

US EPA ARCHIVE DOCUMENT



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

7-10-03

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

10/JULY/2003

MEMORANDUM

Subject: EPA I.D. No: 19713-301 Drexel Copper Hydroxide
DP Barcode: D289124
Decison No. 14951
PC Code: 023401

From: Masih Hashim, Toxicologist *MH*
Technical Review Branch *SR*
Registration Division (7505C)

To: Dennis McNeilly, PM Team 22
Fungicide Branch
Registration Division (7505C)

Applicant: Drexel Chemical Company
1700 Channel Avenue
Memphis, TN 38113-1327

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Copper hydroxide	37.5
Inert Ingredients	<u>62.5</u>
Total:	100.0

ACTION REQUIRED: PM requests a review of the acute eye irritation study for File Symbol 19713-301.

BACKGROUND: The Drexel Company's product has the signal word Danger because of eye study which has Tox Category I. The Company submitted a new eye study for a revision of the acute toxicity profile.

RECOMMENDATIONS: The eye irritation study (MRID 45880601) is in compliance with the Sub Division F guidelines. The study changes the Signal Word from Danger to Caution.

The revised toxicology profile for File Symbol 19713-301 is as follows:

acute oral toxicity	III	cited	MRID 00145518
acute dermal toxicity	III	cited	MRID 00145517
acute inhalation	IV	cited	MRID 00145520
primary eye irritation	III	acceptable	MRID 00145519
primary dermal irritation	IV	acceptable	MRID 00145516
dermal sensitization	pos.	waived	from label

LABELING:

PRODUCT ID #: 019713-00301

PRODUCT NAME: Drexel Copper Hydroxide

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. Avoid contact with eyes or clothing. Wear protective eyewear. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

DATA EVALUATION RECORD

STUDY TYPE: PRIMARY EYE IRRITATION TESTING (870-2400)

PRODUCT MANAGER: 22

REVIEWER: M. HASHIM

TEST MATERIAL: Drexel KOP-Hydroxide (Copper Hydroxide 37.5%[Batch No. 241002-LB]), Torquoise fine powder.

CITATION: Bossotto, A. (2003) Eye Irritation/Corrosion Effects in Rabbits. KOP - Hydroxide Flowable. Microquim S.A., AV. Triunvirato 3447 (1427) Buenos Aires, Argentina. Study No. B1-2519/02 dated 2-4-03, MRID 45880601.

SPONSOR: Drexel Chemical Company, Memphis, TN 38113-0327.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 45880601), 0.1 ml of KOP-Hydroxide Flowable [Batch No. 241002-LB] was placed into the conjunctival sac in one eye of each of the 3 NZW rabbits (Source: Cottage, Los Carpinchos, Murillo s/n- Escobar, Buenos, Aires-Argentina. T.E: 03488-4211774). Ocular irritation was assessed up to 7 days.

There was corneal opacity and conjunctivitis in the rabbits (Table 1). All eyes were clear within 6 days of instillation. Eye irritation grade was 42.66. The study is classified as Tox Category III. The product is a moderate Irritant.

This study (870-2400) is in compliance with the Sub Division F guidelines.

COMPLIANCE: The study meets GLP requirements.

RESULTS:

Table 1. Eye lesions/ Total number of animals affected

Lesion	1 hr	24	48	72	96	5 days	6 days	7 days
Corneal opacity	0/3	0/3	3/3	3/3	3/3	1/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3	0/3	0/3	0/3	0/3
Conjunctivitis	1/3	3/3	3/3	3/3	0/3	0/3	0/3	0/3

Note: Positive reading is 2 for conjunctiva.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D289124
2. PC CODE: 023401
3. CURRENT DATE: 7-10-03
4. TEST MATERIAL: Copper Hydroxide

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Primary eye irritation study/ rabbit/ Microquim Lab/ B1-2519/02/ 2-4-03,	45880601	moderate irritant	III	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated