

009711

Reviewed by: Dan W. Hanke, Ph. D.
Section III, Tox. Branch II (H7509C)
Secondary Reviewer: K. Clark Swentzel
Section II, Tox. Branch II (H7509C)

Dan W. Hanke 06 July 92
K. Clark Swentzel
JUL 7 1992

DATA EVALUATION RECORD

1992

STUDY TYPE: Acute Oral Toxicity (§81-1)

DP BARCODE: D176468

SUBMISSION NO.: S415122

CASE TYPE: Registration

TOX. CHEM. NO. (CASWELL NO.): 271N

MRID NO. (ACCESSION NO.): 418695-14

ID#: 000100-TEO Primo Turf Growth Regulator (12.0% active ingredient/Cimectacarb)

CAS REG. NO.: 95266-40-3

EPA PESTICIDE CHEMICAL CODE/ACTIVE INGREDIENT CODE (SHANGHNESSY NO.): 112602

FIFRA 88 LIST: NA

PRODUCT MANAGER/NO.: Joanne Miller/23

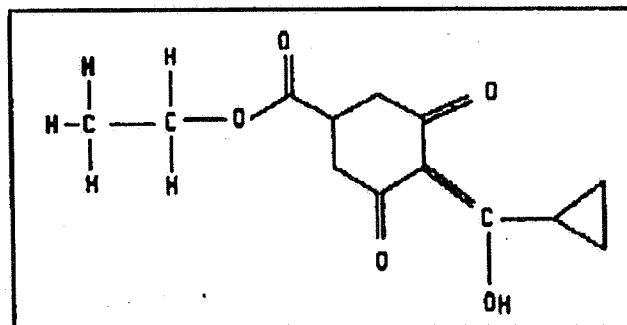
HED PROJECT NO.: 0-1874

TEST MATERIAL: Cimectacarb; turf growth regulator;
4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane
carboxylic acid ethylester; the formulation used in this study is
Primo, which is 1-E on the label, which is 12.0% active
ingredient

SYNONYMS: Vision (22.8%, 2-E),
Primo (12%, 1-E)

STUDY NUMBER: 7674-90

SPONSOR: Agricultural Division
Ciba-Geigy Corp.
P. O. Box 18300
Greensboro, NC 27419-
8300



TESTING FACILITY: Still meadow, Inc.
12852 Park One Drive
Sugar Land, Texas 77478

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TITLE OF REPORT: Acute Oral Toxicity Study in Rats**AUTHOR(S):** Janice O. Kuhn, Ph. D.**STUDY COMPLETED:** January 14, 1991**SUMMARY AND CONCLUSIONS:**

The acute oral LD₅₀ for Primo turf growth regulator (12% Cimectacarb, 1-E formulation) was 5010 mg/kg and 5730 mg/kg body weight for female and male rats respectively. The overall LD₅₀ for both male and female rats was 5130 mg/kg body weight. The test article was administered one time undiluted via gavage to three groups each composed of five female and five male Harlan Sprague Dawley rats at doses of 4000 mg/kg, 5050 mg/kg, and 5500 mg/kg respectively. At the lowest dose tested (LDT) none of the rats died on study (DOS). At the mid and high doses tested (MDT and HDT respectively), however, 3/5 males or females in each MDT group and 1/5 males versus 5/5 females in the HDT groups died. Clinical signs included piloerection, polyuria, salivation, nasal discharge decrease in activity, ataxia, diarrhea, and lacrimation.

Toxicity Category: IV**A signed quality assurance statement was present.****Core Classification:** Minimum**This study satisfies the guideline requirements (§81-1) for an Acute Oral Toxicity study.****MATERIALS:**

1. **Test Compound:** CGA-163935 1E-B FL-901930, which is the Primo formulation; Cimectacarb turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester. Description: amber or dark-brown liquid. Density: 1.0116 g/ml. Batch Code: GP-901102. Purity: The purity is not reported in this study; however, the purity (92.0%) and chemical structure (see inset box on page one of this DER) of the active ingredient (A.I.) are reported in volume 34 of 46 of the EUP submission, which is MRID # 416042-06. The test article was administered undiluted. The test article in this study was Primo turf growth regulator, which is 12% A.I. with a density of 1.0116 g/ml.

2. **Test animals:** Species: Rat, 15 of each sex (females were nulliparous and non-pregnant). Strain: Harlan Sprague Dawley (HSD) BR. Age: not reported. Weight: at time of dosing the males were 212-289 g, and females were 177-235 g. Source: Harlan Sprague Dawley, Inc., Houston, Texas.

METHODS:

Rats were fasted at least 16 hours before dosing. Food and water were returned to the rats ad libitum after dosing. Test material was administered orally by gavage as neat material (density = 1.0116 g/ml) at doses (and volumes) of 4000 mg/kg (3.954 ml/kg), 5050 mg/kg (4.992 ml/kg), and 5500 mg/kg (5.437 ml/kg) body weight. Animals were observed at least three times after dosing and daily for a total of 14 days after dosing on day zero (0). Rats were weighed on days 0, 7, and 14. Gross necropsy was performed on all animals that died on study (DOS) and on all survivors which were sacrificed on day 14. Doses and lethality are presented in table 1 under results.

RESULTS AND DISCUSSION:**Clinical Signs.**

Some of the clinical signs frequently noted in the rats were piloerection, polyuria, salivation, nasal discharge decrease in activity, ataxia, diarrhea, and lacrimation. The data for these clinical signs are in appendix 1 of this DER taken from pp. 19-21 of the study report.

Additionally, although there were no deaths in the low dose tested (LDT) groups, there were deaths of each sex in the MDT group and the HDT group. The mortality results are shown in table 1 of this DER, where the data are reproduced from pp. 12-15 of the study report. The dosing volumes in table 1 are listed in ml/kg body weight and were added by this reviewer.

Table 1. Doses and Deaths

Dose		Volume		Males		Females		Overall		Percent
mg/kg	ml/kg	deaths/dosed		deaths/dosed		deaths/dosed		deaths/dosed		Mortality
4000	3.954	0	/ 5	0	/ 5	0	/ 10			
5050	4.992	3	/ 5	3	/ 5	6	/ 10			
5500	5.437	1	/ 5	5	/ 5	6	/ 10			
LD ₅₀ (+95%CL) = 5734 mg/kg (4657-7061)		5006 mg/kg (4797-5223)		5130 mg/kg (4736-5510)						

There were no observable abnormalities (NOA) at the LDT, however, a variety of abnormalities were present in the animals of the MDT and HDT groups at necropsy. These abnormalities included polyuria, nasal discharge, diarrhea, distention of the gastrointestinal tract with gas, salivation, cannibalism, testes drawn into the abdominal cavity, and protrusion of the penis. Body weights and the gross necropsy findings are presented in Table 2. DER reproduced from pp. 16-18 of the study report.

