UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 5, 1995

MEMORANDUM

ID No.:	062190-RE; Wolman 3488 Wood Preservative
DP Barcode:	D219194
Test Material:	Hickson 3488
Chemicals:	022901 Copper carbonate 011001 Boric acid 122101 Propiconazole
From:	S. Oonnithan Precautionary Review Section Registration Support Branch Registration Division (H7505W)
To:	Connie Welch, PM 21 Fungicide-Herbicide Branch Registration Division (H7505C)
Applicant:	Hickson Corporation 3941 Bonsal Road Conley, GA 30027

FORMULATION FROM LABEL

Ingredient(s)	% by wt.
Copper carbonate	18.18
Boric acid	9.74
Propiconazole	4.00
Inerts	68.08
Total	100.00

62190-RE

BACKGROUND

Hickson Corporation has submitted acute oral toxicity (MRID No. 432788-02), acute dermal toxicity (MRID No. 432788-03), primary eye irritation (MRID No. 432788-04), primary skin irritation (MRID No. 432788-05), and dermal sensitization (MRID No. 432788-06) studies on Hickson 3488 wood preservative fungicide (pH = 11; Lot No. 1094-74-6). The acute toxicity studies were performed by IRDC, Mattawan, MI.

USE DIRECTIONS

Hickson 3488 (Wolman 3488) fungicide is a water based formulation used for industrial pressure treating of wood and wood products. The product is packaged in 55 gal drums and 4000 gal tank cars.

RECOMMENDATION

81-1. Acute Oral: Category III. The submitted study is acceptable.

81-2. Acute Dermal: Category II. The submitted study is acceptable.

81-3. Acute Inhalation: Waived. The submitted data indicate that exposure of mixers and equipment operators to the product while pressure treating wood is unlikely.

81-4. Eye Irritation: Category I. The submitted study is acceptable.

81-5. Skin Irritation: Category I. The submitted study is acceptable.

81-6. Dermal Sensitization: Not a sensitizer to guinea pigs. The submitted study is acceptable.

LABELING

Date: 12/05/95 LABEL REVIEW SYSTEM
ID #: 062190-00012 WOLMAN 3488 WOOD PRESERVATIVE

SIGNAL WORD: DANGER

PRECAUTIONARY STATEMENTS

Corrosive. Causes irreversible eye damage or skin burns. May be fatal if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

NOTE TO PHYSICIAN:

The proposed label should contain the following types of guidance:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Probable mucosal damage may contraindicate the use of gastric lavage.

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

Product Manager: 21
MRID No.: 432788-02
Author(s): E.J.F. Spicer

Reviewer: S. Oonnithan
Report No.: 707-001
Report Date: 02/02/94

Conclusion:
LD_{50}: Males: 1089 mg/kg; Females: 838 mg/kg; Combined: 955 mg/kg
Toxicity Category: III
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure (Deviations from §81-1): None

Testing Facility: IRDC, Mattawan, MI.

Test Material: Hickson 3488 (Lot No. 1094-74-6); Blue colored liquid.

Test Animal: Rat; Charles River
Age: Young adult (9 weeks)
Weight: Males 284-345 g; Females 179-229 g
Source: Charles River Labs, Portage, MI.

Test Method: Diluted with water and dosed at 10 ml/kg constant volume.

Results: The LD_{50} of female and male rats are 838 and 1089 mg/kg, respectively.

Dosage (mg/kg)	Number Dead/Tested		
	Males	Females	Combined
700	0/5	1/5	1/10
900	1/5	3/5	4/10
1300	4/5	5/5	9/10

Symptoms & Gross Necropsy Findings: Pharmacologic and/or toxicologic symptoms included decreased activity, anogenital staining, decreased defecation. Normal weight gain was observed in the survivors. Gross necropsy of revealed discoloration of stomach glandular mucosa, spleen, and lungs.

