

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

22/April/1999
MEMORANDUM

Subject: EPA Reg. No.: 7969-RNU; MC-6
DP Barcode: D253014
Case No: 030848
PC CODE(s): 109101

From: John C. Redden, Team Leader
Technical Review Branch
Registration Division (7505C) JCR

To: C.P. Moran, PM Team 22
Fungicide Branch
Registration Division (7505C)

Applicant: BASF Corporation
Agricultural Chemicals Group
P.O. Box 13528
Research Triangle Park, NC 27709-3528

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Mepiquat chloride	60.0%
<u>Inert Ingredient(s):</u>	<u>40.0%</u>
Total:	100%

BACKGROUND:

Previously (1/31/96) the Precautionary Review Section reviewed five of the six required studies for EPA Reg. No. 7969-RNU. The sixth study, MRID 00071943 (eye irritation), was illegible, and PRB requested that the registrant resubmit the study.

On January 22, 1999 the Agency received a letter from the BASF Corporation indicating that an eye irritation study had not been conducted on EPA Reg. No. 7969-RNU. The registrant submitted two studies with the letter. Both were eye studies done at both a higher and lower concentration of mepiquat chloride. It is BASF's contention that these studies considered together will satisfy the eye irritation requirement. The registrant indicates the following:

"Two studies are submitted to indicate the toxicology classification for 60% mepiquat chloride. One study was conducted using technical (100%) mepiquat chloride (Reg. Doc. # 77/0034). Another study was conducted using a 460 g/l formulation of mepiquat chloride and water (Reg. Doc. # 77/9010, MRID # 00071943). Both studies indicate that mepiquat chloride at either concentration is very hygroscopic thus what is tested in the rabbit eye is virtually a liquid formulation of technical mepiquat."

RECOMMENDATIONS:

Although both eye irritation studies were classified as supplementary, due to deficiencies, TRB has determined that they are acceptable for regulatory purposes. In light of this latest information TRB has compiled a complete acute toxicity database for EPA Reg. No. 7969-RNU.

The acute toxicity profile for EPA Reg. No. 7969-RNU is as follows:

acute oral toxicity	II	Acceptable
acute dermal toxicity	III	Acceptable
acute inhalation toxicity	III	Acceptable
primary eye irritation	III	Supplementary
primary skin irritation	IV	Acceptable
dermal sensitization	No	Acceptable.

LABELING:

ID #: 007969-00104 MC-6

SIGNAL WORD: WARNING

PRECAUTIONARY STATEMENTS:

May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or

2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.

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

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

NOTE TO PHYSICIAN:

Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician." The following statements are suggested types of information that may be included, if applicable:

- 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.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: C.P. Moran
MRID No.: 447412-01

Reviewer: John C. Redden
Study Completion Date: 1/20/1977
Study No.: BASF Reg. Doc. No. 77/0034

Testing Facility: Laboratory for Pharmacology & Toxicology
Hamburg, FRG

Author: Prof. Leuscher

Quality Assurance (40 CFR §160.12): This study does not meet the requirements for 40 CFR 160. The study was conducted prior to the effective date requiring that the study be done under GLP.

Test Material: In the letter accompanying the action, BASF states that in this study the test material was 100% technical mepiquat chloride (Technical 1, 1-dimethylpiperidinium chloride, which is synonymous to mepiquat chloride).

Dosage: 0.1 gram was instilled into the left eye (conjunctival sac) of the animals. The right eye serves as the control.

Species: 6 NZW rabbits (3 males and 3 females)

Age: From body weight we assumed that the animals are young adult.

Weight: 2.3 to 2.8 kg

Source: Laboratory for Pharmacology & Toxicology Breeding Colony

Conclusion:

1. **Toxicity Category:** IV
2. **Classification:** Supplementary, non upgradable but useful for regulatory purposes.

Procedure (Deviations from §81-4): Not a GLP study, No observations at 1 hour.

Observations	Number "positive"/number tested							
	Hours				Hours			
	1	24	48	72	1	24	48	72
	Unwashed eyes				Washed eyes			
Corneal Opacity	ND	0	0	0	NA	NA	NA	NA
Iritis	ND	0	0	0	NA	NA	NA	NA
Conjunctivae:								
Redness	ND	0.7	0	0	NA	NA	NA	NA
Chemosis	ND	0	0	0	NA	NA	NA	NA
Discharge	ND	0	0	0	NA	NA	NA	NA

ND = Not Done; the protocol did not required a 1 hour examination.

NA= Not Applicable; there were no washed eyes.

Summary: After 24 hours four animals had slight erythema. After 48 and 72 hours the redness had disappeared. This study indicates that technical mepiquat chloride, at a dose of 0.1 g, is a non irritant.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: C.P. Moran
MRID No.: 00071943

Reviewer: John C. Redden
Study Completion Date: April 12, 1977
Study No.: BASF 77/9010

Testing Facility: BASF Aktiengesellschaft
 Department of Toxicology
 D-6700 Ludwighafen/Rhein
 Germany

Author: Dr. med. Vet. Hildebrand

Quality Assurance (40 CFR §160.12): This study does not meet the requirements for 40 CFR 160. The study was conducted prior to the effective date requiring that the study be done under GLP.

Test Material: BAS 083; XXVII/433; 1,1-dimethyl-piperidinium-chloride; a 460 g/l formulation of mepiquat chloride and water (assuming same density this is a 46% solution).

Dosage: 0.1 ml of undiluted 1,1-dimethyl-piperidinium-chloride.

Species: White Vienna rabbits; 4 males and 2 females

Age: Not reported

Weight: Mean weight of 2.7 kg

Source: Messrs. M. Gaukler, Offenbach

Conclusion: The primary irritation index for the eye of BAS 083 = 1.67.

1. **Toxicity Category:** III
2. **Classification:** Supplementary, not upgradable, but useful for regulatory purposes.

Procedure (Deviations from §81-4): This is not a GLP study (performed prior to 40 CFR 160). The age of the animals was not reported.

Observations	Number "positive"/number tested							
	Hours				Hours			
	1	24	48	72	1	24	48	72
	Unwashed eyes				Washed eyes			
Corneal Opacity	ND	0	0	0	NA	NA	NA	NA
Iritis	ND	0	0	0	NA	NA	NA	NA
Conjunctivae:								
Redness	ND	1	.83	.66	NA	NA	NA	NA
Chemosis	ND	0	0	0	NA	NA	NA	NA
Discharge	ND	0	0	0	NA	NA	NA	NA

ND = Not Done

NA = Not Applicable

Summary: Only finding was a slight reddening of the lid conjunctiva. This sign persist in four of

the six animals through 72 hours. By seven days only one animal had reddening.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D253014
2. PC CODE: 109101
3. CURRENT DATE: 04/22/99
4. TEST MATERIAL: Mepiquat Chloride

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Primary Eye Irritation; 81-4; 1/20/77; BASF Reg. Doc. No. 77/0034	447412- 01	Slight erythema at 24 hours; redness gone after 48 hours; non irritant	IV	Suppl ement ary
Primary Eye Irritation; 81-4; 4/12/77; BASF Reg. Doc. No. 77/9010	00071946 3	Slight reddening of the lid conjunctiva; persisted in 4 of 6 animals through 72 hours; by seven days 1 animal had reddening	III	Suppl ement ary

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