Table 2. Body Weights and Gross Necropsy Findings

Animal Number	Dose (mg/kg)	Body Weights (g)			Time of Death Day	Gross Necropsy Findings
		Day 0	Day 7	Final		
30-M	4000	269	292	329	14	NOA
31-M	4000	289	305	353	14	NOA
32-M	4000	267	283	338	14	NOA
33-M	4000	279	299	343	14	NOA
34-M	4000	276	292	334	14	NOA
35-F	4000	204	230	246	14	NOA
36-F	4000	213	229	261	14	NOA
37-F	4000	177	192	211	14	NOA
38-F	4000	205	225	234	14	NOA
39-F	4000	180	202	227	14	NOA
226-M	5050	282	---	251	2	Signs of polyuria, nasal discharge and gastrointestinal distention with gas and testes drawn into abdominal cavity.
227-M	5050	261	---	232	2	Signs of polyuria, nasal discharge and intestinal distention with gas and red-yellow testes drawn into abdominal cavity; prolapse of penis.
228-M	5050	258	270	311	14	NOA.

Table 2 Continued

Animal Number Dose (mg/kg)		Body Weights (g)			Time of Death		Gross Necropsy
		Day 0	Day 7	Final	Day		
229M	5050	273	---	248	02		Signs of nasal lacrimation, p cannibalism; w material in st in small and l testes drawn i cavity.
230M	5050	266	299	341	14		NOA
231F	5050	218	---	198	02		Signs of nasal salivation; st with gas; red material in in
232F	5050	209	---	181	2		Signs of nasal salivation; st with gas; red material in in
233F	5050	235	245	259	14		NOA
234F	5050	205	220	242	14		NOA
235F	5050	202	---	175	2		Signs of nasal salivation, ga tract distende yellow mucoid
40M	5500	229	258	324	14		NOA
41M	5500	220	256	311	14		NOA
42M	5500	221	---	191	2		Signs of canni discharge and mottled; gast distended with red mucoid mat
43M	5500	212	240	308	14		NOA
					5		

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Table 2 Continued

Animal Number Dose (mg/kg)		Body Weights (g)			Time of Death		Gross Necropsy
		Day 0	Day 7	Final	Day		
44M	5500	215	246	303	14		NOA
45F	5500	198	---	175	2		Signs of nasa polyuria; sto gas and white large intesti gas and brown intestine ful material; liv black edge.
46F	5500	202	---	186	2		Signs of nasa polyuria; sto gas and white large intesti gas and brown intestine ful material; liv black edges.
47F	5500	200	---	175	3		Signs of lacr and diarrhea; with gas; sma distended with mucoid materia
48F	5500	201	---	171	3		Signs of lacr discharge, po diarrhea; sto gas; small in with gas and material.
49F	5500	182	---	158	2		Signs of nasa polyuria; sto gas and white small intesti

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Table 2 Continued

Animal Number Dose (mg/kg)	Body Weights (g)			Time of Death Day	Gross Necropsy
	Day 0	Day 7	Final		
					mucoid material distended with slurry.
1 NOA - No Observable Abnormalities					

RESULTS AND DISCUSSION CONTINUED:

The individual dosing volumes of the undiluted test article for each animal were not provided in the study report. However, the volume for each dose group based on ml/kg was provided along with the density of the test article. Since the overall or average of the mean LD₅₀s for both male (5730 mg/kg) and female (5010 mg/kg) rats was 5130 mg/kg body weight which exceeds the limit dose of 5000 mg/kg, this places the test article in Toxicity Category IV.

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Appendix No. 1

MRID No. 418695.14

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Page ____ is not included in this copy.

Pages 9 through 11 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product inert impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☒ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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Tox. Chem. No. 271 N File Last Updated N/A Current Date 26 Jun 92 Doc

Study/Lab/Study #/Date	Material	EPA MRID No.	Resu LD50, LC50, PI
Acute oral toxicity in rats/ Stillmeadow, Inc/ 7674-90/ 14 Jan 1991	Ciba-Geigy CGA-163935, a turf growth regulator, 4-(cyclopropyl- α -hydroxymethylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester, moist/soft solid brown in color melting 29-32 deg C. The dark brown liquid formulation (1E) of CGA-163935 is 12.0 % active ingredient, which is the Primo formulation used in this study.	418695-14	The overall LE mg/kg body wei for female rat kg, and the LE rats was 5730 The doses were and 5500 mg/kg

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Reviewed by: Dan W. Hanke, Ph. D.
Section III, Tox. Branch II (H7509C)
Secondary Reviewer: K. Clark Swentzel
Section II, Tox. Branch II (H7509C)

Dan W. Hanke 06 July 92
K. Clark Swentzel

JUL 7 1992

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity (\$81-2)

DP BARCODE: D176468

SUBMISSION NO.: S415122

CASE TYPE: Registration

TOX. CHEM. NO. (CASWELL NO.): 271N

MRID NO. (ACCESSION NO.): 418695-15

ID#: 000100-TEO Primo Turf Growth Regulator (12.0% active ingredient/Cimectacarb)

CAS REG. NO.: 95266-40-3

EPA PESTICIDE CHEMICAL CODE/ACTIVE INGREDIENT CODE (SHANGHNESSY NO.): 112602

ELFRA 88 LIST: NA

PRODUCT MANAGER(s)/NO.: Joanne Miller; Steve Robbins/23

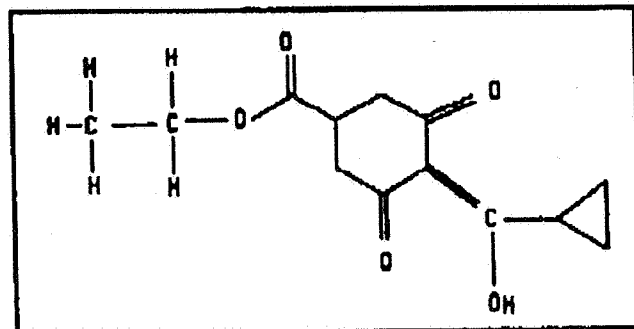
HED PROJECT NO.: 0-1874

TEST MATERIAL: Cimectacarb; turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester; the formulation used in this study is Primo, which is 1-E on the label, which is 12.0% active ingredient.

SYNONYMS: None

STUDY NUMBER: 7675-90

SPONSOR: Agricultural Division
Ciba-Geigy Corp.
P. O. Box 18300
Greensboro, NC 27419-8300



TESTING FACILITY:

Still meadow, Inc.
12852 Park One Drive
Sugar Land, Texas 77478

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TITLE OF REPORT: Acute Dermal Toxicity Study in Rabbits

AUTHOR(S): Janice O. Kuhn, Ph. D.

