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APPENDICES

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act

I. REGULATORY POSITION AND RATIONALE

This chapter contains the general regulatory position and

substantially similar MDL and PDL are addressed here. Both

Chlordimeform and chlordimeform HCl are currently registered for

(hemangioendothelioma--tumor of the liver blood vessels). The

other registrants took similar action with their products.

workers in production and formulating plants. Chlordimeform and

metabolites tested on different animal species and strains), it is

satisfy the data requirements

3) these circumstances, the statistical analysis of these data

The positive mutagenic effects occurred with the metabolites that

produced positive oncogenic effects in the mouse.

Oral LD [illegible] in the [illegible] range of [illegible] 140 to 406 mg/kg

respectively. Acute dermal toxicity is moderate with a LD50 (rabbit)

temperature with N-formyl-4-chloro-o-toluidine being the major

[redacted]

carcinogenic response. Worker exposure studies have shown the

the Agency; however, these data are difficult to interpret into

potential to runoff into and be used near aquatic systems.

for birds and aquatic organisms, may be required. Also, these

Rationale

After one day, the remaining dislodgeable residues are 0.17 $\mu g/cm^2$.

Whereas after five days the residues are 0.02 $\mu g/cm^2$, which are low

to fish and wildlife.

The Agency will propose the revocation of established tolerances

Statements Per End Use Products

1. All end use products must bear the restricted use statement

loaders must also wear a chemical resistant

2. The following cancer warning must appear in caps on labels of technical and manufacturing-use products:

> THIS PRODUCT HAS BEEN SHOWN TO CAUSE CANCER IN LABORATORY ANIMALS. THE USER MUST READ AND FOLLOW ALL PRECAUTIONARY STATEMENTS AND INSTRUCTIONS.

G. Tolerance Reassessment Summary

40 CFR section 180.285 and 21 CFR sections 193.60 and 561.80 list the various established tolerances for chlordimeform and chlordimeform HCl and their metabolites that contain the 4-chloro-o-toluidine moiety. These are as follows:

Crop	Tolerances(ppm)
Pears	12.
*Cottonseed oil	5.
*Cottonseed hulls	10.
Cherries	5.
Nectarines	5.
Peaches	5.
Plums, incl. fresh prunes	4.
Prunes, dried	15.
Apples	3.
Apple pomace	25.
Broccoli	2.
Brussel sprouts	2.
Cabbage, sauerkraut	2.
Cauliflower	2.
Tomatoes	1.
*Cattle	0.25
*Goats	0.25
*Hogs	0.25
*Poultry	0.25
*Sheep	0.25
*Horses	0.25
*Eggs	0.05
*Milk & Dairy Products	0.05
Walnuts	0.10

*Tolerances which are associated with the application to cotton.

The above tolerances were established between 1968 and 1976 and were based on a chronic toxicity data base that included subchronic

Should the required metabolism data indicate the presence of

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Guideline Citation and Name of Test	Test Substance[1]	Guidelines Status	Are Data Required ? Yes	No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below [2]
<u>§158.120 Product Chemistry (Continued)</u>						
<u>Physical and Chemical Characteristics (Continued)</u>						
63-5 - Melting Point	TGAI	R	☒	☐		6 Months
63-6 - Boiling Point	TGAI	R	☒	☐		6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	☒	☐		6 Months
63-8 - Solubility	TGAI or PAI	R	☒	☐	7	6 Months
63-9 - Vapor Pressure	PAI	R	☒	☐		6 Months
63-10 - Dissociation constant	PAI	R	☒	☐		6 Months
63-11 - Octanol/water partition coefficient	PAI	R	☒	☐		6 Months
63-12 - pH	TGAI	R	☒	☐		6 Months
63-13 - Stability	TGAI	R	☒	☐		6 Months
<u>Other Requirements</u>:						
64- 1 - Submittal of samples	TGAI, PAI	CR	Reserved [8]			6 Months

TABLE A

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE (HCl)

