS-767)

From: Carolyn K. Offutt, Chief
Environmental Processes and Guidelines Section
Exposure Assessment Branch, HED (TS-769)

Attached please find the environmental fate review of:

Reg./File No.: 100-ALU

Chemical: Cyromazine

Type Product: Insecticide

Product name: Trigard® 75W

Company name: CIBA-GEIGY Corp.

Submission Purposes: Data for estimation of fieldworker exposure to residues of Cyromazine after application of Trigard 75W to lettuce or celery. Data presented at a meeting on 9/18/85.

Data In: 9/18/85

Action Code _____

Date Completed: _____

EAB #: Addendum to 5739

TAIS (Level II) Days

Deferrals To:

___ Ecological Effects Branch

___ Residue Chemistry Branch

_X_ Toxicology Branch

REVIEW OF REENTRY DATA

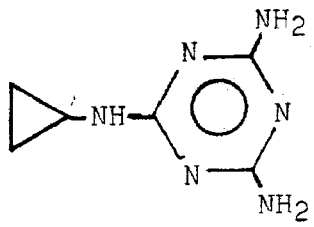
1. CHEMICAL:

Common name: Cyromazine

Product name: Trigard® 75W

Chemical name: N-Cyclopropyl-1,3,5-triazine-2,4,6-triamine

Structure:



Other names: CGA-72662; Vetrazin, Larvadex™, Armor™

2. TEST MATERIAL:

Lettuce or celery after application of Trigard® 75W.

3. STUDY/ACTION TYPE:

Review of data presented by Ciba-Geigy representatives at a meeting held on 9/18/85 to support their previous submission of data for estimation of fieldworker exposure to residues of Cyromazine after application of Trigard® 75W to lettuce or celery.

4. STUDY IDENTIFICATION:

CIBA-GEIGY Corp. data/information presented at a meeting with OPP on 9/18/85 [No Record number available 9/23/85] to support their previous 6/13/85 Submission; "Estimation of Exposure to CGA-72662 from Harvesting Lettuce and Celery", by Dr. R. C. Honeycutt, dated 6/10/85 [with 11 references included], received 6/19/85; Reg. No. 100-ALU; Record No. 154143; Accession No. 073647.

5. REVIEWED BY:

James D. Adams, PhD
Chemist
Environmental Processes and Guidelines Section — James D. Adams — 9/25/1985

6. APPROVED BY:

Carolyn K. Offutt, Chief
Environmental Processes and Guidelines Section
Exposure Assessment Branch, HED (TS-769) — Carolyn K. Offutt — 9/25/1985

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7. CONCLUSIONS:

Based on limited, additional residue data presented at the 9/18/85 meeting and using an exposure data correlation for dislodgeable residue in tree fruit harvesting, the fieldworker exposure levels at 7 days after pesticide application [the proposed PHI] will be 120 ug/hr on lettuce and 56 ug/hr on celery assuming the use of impervious gloves and long-sleeved shirts by the workers.

8. RECOMMENDATIONS:

These levels of reentry exposure to Cyromazine should be evaluated by Toxicology Branch to determine whether the levels are acceptable. If the exposure levels are acceptable to Toxicology, the reentry interval will be 7 days [this reentry interval would be identical to the PHI] for both lettuce and celery; and a restriction must be placed on the label to require fieldworkers to wear impervious gloves and long sleeved shirts. The exposure levels calculated here are based on limited data and to some extent a worst-case analysis. If registration is granted, it should be conditioned upon submission of the reentry data required under 40 CFR § 158.140 to allow full evaluation of fieldworker exposure levels.

9. BACKGROUND:

Cyromazine is an insect-growth-regulator (insecticide) proposed for use in control of immature insects on lettuce and celery. It has also been accepted for registration as an additive for chicken feed with the trade name Larvadex® [Federal Register; Vol. 50 pp. 20370-20381; May 15, 1985 (50 FR 20370)]. At 50 FR 20373, the Agency accepted a NOEL of 5 mg/kg/day based on the teratogenic effect of cyromazine. At 50 FR 20375, the Agency imposed a 3-day PSI [Pre-Slaughter-Interval] for protection of consumers to allow for clearance of Cyromazine from chickens.

The previous review [EAB no. 5739; Dated 8/15/85] was based on theoretical calculations in the absence of the data required by 40 CFR § 158.140. The Registrant presented further data in a meeting held here on 9/18/85 to support their request for registration for use of Cyromazine on lettuce and celery. The purpose of this review is to determine expected fieldworker exposure levels based on the new data presented.