STUDY COMPLETED: January 3, 1991

SUMMARY AND CONCLUSIONS:

The acute dermal LD₅₀ for CGA-163935 1E-B FL-901930, Primo turf growth regulator, was determined to be greater than 2020 mg/kg body weight (2g/kg is the limit dose) in five male and five female albino rabbits. All the rabbits were asymptomatic throughout the study, and no abnormalities were found at necropsy.

Toxicity Category: III

A signed quality assurance statement was present.

Core Classification: Minimum

This study satisfies the guideline requirements (§81-2) for an Acute Dermal Toxicity study.

MATERIALS:

1. **Test Compound:** CGA-163935 1E-B FL-901930, which is the Primo formulation; Cimectacarb turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester. Description: amber or dark-brown liquid. Density: 1.0116 g/ml. Batch Code: GP-901102. Purity: The purity is not reported in this study; however, the purity (92.0%) and chemical structure (see inset box on page one of this DER) of the active ingredient (A.I.) are reported in volume 34 of 46 of the EUP submission, which is MRID # 416042-06. The test article was administered undiluted. The test article in this study was Primo turf growth regulator, which is 12% A.I. with a density of 1.0116 g/ml.

2. **Test animals:** Species: Rabbit. Strain: New Zealand White. Source: Ray Nichols Rabbitry, Lumberton, TX. Quantity and Sex: five males and five females (nulliparous and non-pregnant). Weight: at initiation of the study the males were 3.225-3.80 kg, and the females were 2.675-3.625 kg. Age: young adult - 3 to 6 months old.

METHODS:

The rabbits were carefully clipped on the dorsal surface of the trunk to expose at least 10 % of total body surface area on the day before dosing. On the day of dosing, surgical gauze was applied with non-irritating adhesive tape, which would hold the test article in contact with the skin. The animal's trunk was

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then wrapped in an orthopedic stockinette, which would help keep the test article from evaporating. Next each rabbit was dosed on day zero (0) with 2020 mg/kg of undiluted test article (1.997 ml/kg), which was introduced up under the dressings using a needle and syringe. After 24 hrs the dressings were removed and the skin washed. Observations for toxic effects were made at 30 min, 3 hrs, and 6 hrs after dosing and, further, at least once each day for 14 days. Body weights were recorded on days 0, 7, and 14. Gross necropsies were performed on each animal at the end of the observation period on day 14.

RESULTS AND DISCUSSION:

All of the rabbits were asymptomatic throughout the study, and none of the animals died on study (DOS). Gross necropsies were negative for abnormalities. The dose applied at 2020 mg/kg exceeded the limit dose of 2000 mg/kg body weight. The acute dermal LD₅₀ for the test article, Primo turf growth regulator, is, therefore, greater than 2020 mg/kg body weight.

Tox. Chem. No. 271 N File Last Updated N/A Current Date 29 Jun 92 Docu

Study/Lab/Study #/Date	Material	EPA MRID No.	Resul LD50, LC50, PIS
Acute dermal toxicity rabbits Stillmeadow, Inc 7675-90/ 3 Jan 1991	Ciba-Geigy CGA-163935, a turf growth regulator, 4-(cyclopropyl- α -hydroxy- methylene)-3,5-dioxo-cyclo- hexane carboxylic acid ethylester, moist/soft sol- id brown in color melting 29-32 deg C. The dark brown liquid formulation (1E) of CGA-163935 is 12.0 % active ingredient, which is the Primo formu- lation used in this study.	418695-15	The LD50 was gr 2020 mg/kg body There were no a noted for any r none of the rab

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Reviewed by: Dan W. Hanke, Ph. D.
 Section III, Tox. Branch II(H7509C)
 Secondary Reviewer: K. Clark Swentzel
 Section II, Tox. Branch II(H7509C)

Dan W. Hanke 07 July 82
K. Clark Swentzel JUL 7 1982

DATA EVALUATION RECORD

STUDY TYPE: Acute Inhalation Toxicity Study (§81-3)

DP BARCODE: D176468

SUBMISSION NO.: S415122

CASE TYPE: Registration

TOX. CHEM. NO. (CASWELL NO.): 271N

MRID NO. (ACCESSION NO.): 418695-16

ID#: 000100-TEO Primo Turf Growth Regulator (12.0% active ingredient/Cimectacarb)

CAS REG. NO.: 95266-40-3

EPA PESTICIDE CHEMICAL CODE/ACTIVE INGREDIENT CODE (SHANGHNESSY NO.): 112602

FIFRA 88 LIST: NA

PRODUCT MANAGER(s)/NO.: Joanne Miller; Steve Robbins/23

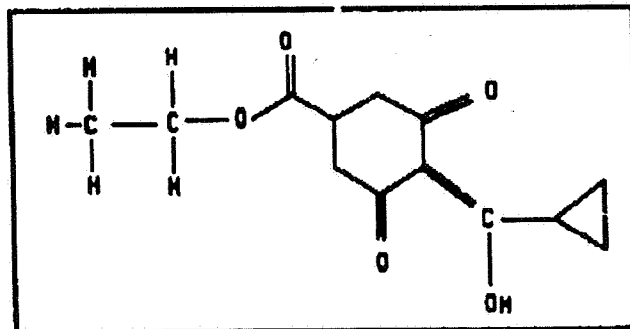
HED PROJECT NO.: 0-1874

TEST MATERIAL: Cimectacarb; Primo turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester; the formulation used in this study is Primo, which is 1-E on the label, which is 12.0% active ingredient.

SYNONYMS: None

STUDY NUMBER: 7676-90

SPONSOR: Agricultural Division
 Ciba-Geigy Corp.
 P. O. Box 18300
 Greensboro, NC 27419-8300



TESTING FACILITY:

Still meadow, Inc.
 12852 Park One Drive
 Sugar Land, Texas 77478

17 000118

TITLE OF REPORT: Acute Inhalation Toxicity Study in Rats

AUTHOR(S): Mark S. Holbert

STUDY COMPLETED: March 28, 1991

SUMMARY AND CONCLUSIONS:

The LC₅₀ of CGA-163935 Primo turf growth regulator (12.0% Cinectacarb) determined in a whole body 4-hour exposure inhalation study using 5 male and 5 female rats was greater than 0.888 mg/L, where at least 25% of the liquid aerosol particles were 1.1 microns or less generated from undiluted test article. Clinical signs of slight to moderate severity included activity decrease, nasal discharge, piloerection, polyuria, ptosis, and salivation. None of the rats died on study (DOS), and there were no observable abnormalities (NOA) recorded at necropsy.

Toxicity Category: III

A signed quality assurance statement was present.

