

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 9, 2000

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 3573-TE / Mariner
DP Barcode: D267062
Case No: 068860

To: Adam Heyward, PM 34
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *Ian Blackwell*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader *Karen Hicks*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: The Procter & Gamble Company

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Citric acid	4.5
<u>Other Ingredient(s):</u>	<u>95.5</u>
Total:	100%

BACKGROUND: The Procter & Gamble Company has submitted a primary eye and a primary skin irritation study in support of their product "Mariner". The MRID Numbers are 451128-06 and 451128-07. The studies were conducted by Springborn Laboratories, Inc.

These two studies have been submitted in response to a 3/22/99 PSB/AD acute toxicity review. That review requested the submission of these studies to complete the acute toxicity profile of Mariner. In the 3/22/99 review of Mariner (review ID# 290773 - at that time Mariner was not assigned a File Symbol), PSB/AD allowed Procter & Gamble to cite four of six acute toxicity studies conducted on Reg. No. 3573-54 to be used to support Mariner. Primary eye and skin irritation studies were requested to support Mariner.

RECOMMENDATIONS: PSB findings are:

1. MRID Number 451128-06: The primary skin irritation study is acceptable.
2. MRID Number 451128-07: The primary eye irritation study is unacceptable at this time. This study was conducted using the Low-Volume Eye Test (LVET) method. OPP/AD is currently deciding whether or not we will accept this test methodology, and, is currently not accepting studies conducted using this method.

The acute toxicity profile for File Symbol 3573-TE is currently:

acute oral toxicity	IV	acceptable
acute dermal toxicity	IV	acceptable
acute inhalation toxicity	IV	acceptable
primary eye irritation		unacceptable
primary skin irritation	IV	acceptable
dermal sensitization	Nonsensitizer	acceptable

LABELING:

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS: (none required)

STATEMENT OF PRACTICAL TREATMENT (SOPT): (none required)

Note To PM: The precautionary labeling requirements of this study may change upon the acceptance of a primary eye irritation study to support File Symbol 3573-TE.

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

Product Manager: 34
MRID No.: 451128-07

Reviewer: Ian Blackwell
Study Completion Date: 8/6/99
SLI Study No.: 3029.2218

Testing Laboratory: Springborn Laboratories, Inc.
Author(s): Kimberly L. Bonnette, M.S., LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: SS0623.01; EPA File Symbol 3573-TE; "clear, colorless liquid"

Dosage: 0.01 mL (This was a Low-Volume Eye Test)

Species: New Zealand White rabbits

Sex: 2 males + 1 female

Weight: 3.558-4.100 kg

Age: young adult

Source: Myrtle's Rabbitry

Summary:

- Toxicity Category:**
- Classification:** unacceptable

Procedure (Deviations From §81-4):

❖ This study was conducted using the Low-Volume Eye Test method.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	0/3	0/3	—	—
Iritis	3/3	0/3	0/3	0/3	0/3	0/3	—	—
Conjunctivae								
Redness	2/3	0/3	0/3	0/3	0/3	0/3	—	—
Chemosis	0/3	0/3	0/3	0/3	0/3	0/3	—	—
Discharge	0/3	0/3	0/3	0/3	0/3	0/3	—	—

— = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 34
MRID No.: 451128-06

Reviewer: Ian Blackwell
Study Completion Date: 8/6/99
SLI Study No.: 3029.2217

Testing Laboratory: Springborn Laboratories, Inc.
Author: Kimberly L. Bonnette, M.S., LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: SS0623.01; EPA File Symbol 3573-TE; "clear, colorless liquid"

Dosage: 0.5 mL

Species: New Zealand White rabbits

Age: August 7, 2000adult

Sex: 2 males + 1 female

Weight: 2.926-3.223 kg

Source: Myrtle's Rabbitry

Summary:

1. **Toxicity Category:** IV
2. **Classification:** acceptable

Procedure (Deviations From §81-5):

Results:

One hour after exposure: Very slight erythema in 3/3.

Twenty-four hours after exposure: Very slight erythema in 2/3.

Forty-eight hours after exposure: Very slight erythema in 1/3.

Seventy-two hours after exposure: Irritation clearing in 3/3. (No irritation observed.)