

US EPA ARCHIVE DOCUMENT



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

February 7, 2001

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 3573-TE / Mariner  
DP Barcode: D271708  
Case No: 068860

To: Adam Heyward, PM 34 / Portia Jenkins  
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) 2/7/01

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

Applicant: The Procter & Gamble Company

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% bv wt.</u>
Citric acid	4.5
<u>Other Ingredient(s):</u>	<u>95.5</u>
Total:	100.0%

BACKGROUND: The Procter & Gamble Company (P&G) is asking that AD/PSB reconsiders the acceptance of a Low-Volume Eye Test (LVET) conducted on their its product, "Mariner". P&G has been attempting to get AD/PSB to accept this study for a period of months. In 2000, they have met with several toxicologists and acute toxicity reviewers to discuss the details of this test method. OPP has agreed to accept this study when it is properly conducted and pertains to the product at hand.

In this presentation, P&G has a comparison of the formulations of "Mariner Bathroom Cleaner" with "Comet Bathroom Spray" and "Mr. Clean Bathroom Liquid". LVET results for Mariner and a discussion of the LVET results for Mariner. No actual study or report was included in this submission. The DER for this study was taken from a previous review of File Symbol 3573-TE.

RECOMMENDATIONS: PSB findings are:

The primary eye irritation study is acceptable.

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	IV	acceptable
primary skin irritation	IV	acceptable
dermal sensitization	Nonsensitizer	acceptable

LABELING:

Date: 02/07/01                      LABEL REVIEW SYSTEM

ID #: 003573-00072 Mariner

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS: (none required)

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

**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:**

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

**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	---	---
<b>Conjunctivae</b>								
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