Core Classification: Minimal

This study satisfies the guideline requirements (581-3) for an Acute Inhalation Toxicity Study.

MATERIALS:

1. **Test Compound:** CGA-163935 1E-B FL-901930, which is the Primo formulation; Cinectacarb turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester. Description: amber or dark-brown liquid. Density: 1.0116 g/ml. Batch Code: GP-901102. Purity: The purity is not reported in this study; however, the purity (92%) and chemical structure (see inset box on page one of this DER) of the active ingredient (A.I.) are reported in volume 34 of 46 of the EUP submission, which is MRID # 416042-06. The test article aerosol was generated undiluted. The test article in this study was Primo turf growth regulator, which is 12% A.I. with a density of 1.0116 g/ml. The exposure chamber concentration of Primo was 0.888 mg/L as a liquid aerosol with at least 25% of the particles less than 1.1 microns.

2. **Test animals:** Species: Rat. Strain: HSD (SD). Source: Harlan Sprague Dawley, Inc., Houston, Texas. Quantity and Sex: five males and five females (nulliparous and non-pregnant). Weight at Dosing: Males 190-208 g. Females 1840199 g. Age: young adult.

METHODS:

Except during dosing the rats had food and water available ad libitum. The rats were dosed for four hours at a test article concentration of 0.888 mg/L under whole-body exposure conditions, where at least 25% of the particles were 1.1 microns or less. An attempt was made to generate the limit dose exposure concentration of 5.0 mg/L, with at least 25% of the particles 1.0 microns or less, however the limit dose could not be attained under these conditions.

The test article liquid aerosol was prepared by forcing the undiluted test article through a pressure regulated air atomizer (Spraying System Company, 1/4 JSS) with an attached nebulizer ball. This concentrated aerosol was elutriated through a baffling chamber and then diluted with dried, filtered air and introduced into the exposure chamber. Aerosol flow into the exposure chamber was regulated using a calibrated critical orifice. Furthermore, aerosol flow was recorded at 30 minute periods during animal exposure, and assay of the samples indicated at least 19% of the aerosol was oxygen. Additionally, the temperature and humidity were recorded at 30 minute intervals from a Taylor wet bulb/dry bulb hygrometer placed in the exposure chamber. Determination of the test material concentration in hourly samples (and at the end of the exposure) taken in the exposure chamber from the breathing zone of the animals was performed on a Bausch and Lomb Spectronic 2000 spectrophotometer. Then the nominal concentration of test article was determined by dividing the loss in volume of the test material after exposure by the total volume of aerosol that passed through the chamber. Finally, the determination of the particle size in the breathing zone of the rats was made twice during exposure, using an Andersen cascade impactor running at a rate of 28.31 L/minute for two minutes. Then the mass median aerodynamic diameter and percent of particles under 1 micron was calculated from these data. Appendix 1 of this DER contains the methods relating to generation of the liquid aerosol, etc., taken from pp 10-12, and 15-19 of the study report.

The rats were frequently observed for clinical signs and toxicity on the day of dosing (day zero) and at least once a day for 14 days. Body weights were recorded on days 0, 7, and 14, and gross necropsy was performed on each rat at the end of the study.

RESULTS AND DISCUSSION:

Clinical signs of slight to moderate severity included activity decrease, nasal discharge, piloerection, polyuria, ptosis, and salivation. The clinical signs are reproduced in appendix 2 of this DER taken from p. 14 of the study report. None of the rats died on study (DOS), and there were no observable abnormalities (NOA) recorded at necropsy. The LD₅₀ for CGA-163935 1E-B FL-

901930 Primo formulation (12.0% Cimectacarb), with at least 25% of the liquid aerosol particles 1.1 microns or less, was greater than the maximum attainable concentration of 0.888 gm/L using undiluted test article.

CONCLUSIONS:

The LC_{50} was > 0.888 mg/L, which places CGA-163935 1E-B FL-901930, the Primo formulation (12.0% Cimectacarb) of this turf growth regulator, in Toxicity Category III.

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Appendix 1

MRID No. 418695-16

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Page ____ is not included in this copy.

Pages 22 through 31 are not included in this copy.

The material not included contains the following type of information:

- ____ Identity of product inert ingredients.
- ____ Identity of product inert impurities.
- ____ Description of the product manufacturing process.
- ____ Description of quality control procedures.
- ____ Identity of the source of product ingredients.
- ____ Sales or other commercial/financial information.
- ____ A draft product label.
- ____ The product confidential statement of formula.
- ____ Information about a pending registration action.
- ☒ FIFRA registration data.
- ____ The document is a duplicate of page(s) ____.
- ____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Study/Lab/Study #/Date	Material	EPA MRID No.	Result LD50, LC50, PIS
Acute inhalation tox. in rats/Stillmeadow, Inc 7675-90/ 28 Mar 1991	Ciba-Geigy CGA-163935, a turf growth regulator, 4-(cyclopropyl- α -hydroxy- methylene)-3,5-dioxo-cyclo- hexane carboxylic acid ethylester, moist/soft sol- id brown in color melting 29-32 deg C. The dark brown liquid formulation (1E) of CGA-163935 is 12.0 % active ingredient, which is the Primo formu- lation used in this study.	418695-16	The LC50 was gr 0.89 mg/kg body There were no s noted for any none of the rat

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Reviewed by: Dan W. Hanke, Ph. D.
Section III, Tox. Branch II(H7509C)
Secondary Reviewer: K. Clark Swentzel
Section II, Tox. Branch II(H7509C)

Dan W. Hanke 07 July 92
K. Clark Swentzel
JUL 7 1992

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation (§81-4)

DP BARCODE: D1764C8

SUBMISSION NO.: S415122

CASE TYPE: Registration

TOX. CHEM. NO. (CASWELL NO.): 271N

MRID NO. (ACCESSION NO.): 418695-17

ID#: 000100-TEO Primo Turf Growth Regulator (12.0% active ingredient/Cimectacarb)

CAS REG. NO.: 95266-40-3

EPA PESTICIDE CHEMICAL CODE/ACTIVE INGREDIENT CODE (SHANGHNESSY NO.): 112602

EPA 88 LIST: NA

PRODUCT MANAGER(S)/NO.: Joanne Miller; Steve Robbins/23

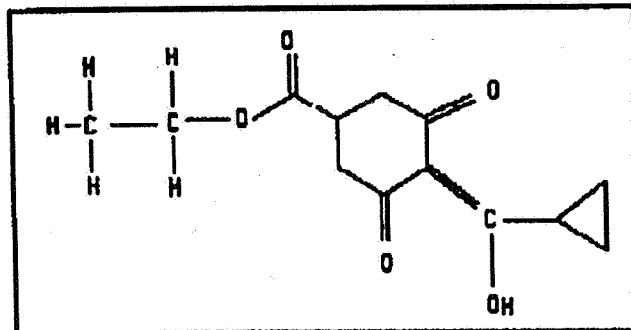
HED PROJECT NO.: 0-1874

TEST MATERIAL: Cimectacarb; Primo turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester; the formulation used in this study is Primo, which is 1-E on the label, which is 12.0% active ingredient.