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission [2]
§158.125 Residue Chemistry				
171-2 - Chemical Identity	TGAI	Yes	00098977, 00100811 00099014, 00073479	No
171-3 - Directions for Use	--		00104272, 00103369	No
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partial	00098991, 00087052 00087053, 00087056	Yes[3] 18 Months
- Livestock	PAIRA and Plant Metabolites	Partial	00087050, 00087051 00087054, 00087055	Yes[3,4] 18 Months
171-4 - Residue Analytical Method				
- Plant residues	TGAI and Metabolites	No		Yes[5] 15 Months
- Animal residues	TGAI and Metabolites	No		Yes[5] 15 Months
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Cotton				
-- Crop field trials	TEP	Yes	00097467, 00086695 00036949, 00080099 00069682, 00099031 00102410, 00099011 00098957, 00087046	Reserved

TABLE A

[redacted]

TABLE A

TABLE A

TABLE A

TABLE A

TABLE A

TABLE A

TABLE A

[redacted]

TABLE A

TABLE B

CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE

CHLORDIMEFORM AND CHLORDIMEFORM HYDROCHLORIDE

Guideline	Citation	Test	Guidelines	Are Data	Protocol	Data Must Be Submitted Within

TABLE B

C05970 CHLORDIMEFORM*

FORMULATIONS:

EC (4 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Do not mix

(Agricultural Crops)

/28007AA	Cotton	5 ppm (cottonseed)
		0.25 pound per acre for foliar application. 24 hour reentry period. Do not feed treated foliage or gin

Site and Pest Dosages and Tolerance. Use. Limitations

Formulation (s)

Cotton (continued)

CHLORDIMEFORM

Listing by Site/Pest and Site/Formulation/Registration Number

TERRESTRIAL FOOD CROP

P77777A Increase yield

TYPE PESTICIDE: Insecticide, Plant Regulator

FORMULATIONS:

SC/S (95%, 97%)

TERRESTRIAL FOOD CROP

(Agricultural Crops)

007AA	Cotton	5 ppm (cottonseed)

CHLORDIMEFORM HYDROCHLORIDE

Code	(source)	Common/Chemical Name

Appendix B

Listing by Site/Pest and Site/Formulation/Registration Number

TERRESTRIAL FOOD CROP

TBCROA	Bollworm (including eggs)
177777A	Increase yield
TBCRWA	Tobacco budworm (including eggs)

for each major formulation category (e.g., emulgifiable concen

as generic data and when needed are specified in Table A

OR

Note: Unless stated otherwise in Section I. Regulatory Position and Rationale, this Section applies only to manufac-

A necessary first step in determining which statements

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to all products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

[illegible] EPA REGISTRATION NUMBER. The registration

Item 7D SIGNAL WORD The signal word (DANGER, WARNING

the child hazard warning statement. See Appendix IV.)

label if it meets the criteria in Appendix IV-3. The require-

requires that all pesticide formulations be classified

Bulletins, leaflets, circulars, brochures, data sheets

text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft

1 Within 90 days from receipt of this document, you must

a. Author. Whenever the Agency could confidently identify

REGISTRATION STANDARD BIBLIOGRAPHY

Registrations Under the Chlordimeform Standard

MRID	CITATION

REGISTRATION STANDARD BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting

Registrations Under the Chlordimeform Standard

MRID	CITATION
00066881	Blackmore, R.H. (1969) Final Report: Three-generation Reproduction

OFFICE OF PESTICIDE PROGRAMS

REGISTRATION STANDARD BIBLIOGRAPHY

Registrations Under the Chlordiuroform Standard

REGISTRATION STANDARD BIBLIOGRAPHY

Registrations Under the Chlordimeform Standard

Citations Considered to be Part of the Data Base Supporting

Citations Considered to be Part of the Data Base Supporting

Citations Considered to be Part of the Data Base Summaries

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REGISTRATION STANDARD BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting

OMB Approval No. 2000-0450 (E

[OPP-36103;FRL]

whether they meet the criteria for continued registration

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