US EPA ARCHIVE DOCUMENT

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 279 GRNO.
Cynoff® 50 WP

FROM: Sheila A. Moats, Ph.D. SM 10/24/90
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C) E 11/26/90

TO: George La Rocca (PM 15)
Registration Division (H75-05C)

APPLICANT: FMC Corporation
Agricultural Chemical Group
2200 Market St.
Philadelphia PA 19103.

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
211D	Cypermethrin	50.0
	Inert Ingredient(s):	50.0
	Total	100.0%

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Background

FMC Corporation submitted acute oral, dermal, inhalation, primary eye + skin irritation + dermal sensitization studies to support registration of Cynoff^{R} 50WP Insecticide.

MRID Nos used were 416290-02-07.

Recommendations

1. The acute toxicity studies submitted by FMC Corporation are acceptable to RSB/LRS

2. No further acute toxicity tests are required.

3. The dermal sensitization study was designated Core "Minimum" since data on positive control testing is lacking. Positive control testing should be done periodically (once every 6 months). Data submitted should include date + results of last positive control testing.

Labeling

1. The "Warning" signal word is acceptable.

2. The Precautionary Statements must be stated as follows:

"May be fatal if swallowed harmful if

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absorbed through skin, or inhaled. Causes moderate eye injury or irritation. Avoid breathing dust (vapor or spray mist). Avoid contact with skin eyes or clothing. Remove contaminated clothing, + wash contaminated clothing ~~MMMMMM~~ before re-use. Wash thoroughly with soap + water after handling and before eating, drinking or using tobacco.

3 The Statements of Practical Treatment for "IF Swallowed" + "IF in Eyes" are acceptable. "IF Inhaled", add "get medical attention". "IF on Skin" must be stated as follows

"If on Skin: Wash with plenty of soap + water. Get medical attention.

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DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (15)
MRID No.: 416290-02
Testing Facility: FMC Toxicology lab.
Author(s): Freeman Christine
Species: Sprague Dawley - Rats
Age: Young
Weight: 233-277 gms.
Source: Taconic Farms, Germantown N.Y
Test Material: Cynoff® 50 WP Insecticide
Quality Assurance (40 CFR §160.12): Adequate.

Reviewer: S. Moats
Report Date: 10/24/90
Report No. A89-2992
Observation Days (Post Exposure): (14); other ( )

Conclusion:

1. LD_{50} (mg/kg): Males = 406 (340-472) ; Females = 352 (284-420) ; Combined = 380 (341-419)
2. The estimated LD_{50} is
3. Tox. Category: II . Classification: Guidelines

Procedure (Deviations From §81-1): 5 ♂ + 5 ♀ rats were given various doses of the test article orally (20% w/v suspension in water). Observations for toxicity were made at 30 mts, 1, 2, 3, 4 + 6 hrs on the day of dosing + twice daily thereafter until Day-13 + once on Day 14.

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
500	5/5	5/5	10/10
400	2/5	4/5	6/10
300	0/5	1/5	1/10

Symptomology & Gross Necropsy Findings:

Clinical signs ranged from tremors, loss of muscle control, convulsions, + genital staining. Gross necropsy findings showed no abnormalities.

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager: (15)
MRID No.: 416290-03
Testing Laboratory: FMC Toxicology Lab
Author(s): Eseeman, Christine
Species: New Zealand Whites — Rabbits
Sex: 5♂ + 5♀ Wt.: 2.24 - 2.84 kg
Test Material: Cynoff R 50 WP
Quality Assurance (40 CFR §160.12): Adequate

Reviewer: S. Moats
Report Date:
Report No. A89-2993

Summary:

1. LD_{50} (mg/kg): Males = ; Females = ; Combined = > 2000 mg/kg
2. The estimated LD_{50} is
3. Tox. Category: III. Classification: Guidelines

Procedure (Deviations From §81-2): 5♂ + 5♀ rabbits were each dosed with 2000mg/kg body wt of the test material. Prior to dosing the trunks of the rabbits were clipped free of hair. The test material moistened with saline was placed on a 4X4 inch² gauze pad positioned on the intact test site + held in place with tape. The site was occluded with plastic sheeting for 24hrs. Elizabethan collars were placed on the animals after dosing. After the exposure period the wrappings were removed + sites cleansed of residues, observations were made frequently on the day of dosing. Reported Mortality + twice daily for 13 days + once on the 14th day

DOSAGE (mg/kg)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
2000	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

There were no mortalities. All animals remained healthy during the study. Necropsy findings showed no abnormalities.