SYNONYMS: None

STUDY NUMBER: 7314-90

SPONSOR: Agricultural Division
Ciba-Geigy Corp.
P. O. Box 18300
Greensboro, NC 27419-8300



TESTING FACILITY:

Stillmeadow, Inc.
12852 Park One Drive
Sugar Land, Texas 77478

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000102

TITLE OF REPORT: Primary Eye Irritation Study in Rabbits

AUTHOR(S): Janice O. Kuhn, Ph. D.

STUDY COMPLETED: September 24, 1990

SUMMARY AND CONCLUSIONS:

The Primo formulation (12% Cimectacarb) of CGA-163935 was applied undiluted and evaluated over 21 days as a primary eye irritant (non-wash) in three male and three female white rabbits with an additional three male rabbits, whose eyes were washed 30 seconds after treatment for one minute. The Primary Irritation Score (PIS) was 22.0 or moderately irritating in non-washed eyes and 12.0 or mildly irritating in washed eyes. The Primo formulation of CGA-163935 (12% Cimectacarb) falls into Toxicity Category II, because the corneal involvement and conjunctival irritation did not clear within seven days. Additionally, the product label should include the appropriate precautionary statements.

Toxicity Category: II

A signed quality assurance statement was present.

Core Classification: Minimum

This study satisfies the guideline requirements (§81-4) for a Primary Eye Irritation Study.

MATERIALS:

1. **Test Compound:** CGA-163935 1E-B FL-901930, which is the Primo formulation; Cimectacarb turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester. Description: amber or dark-brown liquid. Density: 1.0116 g/ml. Batch Code: GP-901102. Purity: The purity is not reported in this study; however, the purity (92.0%) and chemical structure (see inset box on page one of this DER) of the active ingredient (A.I.) are reported in volume 34 of 46 of the EUP submission, which is MRID # 416042-06. The test article was administered undiluted. The test article in this study was Primo turf growth regulator, which is 12% A.I.

2. **Test Animals:** Species: Rabbit. Strain: New Zealand White. Source: Ray Nichols Rabbitry, Lumberton, Texas. Quantity and Sex: Three males and three females (nonwash), and three males (wash). Age: Young adult (3 to 6 months old).

METHODS:

A dose of 0.1 ml of undiluted test article was placed in the conjunctival sac of the right eye of six male and three female rabbits. The left eye of each animal served as the control. Thirty seconds after dosing three male rabbits' right eyes were washed with room temperature deionized water for one minute. All animals were evaluated for ocular involvement at 1, 24, 48, and 72 hrs post dosing, and at 4, 7, 10, 14, 17, and 21 days post dosing. Irritation scores and ratings of the test article based on the findings in washed and nonwashed eyes were determined according to the charts in appendix 1 of this DER reproduced from pp. 14-16 of the study report.

RESULTS AND DISCUSSION:

None of the rabbits died on study (DOS). None of the rabbits whose right eyes were washed showed any involvement of the cornea or the iris in response to the test article. The test article did, however, affect the conjunctivae of the washed eyes to the extent there was redness, chemosis, and discharge all of which cleared up essentially within seven days, which translates into Toxicity Category II. The maximum average Primary Irritation Score (PIS) for the animals whose eyes were washed was 12.0, which translates into a rating of Mildly Irritating. The rating is Mildly Irritating instead of Minimally Irritating (score of 2.5-15.0), because the score was not down to zero by day seven which automatically raises the evaluation to the next higher category (see appendix 1).

There was more pronounced involvement in the non-washed eyes of the male and female rabbits with regard to test article effects in the cornea and the conjunctivae. Cornea involvement was evaluated according to degree of opacity, area of involvement, fluorescein staining, and stippling. The parameters indicating conjunctival involvement are the same as above for washed eyes. With the exception of one rabbit the iris in each of these animals, however, was essentially unaffected by the test article. The maximum average PIS for this group of rabbits was 22.0, which translates into a category of Moderately Irritating instead of Mildly Irritating for the same reason cited at the end of the paragraph above for washed eyes. See appendix 2 of this DER for individual and summary animal data reproduced from pp 17-22 of the study report.

CONCLUSIONS:

The Primo formulation of CGA-163935 (12% Cimectacarb) falls into Toxicity Category II, because the corneal involvement and conjunctival irritation did not clear within seven days (see appendices 1 and 2). Additionally, the product label should include the appropriate precautionary statements.

Appendix 2

MRID No. 418695-17

000105

009711

Appendix 1

NRID No. 418695-17

37

000106

Page ____ is not included in this copy.

Pages 38 through 47 are not included in this copy.

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- ☐ Identity of product inert ingredients.
- ☐ Identity of product inert impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☒ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Study/Lab/Study #/Date	Material	EPA MRID No.	Resul LD50, LC50, PIS
Primary Eye Irritation in rabbits/Stillmeadow 7314-90/ 24 Sep 1990	Ciba-Geigy CGA-163935, a turf growth regulator, 4-(cyclopropyl- α -hydroxy- methylene)-3,5-dioxo-cyclo- hexane carboxylic acid ethylester, moist/soft sol- id brown in color melting 29-32 deg C. The dark brown liquid formulation (1E) of CGA-163935 is 12.0 % active ingredient, which is the Primo formu- lation used in this study.	418695-17	The PIS for the in rabbits was irritating. Th washed eyes was moderately irri signs had not c seven days plac formulation of in Toxicity Cat

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SP

009711

Reviewed by: Dan W. Hanke, Ph. D.
Section III, Tox. Branch II (H7509C)
Secondary Reviewer: K. Clark Swentzel
Section II, Tox. Branch II (H7509C)

Dan W. Hanke 6 July 92
K. Clark Swentzel

JUL 7 1992

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation (S81-5)

DP BARCODE: D176468

SUBMISSION NO.: S415122

CASE TYPE: Registration

TOX. CHEM. NO. (CASWELL NO.): 271N

MRID NO. (ACCESSION NO.): 418695-19

ID#: 000100-TEO Primo Turf Growth Regulator (12.0% active ingredient/Cimectacarb)

CAS REG. NO.: 95266-40-3

EPA PESTICIDE CHEMICAL CODE/ACTIVE INGREDIENT CODE (SHANGHNESSY NO.): 112602

FIFRA 88 LIST: NA

PRODUCT MANAGER(s)/NO.: Joanne Miller; Steve Robbins/23

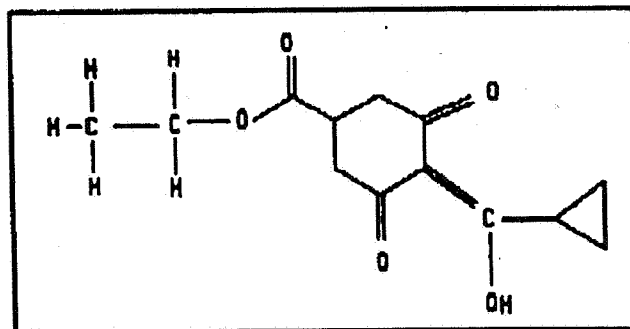
HED PROJECT NO.: 0-1874

TEST MATERIAL: Cimectacarb; Primo turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester; the formulation used in this study is Primo, which is 1-E on the label, which is 12.0% active ingredient.