10. DISCUSSION OF THE SUBMITTED DATA AND CALCULATIONS

LETTUCE

At the 9/18/85 meeting, the Registrant presented total residue levels that had been determined on the outer leaves of lettuce. These levels were taken at 0, 7, and 14 days after application of Cyromazine and were previously submitted to Residue Chemistry Branch as support for proposed PHIs of 7 days. The presented

data indicate that the maximum residue level is 4.1 ppm in the outer leaf at 7 days after the last pesticide application. With that level and the previously submitted conversion factor of 0.11 g/cm^2 for lettuce leaves, the total residues in and on outer leaves can be calculated to be 451 ng/cm^2 [See the attached calculation page.] seven days after pesticide application.

Company-presented, plant-metabolism data indicate that at least 50% of the residues of the outer leaf have penetrated into the leaf structure and been metabolized. Metabolic conversion only occurs in living tissue and is usually associated with additional penetration of the residues into the cell interior to be acted upon by enzymes bound to the cell's endoplasmic reticulum. The Registrant's contention that at least 50% of the total foliar residues are penetrated residues is consistent with the data presented and with Cyromazine's water solubility and strong tendency to be systemic. Use of this 50% factor allows calculation of total surface residues to be 226 ng/cm^2.

The Company also presented data collected from eight published papers and from the CREAMS Manual indicating that dislodgeable residue levels are generally 50% or less of the total surface residues and claimed that the CREAMS Manual recommends use of an assumed 40% dislodgeable-residue level in absence of data. The use of this second 50% factor allows estimation of the dislodgeable residue level as 113 ng/cm^2.

Dislodgeable residue levels are the appropriate data for estimation of human exposure from surrogate data such as the Popendorf correlation. From the dislodgeable residue level of 113 ng/cm^2 and Popendorf's correlation in combination with other surrogate data in my files, the human exposure at 7 days after last pesticide application is estimated to be 1200 ug/hr for lettuce.

That estimate is a worse-case calculation. It can be substantially reduced by use of impervious gloves and long sleeved shirts. In this case the reduction could be 90%, and the resulting reentry exposure would be 120 ug/hr or 0.90 mg/day for a 7.5 hour exposure day.

CELERY

The data presented indicate that the average residue level for celery seven days after last Cyromazine application would be 2.1 ppm and that the residues are distributed throughout the stalk. Assuming that the same principles used for estimation of dislodgeable Cyromazine residues on lettuce will apply for estimation of dislodgeable Cyromazine residues on celery, a ratio and proportion calculation can be made to give 58 ng/cm^2.

This value in turn used in conjunction with the surrogate data used above gives a reentry exposure of 560 ug/hr. This can be further reduced by fieldworker's use of impervious gloves and long-sleeved shirts to about 56 ug/hr or 0.42 mg/day for a 7.5 hour exposure day.

11. COMPLETION OF ONE-LINER:

Not applicable

12. CBI APPENDIX:

Not applicable

9/23/85

Estimation of Cyromazine Residues on Lettuce and Celery and Fieldworker Exposure to the Residues

LETTUCE

Given: Residue level is 4.1 ppm; less than 50% of the residues are on the surface and about 50% of those are dislodgeable.

Total residues in/on outer leaves = $(4.1\ ug/g)(0.11 g/cm^2)$

$= 0.451\ ug/cm^2 = 451\ ng/cm^2$

Total surface residues on outer leaves = $(451\ ng/cm^2)(0.50)_a$

$= 226\ ng/cm^2$

Dislodgeable residues = $(226\ ng/cm^2)(0.50)_b = 113\ ng/cm^2$

Human Exposure$_c$ = 1200 ug/hr

Human Exposure corrected for use of protective equipment = $(1200\ ug/hr)(0.10)_d = 120\ ug/hr$

CELERY

Given: The residue level is 2.1 ppm at 7 days after application; and the same principles apply to celery and lettuce [i.e. the residues are distributed throughout the stalk and leaves; less than 50% of the residues are on the surface; less than 50% of the surface residues are dislodgeable].

Dislodgeable residues on celery = $\frac{(2.1\ ug/g)(113\ ng/cm^2)}{(4.1\ ug/g)}$

$= 58\ ng/cm^2$

Human Exposure$_c$ = 560 ug/hr

Human Exposure corrected for use of protective equipment =

$(560\ ug/hr)(0.10)_d = 56\ ug/hr$

a) Factor based on Registrant data showing that at least 50% of the residues have penetrated into the plant.
b) Factor based on Registrant data showing that less than 50% of the surface residues are dislodgeable.
c) From surrogate fieldworker exposure data correlation with dislodgeable residues in tree fruit harvesting.
d) Protective equipment considered here are impervious gloves and long-sleeved shirts.