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DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: (15)
MRID No.: 416290-04
Testing Laboratory: EMC Toxicology Lab
Author(s): Maud Everett
Species: Sprague Dawley - Rats
Sex: 5 ♂ 5 ♀ Weight: 230 - 281 g
Source: Taconic Farms Germantown, NY
Test Material: Cyno/IK 50 WP
Quality Assurance (40 CFR §160.12): Adequate

Reviewer: S. Moats
Report Date: 10/24/90
Report No. A90-3177

Summary:

1. LC_{50} (mg/kg): Males = _____ : Females = _____ : Combined = 0.753 mg/kg
2. The estimated LC_{50} is _____
3. Mean Concentration: _____
4. Tox. Category: III. Classification: Guidelines

Procedure (Deviations From §81-2): A group of 5 ♂ + 5 ♀ rats were exposed to the test article for 4 hrs. The test material was delivered in the form of powder delivered in a jet of compressed air + mixed with dilution air to form the test atmosphere. The chamber air was exhausted from the bottom + passed thru a filter box + this was connected to a line leading to more filters + an exhaust fan on the roof. Test animals were housed individually within a 150 liter dynamic flow chamber. Temp. press + humidity were reported every 30 mnts. chamber air samples were taken from fiber glass filters, held in cassettes every ½ hr during expos. to determine air-borne gravimetric Reported Mortality concentr. Cascade impactor was used for determining particle size

Exposure Concentration (mg/L)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
0.753	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

There were no mortalities. Clinical signs included abdominogenital staining, decreased locomotion, ataxia, nasal + oral discharge, chromodacryorrhea, squinting eyes, tip-toeing etc.

Gross necropsy findings showed no abnormalities.

Dosage mg/L	Time	Reading	Particle size um	Cumulative %	MMAD um	GSD
0.753	60 mts	a	1.50	51.9	1.36	2.5
		b	0.84	27.9		

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (15)
MRID No.: 416290-05
Testing Laboratory: FMC Toxicology Lab
Author(s): Eggerman, Christian
Species: New Zealand whites
Sex: 2♂ 1♀
Source: Hazleton Research Animals Inc. Denver Pennsylvania.
Dosage: 0.1 g
Test Material: Cyanazine 50 WP
Quality Assurance (40 CFR §160.12): Inadequate

Reviewer: S. Moats
Report Date: 10-24-90
Report No. ABL-2994

Summary:

Tox. Category: III Classification: Guidelines

Procedure (Deviation From §81-4): A dose of 0.1 gm of test article was instilled into the conjunctival sac of each of 9 animals. The eyes of 6 animals remained unwashed while those were rinsed with tap water. The eyes were scored at 1, 24, 48, & 72 hrs & on day 4, 7, 14, & 21. Draize method was used for scoring.

Results:

	Observations (number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	1/6	2/6	1/6	1/6	0/6			
Iris	0/6	0/6	0/6	0/6	0/6			
Conjunctivae Redness	1/6	2/6	1/6	1/6	0/6			
Chemosis	1/6	1/6	0/6	0/6	0/6			
Discharge	1/6	2/6	1/6	0/6	0/6			

Comments: Corneal involvement or irritation clearing in 7 days

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: (15)
MRID No.: 416290-06
Testing Laboratory: EMC Toxicology Lab
Author(s): Freeman, Christine
Species: New Zealand White Rabbits
Age: Young Adults
Sex: 2 ♂ + ♀
Weight: 2.09 - 2.63 kg
Dosage: 0.5 g
Test Material: Cynoff® 50 WP
Quality Assurance (40 CFR §160.12): Adequate

Reviewer: S. Coats
Report Date: 10-14-90
Report No. ABG-2495

Summary:

The Primary Irritation Index = 0

Toxicity Category: IV

Classification: Guidelines

Procedure (Deviations From §81-5): 6 rabbits were used for the study. Prior to dosing, the trunk of each animal was clipped of fur. The test material was moistened with saline & placed on a 2 x 2 inch gauze pad & applied to the test site. The pad was secured with tape & the entire trunk was wrapped with semi-occlusive cheese cloth. The animals were restrained with plastic Elizabethan collars. After a 4-hr exposure period, the pads & wrappings were removed & the sites cleansed of residues. The sites were scored at 3 cmts

Results: 24, 48 & 72 hrs after unwrapping.

The product is not an irritant

Special Comments:

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DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Project Manager: (15)
Reviewer: S. Moats
EPA No.: 41629O-07
Report Date: 10-24-90
Testing Laboratory: ENC Toxicology Ltd
Report No. 889-2996
Author(s): Freeman, Christine
Species: Hartley Strain Guinea Pigs
Age: 5 to 6 Weight: 338-424g
Source: Hazleton Research Animals Inc. Denver PA.
Test Material: Synoff R 50 WP
Positive Control Material:
Quality Assurance (40 CFR §160.12): Adequate

Route: Dermal Epicutaneous

Summary:
a. This product is (is not a dermal sensitizer)
b. Classification: Minimum +

Procedure (Deviation From §81-6): 20 animals were used for the Test Gp. 10 animals were set aside for Naive control Gp. Prior to dosing the left shoulders of the guinea pigs were clipped of fur. The test material was applied to each of 20 Hilltop chambers + placed on the test sites & secured with tape. Next the animals were placed in restrainers. After a six hour exposure period the dosing chambers were removed & the sites cleansed of test. dust. The guinea pigs were dosed in this manner once weekly for a total of 3 applications. After a 14-day rest period the guinea pigs were challenged at a virgin site on the right shoulder. Same procedure as above was followed. Ten naive control animals were also treated with the test material. The animals were scored for irritation at 24 + 48 hours after each application.

Results: The test material did not sensitize guinea pigs.

+ This study is designated core Minimum since data on positive control testing is lacking. Positive control testing should be done periodically (once every 6 months). Data submitted should state date of last positive control testing & results.

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