SYNONYMS: None

STUDY NUMBER: 7677-90

SPONSOR: Agricultural Division
Ciba-Geigy Corp.
P. O. Box 18300
Greensboro, NC 27419-8300



TESTING FACILITY:

Stillmeadow, Inc.
12852 Park One Drive
Sugar Land, Texas 77478

49

000031

TITLE OF REPORT: Primary Dermal Irritation Study in Rabbits

AUTHOR(S): Janice O. Kuhn, Ph. D.

STUDY COMPLETED: January 5, 1991

SUMMARY AND CONCLUSIONS:

The Primo formulation (12% Cimectacarb) of CGA-163935 was applied undiluted to the dorsal trunk skin of three male and three female rabbits, and signs of erythema and eschar formation as well as edema were evaluated over 17 days. None of the rabbits died on study (DOS). The mean primary irritation score or index was 1.9, which translates to the descriptive rating of slightly irritating. None of the rabbits showed an individual irritation score over 2 at any observation time for any parameter evaluated. Therefore, since there was only slight irritation observed at 72 hrs., this formulation of CGA-163935 or Primo turf growth regulator (12% Cimectacarb) can be placed under Toxicity Category IV.

Toxicity Category: IV

A signed quality assurance statement was present.

Core Classification: Minimum

This study satisfies the guideline requirements (§81-5) for a Primary Dermal Irritation Study.

MATERIALS:

1. **Test Compound:** CGA-163935 1E-B FL-901930, which is the Primo formulation; Cimectacarb turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester. Description: amber or dark-brown liquid. Density: 1.0116 g/ml. Batch Code: GP-901102. Purity: The purity is not reported in this study; however, the purity (92.0%) and chemical structure (see inset box on page one of this DER) of the active ingredient (A.I.) are reported in volume 34 of 46 of the EUP submission, which is MRID # 416042-06. The test article was administered undiluted. The test article in this study was Primo turf growth regulator, which is 12% A.I.

2. **Test Animals:** Species: Rabbit. Strain: New Zealand White. Source: Ray Nichols Rabbitry, Lumberton, Texas. Quantity and Sex: Three males and three females. Age: Young adult (3 to 6 months old).

METHODS:

Each rabbit was clipped the day before dosing so that the dorsal area of the trunk was bare over an area minimally 8 cm x 8 cm. The exposed area was divided into a dosing site and a control site. A dose of 0.5 ml of undiluted test article was placed on the skin (day zero) under a surgical dressing secured with non-irritating adhesive tape. An orthopedic stockinette was applied to the animals to diminish evaporation and ingestion of the test article. Four hours later the dressings were removed, and the test sites were washed with room temperature tap water. The test sites were evaluated at 3/4, 24, 48, and 72 hrs post dosing, and at 7, 10, 14, and 17 days post dosing. The primary irritation scores were based on dermal irritation evaluations for erythema/eschar and edema from just the 3/4, 24, 48, and 72 hour observations. Erythema and eschar formation, as well as edema and other signs of dermal irritation were evaluated according to the charts in appendix 1 of this DER reproduced from pp. 13-14 of the study report.

RESULTS AND DISCUSSION:

None of the rabbits died on study (DOS). The mean primary irritation score or index was 1.9, which translates to the descriptive rating of slightly irritating. None of the rabbits showed an individual irritation score over 2 at any observation time for any parameter evaluated. Therefore, since there was only slight irritation observed at 72 hrs., this formulation of CGA-163935 or Primo turf growth regulator (12% Cimectacarb) can be placed under Toxicity Category IV. The data are in appendix 2 of this DER reproduced from p 15 of the study report.

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Appendix 1

MRID No. 418695-19

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Page __ is not included in this copy.

Pages 53 through 56 are not included in this copy.

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- ☐ Identity of product inert ingredients.
 - ☐ Identity of product inert impurities.
 - ☐ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☐ A draft product label.
 - ☐ The product confidential statement of formula.
 - ☐ Information about a pending registration action.
 - ☒ FIFRA registration data.
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 - ☐ Agency Internal Use Copy of Data Matrix Form.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Study/Lab/Study #/Date	Material	EPA MRID No.	Resul LD50, LC50, PIS
Primary Dermal Irritat. in rabbits/Stillmeadow 7677-90/ 5 Jan 1991	Ciba-Geigy CGA-163935, a turf growth regulator, 4-(cyclopropyl- α -hydroxy- methylene)-3,5-dioxo-cyclo- hexane carboxylic acid ethylester, moist/soft sol- id brown in color melting 29-32 deg C. The dark brown liquid formulation (1E) of CGA-163935 is 12.0 % active ingredient, which is the Primo formu- lation used in this study.	418695-19	The average PIS was based on ev the dermal irri just the first The PIS transla descriptive rat Slightly Irrita

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Reviewed by: Dan W. Hanke, Ph. D.
Section III, Tox. Branch II(H7509C)
Secondary Reviewer: K. Clark Swentzel
Section II, Tox. Branch II(H7509C)

Dan W. Hanke 08 July 72
K. Clark Swentzel July 8, 72

DATA EVALUATION RECORD

STUDY TYPE: Dermal Sensitization Study (§81-6)

DP BARCODE: D176468

SUBMISSION NO.: S415122

CASE TYPE: Registration

TOX. CHEM. NO. (CASWEL NO.): 271N

MRID NO. (ACCESSION NO.): 418695-20

ID#: 000100-TEO Primo Turf Growth Regulator (12.0% active ingredient/Cimectacarb)

CAS REG. NO.: 95266-40-3

EPA PESTICIDE CHEMICAL CODE/ACTIVE INGREDIENT CODE (SHANGHNESSY NO.): 112602

FIFRA 88 LIST: NA

PRODUCT MANAGER(s)/NO.: Joanne Miller; Steve Robbins/23

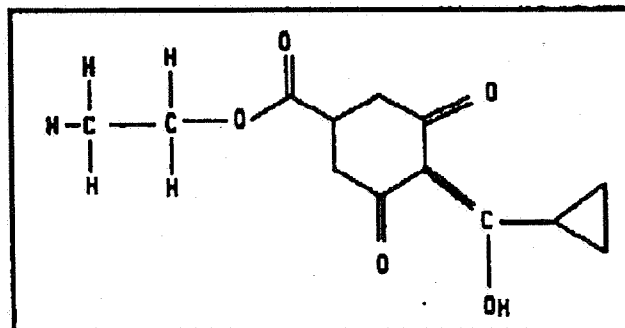
HED PROJECT NO.: 0-1874

TEST MATERIAL: Cimectacarb; Primo turf growth regulator; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester; the formulation used in this study is Primo, which is 1-E on the label, which is 12.0% active ingredient.

