UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 30, 2002

MEMORANDUM

Subject: Data Package D277999
WASH 'N BLEACH EXTRA2, EPA File Symbol 16930-L

From: Wallace Powell, Biologist
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

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

To: Marshall Swindell, Product Manager, Team 33
Tony Kish, Team Reviewer, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

BACKGROUND

The applicant, NorAmTech corporation (as represented by an agent), has submitted a package for registration of the subject product, WASH 'N BLEACH EXTRA2. The package includes studies for acute dermal toxicity, skin irritation, and skin sensitization – MRID's 454790-03, 454790-05, and 454790-04, respectively. The studies were initially reviewed for Product Science Branch (PSB) by Oak Ridge National Laboratory. The reviews are attached to this memorandum. The submitted package also includes waiver requests for acute oral toxicity, acute inhalation toxicity, and eye irritation data.

WASH 'N BLEACH EXTRA2 is a commercial-use peroxy laundry bleach containing two New Chemicals (i.e., currently unregistered pesticidal active ingredients): TAED (tetraacetyl ethylenediamine) and sodium percarbonate. There was some question as to whether the latter should be identified on the product label as *sodium percarbonate* or as *hydrogen peroxide*. The agency reportedly has decided on *sodium percarbonate*. (The hydrogen peroxide is not formed until the product is dissolved in water.) So it appears that the active ingredients listed on the label will be as follows:

Active Ingredient	Percent w/w
Sodium percarbonate (containing hydrogen peroxide)	7.32
Ethane, bis-1,2-([N,N-diacetyl]amino-)	11.76

DISCUSSION AND RECOMMENDATION

Acute oral toxicity: The waiver request is acceptable. Ingestion of significant doses is highly unlikely, based on the physical form and use pattern of the product, also supported by low solubility of the product at ambient temperature.

Acute dermal toxicity: The submitted study, MRID 454790-03, is acceptable and indicates acute dermal Toxicity Category IV.

Acute inhalation toxicity: The waiver request is acceptable. Significant inhalation of product is highly unlikely. The product is an anhydrous solid of waxy consistency. It is transported and stored in a closed container until it is placed in a closed delivery system for use.

Primary eye irritation:

The request for waiver with assignment to Category IV is unacceptable. The data can be waived, but it appears that assignment of Category I would be necessary. The material is potentially corrosive when wet, as indicated by the submitted skin irritation data (and evident in the submitted acute dermal toxicity data).

The applicant claims that the product is intractable and "can not be granulated or crushed to a size small enough for administration to the eye." The applicant has also indicated an "inability to obtain fine and representative particles of the product." Inability to produce a suitable test article does appear likely (although no documentation of attempts was submitted for confirmation).

However, even if the product is too intractable as a test material, there is still a potential for harmful eye exposure. The product label should address the hazard in case such exposure occurs.

The low solubility at ambient temperature and the closed-system use pattern mitigate the likelihood of harmful eye exposure. However, it does not appear that such exposure is virtually eliminated. Should the automatic shutoff ever fail when the container is lifted from the gravity feeder (especially in the event of an unusually high temperature in the water feed), eye damage could occur. Or, should an employee rub his/her eyelids after inadvertently scratching the product tablet with a fingernail, or after handling the tablet with warm wet hands, then eye damage could occur.

(PSB also wonders: Could a product tablet become so dissolved along its curvature that the inverted HDPE container holding the tablet eventually loses its ability to prevent the tablet from falling out when the container is lifted out of the feeder by an employee?)

Primary skin irritation:

The submitted study, MRID 454790-05, is acceptable and indicates Toxicity Category I for skin irritation. Two groups of three animals were tested. In one test group, the anhydrous test material only (the subject product) was used. Tox Category IV resulted. In the other test group, water was used as a vehicle. In this case, Category I resulted, with corrosion evident. (Corrosion was also evident in the submitted acute dermal toxicity study.) From a hazard assessment point of view, consideration of the latter test group is appropriate in assigning a Tox Category. If exposure occurs, it is natural to expect that it could occur in the presence of water.

