



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. No.: 3573-LU / 3573-LG

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

MJP
5-11-95

To: R. Douglas, PM-32 / W. Powell
Registration Division (7505C)

Applicant: The Procter & Gamble Co.
Cincinnati, OH 45202

FORMULATION FROM LABEL:

	% by wt.
<u>Active Ingredient(s):</u> Citric acid	4.5-6.0
<u>Inert Ingredient(s):</u>	94.0-95.5
Total:	100%



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BACKGROUND

Procter & Gamble submitted acute oral, acute dermal, acute inhalation, dermal irritation, dermal sensitization and four eye irritation studies for review. The studies were performed with Comet Disinfecting Bathroom Cleaner (EPA File Symbol 3573-LG); the registrant has requested that these data also support the registration of Mr. Clean Bathroom (EPA File Symbol 3573-LU). Both products contain citric acid as the only active ingredient.

IRDC, Springborn and Hill Top Research are the performing laboratories and the assigned MRID numbers are 427605-05 through 427605-13.

RECOMMENDATIONS

The acute data bridge from EPA File Symbol 3573-LG to EPA File Symbol 3573-LU is acceptable to PRS.

1. Acute Oral; Category IV / Acceptable

The male animal were above the recommended weight range of 200-300 grams.

2. Acute Dermal; Category III / Acceptable

The animal weights were above the recommended range of 2-3 kilograms and 8-ply gauze was used to cover the test site. PRS recommends using a 2/4-ply gauze patch to reduce the potential for absorbance of the material away from the dermal surface.

3. Acute Inhalation; Category IV / Acceptable

Only one particle size evaluation was performed at each dose level. In order to demonstrate the consistency of the generating system, a minimum of two evaluations are recommended.

4. Eye Irritation; Category III

Two of the four eye irritation studies employed the Low-Volume procedure of testing which uses a 0.01 ml dose volume. PRS has concerns that this method may underestimate the irritancy hazard posed by the test material. The remaining two studies were performed on human subjects and included full-volume and low-volume doses. None of these studies were performed in accordance with the Pesticide Assessment Guidelines (subdivision F); however, the results of the human testing are considered adequate for hazard classification purposes.

5. Dermal Irritation; Category IV / Acceptable

An 8-ply gauze patch was used to cover the test site. PRS recommends using a 2/4-ply gauze patch to reduce the potential for absorbance of the material away from the dermal surface.

6. Dermal Sensitization; Sensitizer / Acceptable

The study report failed to specify if the rechallenge was performed at a naive site. Since the rechallenge results were not useful in evaluating the sensitization potential, this deficiency did not effect the outcome of the study.

LABELING

1. The recommended signal word is "caution."
2. The recommended statements of practical treatment are as follows:

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

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

3. The recommended precautionary statements are as follows:

Harmful if absorbed through skin. Causes eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling.

4. The hazard referral statement ("See back panel...") should appear on a separate line just below the signal word. The signal word should also appear on a separate line just below the child hazard warning ("Keep out of reach...").

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

Product Manager: 32

MRID No.:427605-05

Testing Facility:IRDC

Author(s): R. York

Species: Rat

Age:Young adult

Weight:212-384 g

Source:Charles River

Test Material:SS0127.01

Quality Assurance (40 CFR 160.12):Present

Reviewer:M. Perry

Report Date:1/27/93

Report No.:191-1544

Conclusion:

1. LD₅₀ (mg/kg): Males= --
 Females= --
 Combined= 5000 mg/kg
2. The estimated LD₅₀ is greater than 5000 mg/kg.
3. Tox. Category:IV Classification:Acceptable

Deviations from 81-1:See recommendations

Results:

Dosage mg/kg	(Number Killed/Number Tested)		
	Males	Females	Combined
5000	0/5	0/5	0/10

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

Product Manager:32

MRID No.:427605-06

Testing Laboratory:IRDC

Author(s):R. York

Species:Rabbit

Weight:3.4-3.8 kg

Source:Charles River

Test Material:SS0127.01

Quality Assurance (40 CFR 160.12):Present

Reviewer:M. Perry

Report Date:1/27/93

Report No.:191-1545

Summary:

1. LC_{50} (mg/kg): Males= --
Females= --
Combined > 2000 mg/kg
2. The estimated LD_{50} is greater than 2000 mg/kg.
3. Tox. Category:III Classification:Acceptable

Deviation From 81-2:See recommendations

Results:

Reported Mortality

DOSAGE mg/kg	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2000	0/5	0/5	0/10

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

Product Manager:32

MRID No.:427605-07

Testing Laboratory:IRDC

Author(s):C. Ulrich

Species:Rat

Weight: 201-292 g

Source:Charles River

Test Material:SS0127.01

Quality Assurance (40 CFR 160.12):Present

Reviewer:M. Perry

Report Date:1/27/93

Report No.:191-1528

Summary:

1. LC₅₀ (mg/kg): Males= --
Females= --
Combined > 5.3 mg/L
2. The estimated LC₅₀ is greater than 5.3 mg/L
3. Mean Concentration: --
4. Tox. Category: IV Classification:Acceptable

Deviation From 81-3:See recommendations

Results:

Reported Mortality

Exposure Concentration mg/L	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2.0	0/5	0/5	0/10
5.3	0/5	0/5	0/10

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

Product Manager:32
MRID No.:427605-09
Testing Laboratory:Hill Top Research
Author(s):P. Bayhan
Species:Human
Dosage: 0.1 ml / 0.01 ml
Test Material: SS0127.01
Quality Assurance (40 CFR 160.12): --

Reviewer:M. Perry
Report Date:1/20/93
Report No.:92-2255-72B

Summary:

1. **Toxicity Category:** III
2. **Classification:** --

Deviations From 81-4: See recommendations

Results: Irritation cleared between 24 hours and seven days.

DATA REVIEW FOR SKIN IRRITATION TESTING (81-5)

Product Manager:32
MRID No.:427605-12
Testing Laboratory:IRDC
Author(s):R. York
Species:Rabbit
 Age:Young adult
 Sex: 2 male, 4 female
 Weight: 3.6-4.1 kg
Dosage: 0.5 ml
Test Material:SS0127.01
Quality Assurance (40 CFR 160.12):Present

Reviewer:M. Perry
Report Date:1/27/93
Report No.:191-1546

Summary:

1. The Primary Irritation Index= --
2. Toxicity Category: IV
3. Classification: Acceptable

Deviations From 81-5: See recommendations

Results: No irritation was present at or beyond the 72 hour evaluation period.

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DATA REVIEW FOR SKIN SENSITIZATION TESTING (81-6)

Product Manager:32
MRID No.:427605-13
Testing Laboratory:Springborn
Author(s):R. Rush
Species:Guinea pig
Weight: -- (young adult)
Source: Harlan SD

Reviewer:M. Perry
Report Date:1/22/93
Report No.:3029.1749

Test Material: SS0127.01
Positive Control Material: DNCB
Quality Assurance (40 CFR 160.12):Present

Method: Buehler

Summary:

1. According to the study results, this Product is a dermal sensitizer.
2. Classification: Acceptable

Deviation From 81-6: See recommendations

Results: At challenge, a 20% increase in positive scores was present in the test group over the naive control group.

ACUTE TOX ONE-LINER

1. PC CODE: 021801
2. CURRENT DATE: 5/11/95
3. TEST MATERIAL: Citric acid 6.0%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
81-1, Rat, IRDC, 191-1544, 1/27/93	427605-05	LD50 > 5000 mg/kg	IV	A
81-2, Rabbit, IRDC, 191-1545, 1/27/93	427605-06	LD50 > 2000 mg/kg	III	A
81-3, Rat, IRDC, 191-1528, 1/27/93	427605-07	LC50 > 5.3 mg/L	IV	A
81-5, Rabbit, IRDC, 191-1546, 1/27/93	427605-12	Clear at 72 hrs.	III	A
81-6, Guinea pig, Springborn, 3029.1749, 1/22/93	427605-13	Dermal Sensitizer	---	A

Core Grade Key:

A = Acceptable
S = Supplementary
U = Unacceptable