SYNONYMS: None

STUDY NUMBER: 7678-90

SPONSOR: Agricultural Division
Ciba-Geigy Corp.
P. O. Box 18300
Greensboro, NC 27419-8300



TESTING FACILITY:

Stillmeadow, Inc.
12852 Park One Drive
Sugar Land, Texas 77478

58 000134

2. Test Animals: Species: Guinea Pig. Strain: Hartley-Albino. Source: Harlan Sprague Dawley, Inc., Houston, Texas. Quantity and Sex: 22 males. Weight: 295-365 grams at the time of dosing.

METHODS: (Buehler, E.V., 1965. Arch. Dermatol. 91, 171-177)
Each guinea pig was clipped the day before dosing so that the dorsal area of the trunk was bare over an area minimally 8 cm x 10 cm. The solutions of either the positive control or the test article were introduced beneath a 3.8 x 5 cm Beiersdorf Coverlet adhesive dressing. The Coverlet was placed laterally from the midline of the back on the left front quadrant of the exposure area with the edge of the gauze pad adjacent to, but not overlapping, the midline of the back of each guinea pig. Then the entire trunk of each animal was wrapped with clear polyethylene film to keep the patch in place. Next each pig was placed in a restrainer for six hours, after which each pig was removed, unwrapped, and the patches removed. The same procedure was repeated for each of the 10 induction dosing episodes with the addition of the virgin challenge site on the right rear of each pig on day 36.

The shaved animals were split into two groups of ten each. Group I was the positive control group receiving 0.50 ml of the 0.06% w/v 2,4-dinitrochlorobenzene ethanolic solution. Group II animals received 0.50 ml of the 1.0% v/v ethanolic solution of the Primo test material.

There were 10 induction doses at the primary sites (left front) on days 1, 3, 6, 8, 10, 13, 15, 17, 20, and 22 for both the Group I positive control animals and the Group II test material animals. The challenge dose at the virgin sites (right rear) was applied on Day 36 for both groups.

Observations for any skin reactions were made roughly 24 hours after each dosing of each treatment site. Additional observations for skin reactions were made approximately 48 hrs. after induction doses number one and number 10 as well as after the challenge dose on day 36.

The scoring procedure is in appendix 1 of this DER reproduced from p 16 of the study report. An average score for dosing was obtained by summing the scores for each dosing and dividing by the number of dosing sites scored. The material evaluated is a sensitizer if there is a marked increase in positive skin reactions at the virgin challenge dosing site (Day 36) that exceeds any skin reactions observed after the initial dosing (Day 1) at the primary site.

RESULTS AND DISCUSSION:

After the induction period the positive control 2,4-dinitrochlorobenzene produced a mean positive reaction score of 2.2 at the virgin challenge dosing site in excess of the mean Day 1 induction dosing site score (0.3) and is, therefore, a sensitizer.

However, the test material did not produce a positive response at the virgin challenge site in excess of the Day 1 score (both mean scores were 0.3) and, therefore, is not a sensitizer.

The mean reaction scores for both the positive control and the test material are in appendix 2 of this DER reproduced from p. 19 of the study report.

CONCLUSIONS:

The test material CGA-163935, in the Primo turf growth regulator formulation (12% Cimectacarb), is not a dermal sensitizer.

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Appendix 1

MRID No. 418695-20

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Page ____ is not included in this copy.

Pages 63 through 65 are not included in this copy.

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- ☐ Identity of product inert ingredients.
 - ☐ Identity of product inert impurities.
 - ☐ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☐ A draft product label.
 - ☐ The product confidential statement of formula.
 - ☐ Information about a pending registration action.
 - ☒ FIFRA registration data.
 - ☐ The document is a duplicate of page(s) _____.
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 - ☐ Agency Internal Use Copy of Data Matrix Form.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Study/Lab/Study #/Date	Material	EPA MRID No.	Result LD50, LC50, PIS
Dermal Sensitization in guinea pigs/Stillmeadow 7678-90/ 06 Feb 1991	Ciba-Geigy CGA-163935, a turf growth regulator, 4-(cyclopropyl- α -hydroxy- methylene)-3,5-dioxo-cyclo- hexane carboxylic acid ethylester, moist/soft sol- id brown in color melting 29-32 deg C. The dark brown liquid formulation (1E) of CGA-163935 is 12.0 % active ingredient, which is the Primo formu- lation used in this study.	418695-20	The Primo formu- lation using 0.50 ml of solution in etha- nol as a dermal sensit- ization agent. Mean scores for induction and v. challenge in 10 guinea pigs were 0.3. The control 2,4-din- itrobenzene (0.06% v/v) sensitizer, as average scores were 2.2 for the Day and at Day 36 cl respectively.

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00971

Reviewed by: Dan W. Hanke, Ph. D.
Section III, Tox. Branch II (H7509C)
Secondary Reviewer: K. Clark Swentzel
Section II, Tox. Branch II (H7509C)

Dan W. Hanke 14 July 92
K. Clark Swentzel 7/14/92

DATA EVALUATION RECORD

STUDY TYPE: Dermal Sensitization Study (OECD Guideline No. 406)

DP BARCODE: D176468

SUBMISSION NO.: S415122

CASE TYPE: Registration

TOX. CHEM. NO. (CASWELL NO.): 271N

MRID NO. (ACCESSION NO.): 418695-22 (replaces 415639-18)