PSB could point out that the Guidelines call for use of a vehicle when testing solids. But PSB admits that the Guidelines also indicate that a vehicle should not significantly alter the chemical properties or toxic characteristics of the skin irritation test substance.

However, in the case of skin irritation (as with eye irritation), there is still a potential for harmful exposure and, as in the case of eye irritation, the product label arguably should address the hazard in case such exposure occurs.

Consequently, PSB recommends either (1) assigning Category I or (2) assigning no Category but requiring the human-hazard and first-aid label statements to pertain to the product in the presence of water. This would amount to requiring the Category I statements from the *Label Review Manual*, with or without a preceding phrase such as "In the presence of water...." The statements from the *Label Review Manual* are as follows:

> "Corrosive. Causes skin burns. Do not get in eyes or on clothing. Wear protective clothing and gloves*. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse."
>
> *Specify type.

Skin sensitization:

The submitted study, MRID 454790-04, is acceptable and indicates that the test substance was not a sensitizer.

Note: Because reaction to first induction was in many instances severe, moistened gauze was discontinued. I.e., test substance was tested dry for second and third inductions and for challenge and naive control. There does not appear to have been a suitable alternative to this approach, as the applicant apparently has found no suitable vehicle.

Summary:

The acute toxicity regulatory profile is summarized in the table below.

Table: Acute toxicity regulatory status for WASH 'N BLEACH EXTRA2

Data Requirement	Means of Support	Status
Acute Oral Toxicity	Waiver request	Waived
Acute Dermal Tox.	MRID 454790-03 (submitted)	Acceptable/ Category IV
Acute Inhalation Tox.	Waiver request	Waived
Eye Irritation	Request for Waiver and Tox Category IV	Unacceptable. Can be waived if applicant accepts Category I
Skin Irritation	MRID 454790-05 (submitted)	Study Acceptable. Assign Category I; **or** assign no Category but require human-hazard and first-aid statements that refer to product when wet.
Skin Sensitization	MRID 454790-04 (submitted)	Acceptable/ Non-sensitizer

Product labeling:

Determination of the required first-aid and human-hazard precautionary statements will be made after the eye and skin irritation data requirement issues have been resolved for this product.

3 Attachments

DATA EVALUATION RECORD

TETRAACETYLETHYLENEDIAMINE
(WASH `N BLEACH EXTRA[2])

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT
[OPPTS 870.1200 [§81-2]; OECD 402]
MRID 45479003

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K361

Primary Reviewer:
Susan Chang, M.S.

Signature: S. C. Chang
Date: OCT 29 2001

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T. Borges
Date: OCT 29 2001

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: OCT 29 2001

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: OCT 29 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Reviewer: Wallace Powell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat; OPPTS 870.1200 [§81-2]; OECD 402.

PC CODE: 004115

DP BARCODE: D277999
SUBMISSION NO.: S603528

TEST MATERIAL: Wash 'N Bleach Extra[2] (11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide, a.i., given on the CSF)

SYNONYMS: Wash 'N Bleach Extra[2] LDS-49

CITATION: Kuhn, J.O. (2001) Acute dermal toxicity study in rats. Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478. Laboratory study number 6326-01, May 24, 2001. MRID 45479003. Unpublished.

SPONSOR: NorAmTeck Corporation, 2100 Central Street, Kansas City, MO 64108

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 45479003), five male and five female Sprague-Dawley rats were dermally exposed to Wash 'N Bleach Extra[2] (a.i.: 11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide; Batch No. C061) moistened with deionized water for 24 hours to approximately 10% of the body surface area at a dose of 5050 mg/kg body weight. The animals then were observed for 14 days.