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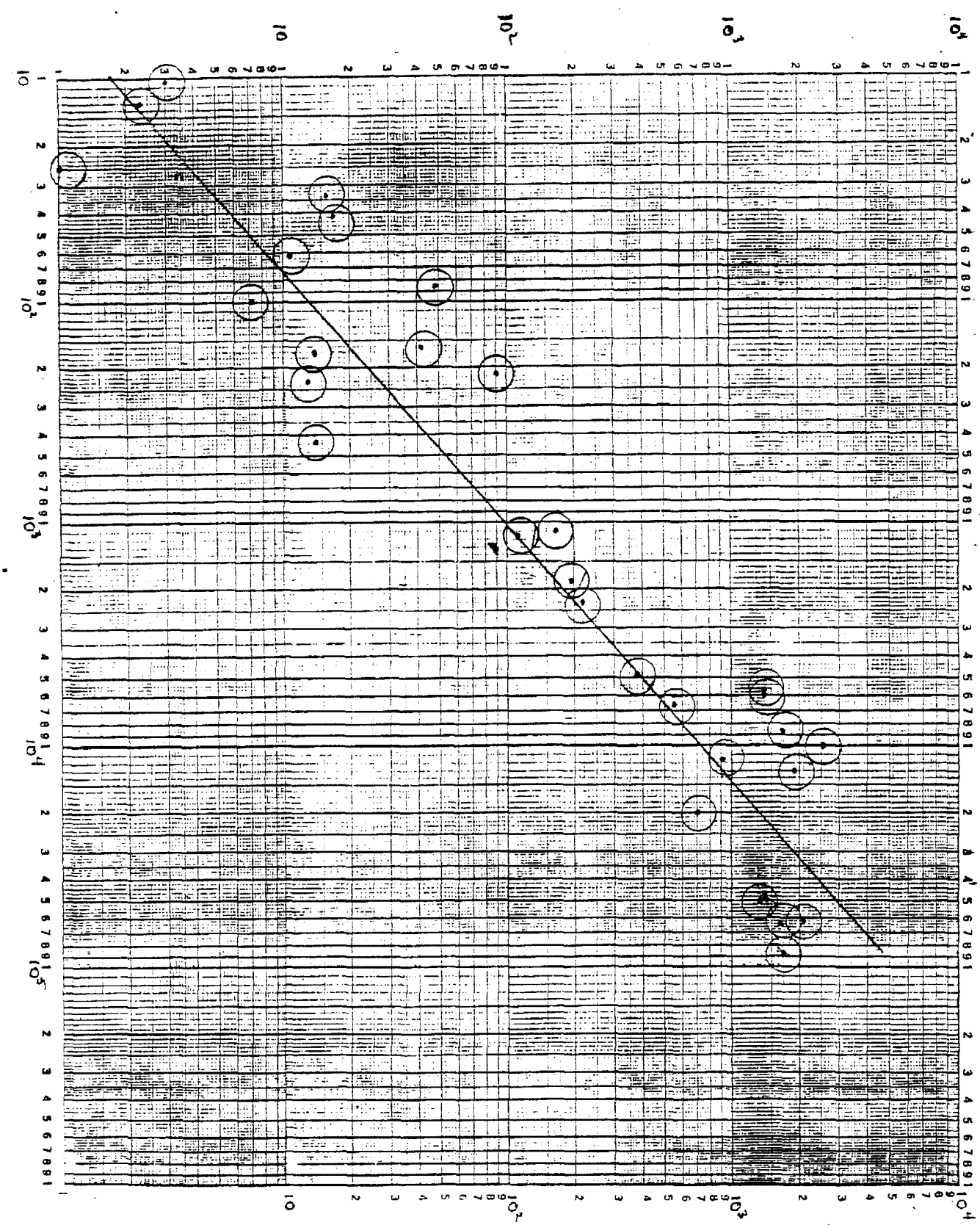
CORRELATION OF DISLODGEABLE RESIDUES WITH FIELDWORKER EXPOSURE



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PC Code:	**121301**
HED File Code	**12000 Exposure Reviews**
Memo Date:	**09/25/85**
File ID:	**00000000**
Accession Number:	**412-05-0040**

HED Records Reference Center
10/29/2004