4

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

Product Manager: 21
MRID No.: 432788-03
Author(s): E.J.F. Spicer

Reviewer: S. Oonnithan
Report No.: 707-002
Report Date: 02/02/94

Conclusion:
LD_{50}: Males/Females: <2000 mg/kg
Toxicity Category: II
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure (Deviations from §81-2): None

Testing Facility: IRDC, Mattawan, MI.
Test Material: Hickson 3488 (Lot No. 1094-74-6); Blue colored liquid.
Test Animal: Rabbit; New Zealand White; **Age:** Young adult (15-19 weeks); **Weight:** Males 2.5-2.9 kg; Females 2.4-2.8 kg; **Source:** Hazleton Research Products, Inc., Kalamazoo, MI.

Test Conditions: Two studies, a limit test with undiluted and a full study with water-diluted test material were conducted. After application of the test substance, the treated area was wrapped with gauze bandaging and secured with a tape.

Results: For better margin of safety, the limit test results (undiluted test substance) were considered for this review. The submitted data indicate that the dermal LD_{50} is <2000 mg/kg to both male and female rabbits.

Dosage (mg/kg)		Number Dead/Tested		
		Males	Females	Combined
Full study	1600	0/5	0/5	0/10
	1800	1/5	0/5	1/10
	2000	1/5	1/5	2/10
Limit test	2000	3/5	4/5	7/10

Symptoms & Gross Necropsy Findings: In the limit test no pharmacotoxic symptoms were observed and three survivors lost weight by day-2 (euthanized afterwards); necropsy of the live animals revealed discolored liver and skin edema.

5

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

Product Manager: 31
MRID No.: None
Author: F. Griffis

Reviewer: S. Oonnithan
Report No.: None
Report Date: 11/22/95

Background: The registrant has requested a waiver for this study. Additional information submitted by the registrant (F. Griffis dated 11/22/95) on application equipment and method indicate the following:

Application equipment: The wood is treated under pressure in a closed steel cylinder (6 ft diameter and 80 ft long).

Mixing of formulation: The product is pumped directly from the drum/tank car into the treatment cylinder and diluted with water to the desired concentrations (0.5 - 7.0%).

Treatment conditions: In the closed system, the preservatives are forced into the wood at 150-180 pounds per square inch. The solution remaining after pressure treatment is pumped back into a storage tank. Possible types of exposure include accidental spilling, break of break of pipe or valve, and exposure to diluted formulation mist when the cylinder is opened after treatment. Exposure of workers to mist is unlikely, as most treatment cylinder doors are opened remotely.

Conclusion: The submitted data indicate that exposure to mixer/worker is unlikely. Therefore the requirement for an inhalation study is waived.

6

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

Product Manager: 21
MRID No.: 432788-04
Author(s): E.J.F. Spicer

Reviewer: S. Oonnithan
Report No.: 707-003
Report Date: 02/03/94

Conclusion:
Toxicity Category: I
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure (Deviations from §81-4): Due to expected severe irritation only one animal was used and that too was euthanized on day-7.

Testing Facility: IRDC, Mattawan, MI.

Test Material: Hickson 3488 (Lot No. 1094-74-6)

Test Animal: Rabbit; New Zealand White
Age: Young adult (5 months)
Weight: 3.1 kg (female for nonwashed)
Source: Hazleton Research Products, Inc., Kalamazoo, MI.

Test Conditions: One animal was used for unwashed test and the test article was administered undiluted (0.1 ml).

Results: The treated eye exhibited marked corneal, iridial, and conjunctival irritation; therefore the test was discontinued after 7 days.

7

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

Product Manager: 21
MRID No.: 432788-05
Author(s): E.J.F. Spicer

Reviewer: S. Oonnithan
Report No.: 707-004
Report Date: 02/03/94

Conclusion:
Toxicity Category: I
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations from §81-5: None

Testing Facility: IRDC, Mattawan, MI.

Test Material: Hickson 3488 (Lot No. 1094-74-6)

Test Animal: Rabbit, New Zealand White
Age: Young adult (7 months)
Weight: 3.0-3.9 kg
Source: Hazleton Research Products, Inc., Kalamazoo, MI.

Test Conditions: A 0.5 ml/site of the test article was applied undiluted under 1 inch square gauze patch and secured with tape. The site was then wrapped with gauze bandage and over-wrapped with tape.

Results: Erythema with eschar were present past 14 days.