Dermal LD50 Males > 5050 mg/kg bw
Females > 5050 mg/kg bw
Combined > 5050 mg/kg bw

Wash 'N Bleach Extra[2] is of **LOW Toxicity** based on the LD_{50} (EPA Toxicity Category IV).

None of the animals died and all rats were normal during the study with the exception that all rats exhibited decreased activity on day 1. Very slight to severe erythema, very slight edema, atonia, focal bleeding, coriaceousness, desquamation, eschar, blanching, necrosis, pustules, alopecia, sloughing, and/or ulceration at the test site were noted on all animals from days 1 through 14. With the exception of one female that lost weight during the study, all other rats had normal body weight gains. No observable abnormalities were noted at necropsy.

This acute dermal study is classified as acceptable (guideline). This study satisfies the guideline requirement for an acute dermal toxicity study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. **Test material:** Wash `N Bleach Extra[2]

Description:	White, solid, waxy soap
Lot/Batch #:	C061
Purity:	11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide; a.i.
CAS # of TGAI:	10543-57-4 for tetraacetylethylenediamine 7722-84-4 for hydrogen peroxide

2. **Vehicle and/or positive control:** Deionized water

3. **Test animals:**

Species:	Rat	
Strain:	Sprague-Dawley	
Age/weight at dosing:	Approximately 9 weeks; males: 271-318 g, females: 180-203 g	
Source:	Texas Animal Specialties, Humble, TX	
Housing:	Individually in stainless steel cages with wire bottoms	
Diet:	PMI Feeds, Inc.™ Formula No. 5008, *ad libitum*	
Water:	Municipal water, *ad libitum*	
Environmental conditions:	**Temperature:**	20±3°C
	Humidity:	30-70%
	Air changes:	10-12/hr
	Photoperiod:	12 hrs dark/12 hrs light
Acclimation period:	5 days	

B. STUDY DESIGN and METHODS:

1. **In life dates** - Start: March 22, 2001; End: April 5, 2001

2. **Animal assignment and treatment** - Animals were assigned to the test groups noted in Table 1. Animals were given a single dose of Wash `N Bleach Extra[2] dermally applied to a clipped area on the dorsal trunk (approximately 10% of the body surface). The application site was covered with a gauze patch moistened with deionized water and secured with non-irritating adhesive tape. The covering was removed 24 hours later and the site washed with tap water and a cloth to remove any residual test material. The rats were observed for clinical signs at least three times on the day of treatment and at least daily thereafter for 14 days. Dermal irritation was observed at approximately 60 minutes after patch removal and on days 4, 7, 11, and 14. They were weighed prior to test material application, and on study days 7 and 14. Survivors were sacrificed and a necropsy was performed.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg bw)	Males	Females	Combined
5050	0/5	0/5	0/10

3. Statistics - Calculation of the dermal LD_{50} was not required.

II. RESULTS AND DISCUSSION:

A. MORTALITY is given in Table 1. None of the rats died during the study.

The dermal LD_{50} (C.I.) for males is > 5050 mg/kg bw
females is > 5050 mg/kg bw
combined is > 5050 mg/kg bw

B. CLINICAL OBSERVATIONS - All rats exhibited decreased activity one hour after treatment and on day 1 with recovery by day 2. Very slight to severe erythema, very slight edema, atonia, focal bleeding, coriaceousness, desquamation, eschar, blanching, necrosis, pustules, alopecia, sloughing, and/or ulceration at the test site were noted on all animals from days 1 through 14.

C. BODY WEIGHT - One female lost weight during the first week and gained weight during the second week, but did not regain her original weight. All other rats had normal body weight gains.

D. NECROPSY - No observable abnormalities were noted at necropsy.

E. REVIEWER'S CONCLUSIONS - The dermal LD_{50} was > 5050 mg/kg bw for males, females, and combined. These conclusions are in agreement with the study author.

