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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.
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

SM 10/24/90

E (11/26/90)

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

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

FORMULATION FROM LABEL:

2118D	Active Ingredient(s):	<u>Cypermethrin</u>	% by wt.
			<u>50.0</u>
	Inert Ingredient(s):		<u>50.0</u>
	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[®] 50WP Insecticide.

MRID Nos used were 416290-02-07.

Recommendations

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

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, ~~must~~ 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. To "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.

002(72)

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (S81-1)

Product Manager: (15) Reviewer: S. Moats
 MRID No.: 416290-02 Report Date: 10/24/90
 Testing Facility: FMC Toxicology Lab. Report No. 189-2992
 Author(s): Freeman Christine
 Species: Sprague Dawley - Rats
 Age: Young Observation Days (Post
 Weight: 233-277 gms. Exposure): (14); other ()
 Source: Taconic Farms Germantown N.Y.
 Test Material: Cyflor 50 WP Insecticide
 Quality Assurance (40 CFR §160.12): Adequate

Conclusion:

- LD₅₀ (mg/kg): Males = 406 (340-472); Females = 352 (284-420); Combined = 380 (341-419)
- The estimated LD₅₀ is
- Tox. Category: II. Classification: Guidelines

Procedure (Deviations From S81-1): 5 ♂ + 5 ♀ rats were given various doses of the test article orally (20% w/s 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 (581-2)

Product Manager: (15)
 MRID No.: 416290-03
 Testing Laboratory: FMC Toxicology Lab
 Author(s): Freeman, Christine
 Species: New Zealand Whites
 Sex: ♂s - ♀s
 Test Material: Cynoff R 50 WP
 Quality Assurance (40 CFR 160.12): Adequate

Reviewer: S. Hoats
 Report Date: 8-29-2993
 Report No. A-89-2993
 Wt.: 2.24 - 2.84 kg

Summary:

1. LD₅₀ (mg/kg): Males = _____; Females = _____; Combined = 2000 mg/kg
2. The estimated LD₅₀ is _____
3. Tox. Category: III. Classification: Guidelines

Procedure (Deviations From 581-2): 5 ♂ + 5 ♀ rabbits were each dosed with 2000 mg/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 inch gauze pad positioned on the intact test site & held in place with tape. The site was occluded with plastic sheeting for 24 hrs. 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 & 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 (S31-3)

Product Manager: (15)
 MRID No.: 414 290-04
 Testing Laboratory: FMC Toxicology Lab
 Author(s): Maud Everett
 Species: Sprague Dawley - Rats
 Sex: ♂ & ♀ Weight: 230 - 281 g
 Source: Taconic Farms, Germantown, N.Y.
 Test Material: Cynofix 50 WP
 Quality Assurance (40 CFR 5160.12): Adequate

Summary:

1. LC₅₀ (mg/kg): Males = ; Females = ; Combined = 70.753 mg/kg
2. The estimated LC₅₀ is
3. Mean Concentration:
4. Tox. Category: III. Classification: Guidelines

Procedure (Deviations From S31-2): 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 to 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 recorded every 30 mins. Chamber air samples were taken from fiber glass filters, held in cassettes every 1/2 hr during expos. to determine air-borne gravimetric. Reported Mortality concentration. Cascade impinger was used for determining particulate S. 24

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, chromatocytopenia, squinting eyes, tip-toeing etc.

Gross necropsy findings showed no abnormalities.

Dosage mg/L	Time	Reading	Particle size um	Cumulative %	MMAAD um	GEI
0.753	60 mts	6	1.50	51.9		
		6	0.84	27.9	1.36	2.3

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (581-4)

Product Manager: (15)
 MRID No.: 416290-05
 Testing Laboratory: FMC Toxicology Lab
 Author(s): Egerman, Christine
 Species: New Zealand white
 Sex: 2 ♂ 6 ♀
 Source: Hazelton Research Animals Inc. Denver Pennsylvania.
 Dosage: 0.109
 Test Material: Cyacofk 50WP
 Quality Assurance (40 CFR 516.12): Adequate

Reviewer: S. Hoats
 Report Date: 10-24-90
 Report No. A29-2994

Summary:

Tox. Category: III Classification: Guidelines

Procedure (Deviation From 581-4): A dose of 0.1 gms of test article was instilled into the conjunctival sac of each of 9 animals. The eyes of 6 animals remained unwashed, while three were rinsed with tap water. The eyes were scored at 1, 24, 48, & 72 hrs & on Day 4. The twist method was used for scoring.

Results:

	Observations (number "positive"/number tested)							
	Hour	Days						
		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 (581-5)

Product Manager: (15)
 WRD No.: 416290-06
 Testing Laboratory: FMC Technology Lab
 Author(s): Freeman, Christine
 Species: New Zealand White Rabbits
 Age: Young Adults
 Sex: 7 M 9 F
 Weight: 2.69 - 2.65 kg
 Dosage: 0.5g
 Test Material: CYNOLIN 50 WP
 Quality Assurance (40 CFR 5160.12): Adequate

Summary:

The Primary Irritation Index = 0

Toxicity Category: IV

Classification: Guidelines

Procedure (Deviations From 581-5): 6 rabbits were used for the study. Prior to dosing the trunk of each animal was clipped of fur. The test material was resuspended with saline & placed on a 2x2 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 24 & 48 hrs after unwrapping.

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 (581-6)

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Product Manager: (15)
 Report No.: 416290-07
 Testing Laboratory: FMC Toxicology Lab
 Author(s): Freeman, Christine
 Species: Hartley strain - Guinea Pigs
 Sex: P + F Weight: 328 - 424 g
 Source: Hazleton Research Products Inc. Denver PA.
 Test Material: Synoff R 50 WLP
 Positive Control Material:
 Quality Assurance (40 CFR 5160.121): Adequate

Strain: Oxon. Epicutaneous

Summary:

1. This product is is not a dermal sensitizer
 2. Classification: Minimum

Procedure (Deviation From 581-6): 20 animals were used for the Tier 1p.
 for Naive control 6p. Prior to dosing the left shoulders of the
 guinea pigs were clipped off fur. The test material was
 applied to each of 20 Hiltop chambers - placed on the test
 sites & secured with tape. Next the animals were placed
 in stainers. After a six hour exposure period the wrappings
 chambers were removed & the sites cleansed of residues.
 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

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