ID#: 000100-TET Cimectacarb Technical

CAS REG. NO.: 95266-40-3

EPA PESTICIDE CHEMICAL CODE/ACTIVE INGREDIENT CODE (SHAUGHNESSY NO.): 112602

EIPRA 88 LIST: NA

PRODUCT MANAGER(s)/NO.: Joanne Miller; Steve Robbins/23

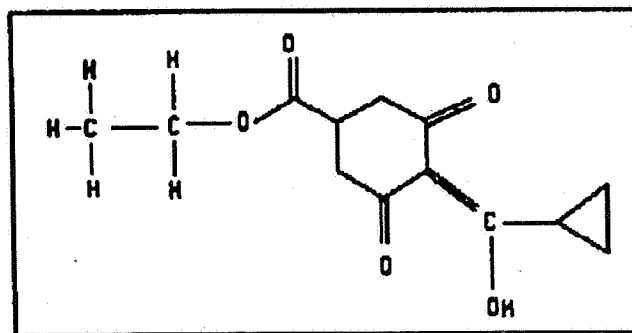
HED PROJECT NO.: 0-1874

TEST MATERIAL: Cimectacarb Technical (96.6%);
4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane
carboxylic acid ethylester

SYNONYMS: None

STUDY NUMBER: 871408

SPONSOR: Agricultural Division
Ciba-Geigy Corp.
P. O. Box 18300
Greensboro, NC 27419-
8300



TESTING FACILITY:

Ciba-Geigy Limited
Basle, Switzerland

TITLE OF REPORT: Dermal Sensitization Study in Guinea Pigs
Optimization Test

AUTHOR(S): Dr. Thomas Maurer

67

000161

STUDY COMPLETED: January 4, 1988

SUMMARY AND CONCLUSIONS:

Cimectacarb Technical (96.6%), CGA-163935, a turf growth regulator was evaluated as a dermal sensitizer in 10 male and 10 female guinea pigs according to OECD guidelines using intradermal and epidermal routes of exposure. The known sensitizer 1,4-diaminobenzene was the positive control.

After the induction period the positive control 1,4-diaminobenzene produced mean positive reaction scores of 1.9 and 2.6 for erythema and edema respectively in male pigs. The mean reaction scores in female pigs were 2.1 and 2.5 for erythema and edema respectively. The positive control, therefore, is a dermal sensitizer.

However, the test material did not produce any positive responses at the challenge epidermal injection site (reaction volume) or challenge epidermal application site (Draize score) and, therefore, is not a sensitizer.

Toxicity Category: NA

A signed quality assurance statement was present.

Core Classification: Minimum

This study satisfies the guideline requirements (§81-6) for a Dermal Sensitization Study.

MATERIALS:

1. Test Compound: CGA-163935 Technical; 4-(cyclopropyl- α -hydroxy-methylene)-3,5-dioxo-cyclohexane carboxylic acid ethylester. Description: amber or dark-brown liquid. Batch Code: P-705002. Purity: 96.6% active ingredient (A.I.). A 0.1% (v/v) solution of the test article was prepared in physiological saline (w/v).

2. A 0.50% w/v solution of the positive control 1,4-diaminobenzene was used for intra-dermal induction; a 10% solution for epidermal induction; and a 1.0% solution for epidermal challenge. The report did not state what solvent was used.

2. Test Animals: Species: Guinea Pig. Strain: Pirbright White. Source: Animal production Ciba-Geigy, 4332 Stein/Switzerland. Quantity and Sex: 10 males and 10 females. Weight: 305-456 grams (about 10 weeks old) at the time of dosing.

METHODS:

This optimization test was based in part on intracutaneous sensitization procedures recommended in the OECD guidelines 1981 (Test No. 406) and listed in the EEC directive 79/831. The substance of the test was based on information from Maurer, T., Contact and Photocontact Allergens. A manual of predictive testing (1983). Marcel Dekker, New York and Basel.

The pigs were given ten 0.10 ml induction doses of a 0.1% test article solution in physiological saline intracutaneously injected every second day into the shaved right flank (only on the first day) and back (first and subsequent days). During the second and third weeks of induction the test article injection solution was made up with a 1:1 formulation of physiological saline and complete Bacto adjuvant.

The test article challenge intradermal injection into the skin of the left flank was given two weeks after the last induction or sensitizing injection.

Skin "reaction volumes" to the injections were recorded according to Maurer (see appendix 1 in this DER reproduced from pp. 10-11 of the study report) 24 hrs. after each induction injection during the first week and 24 hrs. after the challenge injection.

Ten days after the challenge injection a subirritant dose (unspecified amount) of 3% test article in vaseline was applied epidermally under occlusive dressings and left in place for 24 hrs. (see appendix 1 in this DER). Skin reactions were scored 24 and 48 hrs. later according to Draize (see appendix 2 of this DER reproduced from p 21 of the study report).

RESULTS AND DISCUSSION:

After the induction period the positive control 1,4-diaminobenzene produced mean positive reaction scores of 1.9 and 2.6 for erythema and edema respectively in male pigs. The mean reaction scores in female pigs were 2.1 and 2.5 for erythema and edema respectively. See appendix 3 of this DER reproduced from p. 23 of the study report. The positive control, therefore, is a dermal sensitizer.

However, the test material did not produce any positive responses at the virgin challenge injection site (reaction volume) or virgin challenge epidermal application site (Draize score) and, therefore, is not a sensitizer.

CONCLUSIONS:

The test material CGA-163935 Technical is not a dermal sensitizer.

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Appendix 1

MRID No. 418695-22

7/ 000165

Page ____ is not included in this copy.

Pages 72 through 73 are not included in this copy.

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- ____ Identity of product inert ingredients.
- ____ Identity of product inert impurities.
- ____ Description of the product manufacturing process.
- ____ Description of quality control procedures.
- ____ Identity of the source of product ingredients.
- ____ Sales or other commercial/financial information.
- ____ A draft product label.
- ____ The product confidential statement of formula.
- ☒ Information about a pending registration action.
- ☒ FIFRA registration data.
- ____ The document is a duplicate of page(s) ____.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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Appendix 2

MRID No. 418695-22

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Page ____ is not included in this copy.

Pages 76 through 77 are not included in this copy.

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- ____ Identity of product inert ingredients.
- ____ Identity of product inert impurities.
- ____ Description of the product manufacturing process.
- ____ Description of quality control procedures.
- ____ Identity of the source of product ingredients.
- ____ Sales or other commercial/financial information.
- ____ A draft product label.
- ____ The product confidential statement of formula.
- J ____ Information about a pending registration action.
- J ____ FIFRA registration data.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Study/Lab/Study #/Date	Material	EPA MRID No.	Resul LD50, LC50, PIS
Dermal Sensitization in guinea pigs/Ciba-Geigy 971408 / 04 Jan 1988	Ciba-Geigy CGA-163935 Tec./ turf growth regulator, 4-(cyclopropyl- α -hydroxy- methylene)-3,5-dioxo-cyclo- hexane carboxylic acid ethylester, moist/soft sol- id brown in color melting 29-32 deg C. The technical material used in this study is 96.6% pure active ingredient.	418695-22	Cimectacarb tec A.I.) is not a tizer as deter intradermal and routes at injec ml of a 0.1% sc % NaCl and an a unknown amount. control 1,4-dia was effective i tested.

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