F. DEFICIENCIES - None

G. COMMENT - A report titled "Wash `N Bleach Extra[2], solid laundry detergent/disinfectant, toxicity data, acute toxicity" (MRID 45479002) included the summary of this current study as reported by the author/editor. It stated that the dermal LD_{50} was > 5050 mg/kg bw.

DATA EVALUATION RECORD

TETRAACETYLETHYLENEDIAMINE
(WASH 'N BLEACH EXTRA[2])

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT
[OPPTS 870.2500 [§81-5]; OECD 404]
MRID 45479005

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K361

Primary Reviewer: Susan Chang, M.S.	Signature: Date:	Susan Chang OCT 29 2001
Secondary Reviewers: H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature: Date:	H.T Borges OCT 29 2001
Robert H. Ross, M.S., Group Leader	Signature: Date:	Robert H. Ross OCT 29 2001
Quality Assurance: Lee Ann Wilson, M.A.	Signature: Date:	L. Ann Wilson OCT 29 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC, for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Reviewer: Wallace Powell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit; OPPTS 870.2500 [§81-5]: OECD 404.

PC CODE: 004115

DP BARCODE: D277999
SUBMISSION NO.: S603528

TEST MATERIAL: Wash `N Bleach Extra[2] (11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide, a.i., given on the CSF)

SYNONYMS: Wash `N Bleach Extra[2] LDS-49

CITATION: Kuhn, J.O. (2001) Acute dermal irritation study in rabbits. Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478. Laboratory study number 6327-01, May 24, 2001. MRID 45479005. Unpublished.

SPONSOR: NorAmTeck Corporation, 2100 Central Street, Kansas City, MO 64108

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 45479005), two male and four female New Zealand white rabbits were dermally exposed to 500 mg of Wash `N Bleach Extra[2] (a.i.:11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide; Batch No. C061) and covered with a dry gauze patch or a gauze patch moistened with deionized water for four hours to an approximately 6 cm^2 area of body surface on the clipped dorsal trunk. The animals then were observed for 14 days. Irritation was scored by the method of Draize.

The rabbits treated with moistened test material: Very slight erythema was noted on one rabbit and moderate to severe erythema was noted on another rabbit one hour through 72 hours after patch removal with resolution by day 7. Severe erythema with very slight edema was noted on the third animal one hour through day 10 after patch removal with resolution by day 14. Alopecia, desquamation, and blanching were noted on all rabbits and, in addition, one rabbit had eschar and necrosis. All irritation cleared by day 14. The primary dermal irritation index was 3.2.

The rabbits treated with dry test material: Very slight erythema was noted on 3/3 rabbits one hour after patch removal with resolution by 24 hours. The primary dermal irritation index was 0.2.

In this study, non-moistened Wash `N Bleach Extra[2] was essentially non-irritating, but the moistened test material was severely irritating. (EPA Toxicity Category IV and I, respectively, for non-moistened test material and moistened test material).

This study is classified as acceptable (guideline). This study satisfies the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.**I. MATERIALS AND METHODS**

A. MATERIALS:

1. **Test material:** Wash 'N Bleach Extra[2]

Description:	White, solid, waxy soap
Lot/Batch #:	C061
Purity:	11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide; a.i.
CAS # of TGAI:	10543-57-4 for tetraacetylethylenediamine 7722-84-4 for hydrogen peroxide

2. **Vehicle and/or positive control:** Deionized water

3. **Test animals:**

Species:	Rabbit	
Strain:	New Zealand White	
Age/weight at treatment:	Approximately 15 weeks; males: 2.90-3.05 kg, females: 3.05-3.325 kg	
Source:	Ray Nichols Rabbitry, Lumberton, TX	
Housing:	Individually in stainless steel cages with wire bottoms	
Diet:	PMI Feeds, Inc.™ Lab Rabbit Diet No. 5321, in measured amount	
Water:	Municipal water, *ad libitum*	
Environmental conditions:	**Temperature:**	20±3°C
	Humidity:	30-70%
	Air changes:	10-12/hr
	Photoperiod:	12 hrs dark/12 hrs light
Acclimation period:	5 days	