Observations	Number positive/tested at					
	1 Hr	24 Hrs	48 Hrs	72 Hrs	7 Days	14 Days
Erythema	0/6	6/6	5/6	4/6	4/6	2/6
Edema	0/6	6/6	3/6	3/6	3/6	0/6

Comments: Severe erythema and edema were observed in all test animals at 24 hours. Marked erythema with eschar continued in 2/6 animals even after 14 days. Two rabbits exhibited blanching.

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

Product Manager: 21
MRID No.: 432788-06
Author(s): E.J.F. Spicer

Reviewer: S. Oonnithan
Report No.: 707-005
Report Date: 02/02/94

Conclusion:
Toxicity Category: Not a skin sensitizer
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations from §81-6: Irritation scores/animal after each induction were not provided. Submitted raw data sheets indicated sloppy recording of test data.

Testing Facility: IRDC, Mattawan, MI.

Test Material: Hickson 3488 (Lot No. 1094-74-6)
Positive Control: 2,4-Dinitro-1-chlorobenzene (DNCB)

Test Animal: Guinea pig (Hartley albino)
Age: 2 Months
Weight: Males: 404-487 g; Females: 410-460 g
Source: Charles River Labs.; Portage, MI.

Test Method: Buehler method was used. Based on a range finding test with 5, 10, 15, 20, 40, 60, and 80% concentrations of the test material in water, a 10 and 5% dilutions in water were selected for induction and challenge treatments, respectively in the definitive study. For positive control, DNCB was used at 0.1 and 0.05% concentrations in acetone for induction and challenge treatments, respectively.

Group of twenty (10/sex) animals was subjected to induction treatment with the test substance at 0.4 ml/site, once a week for three weeks. Following a two week rest period, a single challenge application was made at a virgin site at 0.4 ml/site. Simultaneously, a naive control group of ten animals (5/sex) was treated at the challenge dose. In a similar manner, another group of ten (5/sex) guinea pigs was applied with DNCB at 0.4 ml/site for induction and challenge treatments. Observations for skin reactions were made at 24 and 48 hours after induction and challenge.

9

Results: The results reported in the MRID and additional data submitted by the registrant (F. Griffis; 11/22/95) indicate that the test substance is not a skin sensitizer to guinea pigs. All animals achieved normal weight gains.

Tests[a]	No. of animals with 0, 0.5, and ≥1 erythema scores (24 Hr)	
	Hickson 3488[b]	DNCB[c]
Treatments	19, 1, 0	0, 0, 10
Naive control	9, 1, 0	Not tested

[a] Post-challenge scores; individual induction scores were not recorded.
[b] 9/20 and 4/1 Test animals exhibited multiple focal areas with blanching in the treatment and naive control studies, respectively.
[c] 8/10 Test animals exhibited edema.

Comments: This is a very poorly conducted study and meets only minimum acceptable standards, because of the following reasons:

- Treatment and irritation scoring data sheets are incomplete and lack the required information, such as name/number of test material used and its concentration.
- A dermal irritation scoring scale was not included in the report.
- Irritation scores after each induction were not provided.
- A naive test group was not used for positive control.
- No documentation was made of the periodic inspection of the study by the study director.

ACUTE TOXICITY ONE-LINER

ID No.: 062190-RE; Wolman 3488 Wood Preservative
DP Barcode: D219194
Chemicals: 022901 Copper carbonate; 011001 Boric acid; 122101 Propiconazole
Applicant: Hickson Corporation
Test Material: Hickson 3488 (Lot No. 1094-74-6)
Date: December 5, 1995

G.L. #, Animal, Test Laboratory, Study #, Date	MRID No.	Results	Tox. Cat.	Core Grade[a]
81-1, Rat, IRDC, 707-001, 02/02/94	432788-02	LD_{50} 838 mg/kg (Female)	III	A
81-2, Rabbit, IRDC, 707-002, 02/02/94	432788-03	LD_{50} <2000 mg/kg	II	A
81-4, Rabbit, IRDC, 707-003, 02/02/94	432788-04	Corrosive	I	A
81-5, Rabbit, IRDC, 707-004, 02/02/94	432788-05	Severe irritant	I	A
81-6, Guinea Pig, IRDC, 707-005, 02/02/94	432788-06	Not a sensitizer	--	A

[a] A = Acceptable

11