B. STUDY DESIGN and METHODS:

1. **In life dates** – Start: March 27, 2001; End: April 10, 2001 (Group 1)
Start: April 24, 2001; End: April 27, 2001 (Group 2)

2. **Animal assignment and treatment** - One male and two female animals (Group 1) were given a single 500 mg dose of Wash 'N Bleach Extra[2] applied to the clipped intact site on the dorsal trunk and the site covered with a 2.5 x 2.5 cm surgical gauze patch moistened with deionized water. An additional one male and two females (Group 2) were treated similarly to the above group, except the gauze patch was dry. The application sites were wrapped with a semi-permeable dressing and secured with tape. The dressings were left in place for 4 hours, after which they were removed and the residual test material removed with tap water and a cloth. The sites were scored for erythema and edema according to the Draize method 1, 24, 48, and 72 hours and 7, 10, and 14 days after patch removal.

II. RESULTS AND DISCUSSION:

A. Group 1: Very slight erythema was noted on one rabbit and moderate to severe erythema was noted on another rabbit one hour through 72 hours after patch removal with resolution by day 7. Severe erythema with very slight edema was noted on the third animal one hour through day 10 after patch removal with resolution by day 14. Alopecia, desquamation, and blanching were noted on all rabbits and, in addition, one rabbit had eschar and necrosis. All irritation cleared by day 14. The primary dermal irritation index was 3.2.

Group 2: Very slight erythema was noted on 3/3 rabbits one hour after patch removal with resolution by 24 hours. The primary dermal irritation index was 0.2.

B. REVIEWER'S CONCLUSIONS: The moistened Wash 'N Bleach Extra[2] was severely irritating, but the dry test material was essentially nonirritating. These conclusions are not in agreement with the study author who stated that the moistened test material was moderately irritating and the dry test material slightly irritating, but are in agreement with the study author in assigning the moistened test material in Toxicity Category I and dry test material in Toxicity Category IV.

C. DEFICIENCIES - None

D. COMMENT - A report titled "Wash 'N Bleach Extra[2], solid laundry detergent/disinfectant, toxicity data, acute toxicity" (MRID 45479002) included the summary of this current study as reported by the author/editor. It stated that the test material was not considered a dermal irritant in the anhydrous state.

DATA EVALUATION RECORD

TETRAACETYLETHYLENEDIAMINE
(WASH `N BLEACH EXTRA[2])

STUDY TYPE: SKIN SENSITIZATION - GUINEA PIG
[OPPTS 870.2600 [§81-6]; OECD 406]
MRID 45479004

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K361

Primary Reviewer:
Susan Chang, M.S.

Signature: S. Chang
Date: OCT 29 2001

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T. Borges
Date: OCT 29 2001

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: OCT 29 2001

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: OCT 29 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Reviewer: Wallace Powell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Skin Sensitization - Guinea Pig; OPPTS 870.2600 [§81-6]; OECD 406.

PC CODE: 004115

DP BARCODE: D277999
SUBMISSION NO.: S603528

TEST MATERIAL: Wash `N Bleach Extra[2] (11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide, a.i., given on the CSF)

SYNONYMS: Wash `N Bleach Extra[2] LDS-49

CITATION: Kuhn, J.O. (2001) Skin sensitization study in guinea pigs. Stillmeadoe, Inc., 12852 Park One Drive, Sugar Land, TX 77478. Laboratory study number 6328-01, May 18, 2001. MRID 45479004. Unpublished.

SPONSOR: NorAmTeck Corporation, 2100 Central Street, Kansas City, MO 64108

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 45479004) with Wash `N Bleach Extra[2] (a.i.: 11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide; Batch No. C061), 15 male and 15 female Hartley guinea pigs (age not given) were tested using the Buehler method.

After three weekly inductions, the 20 test animals had no reaction after challenge. The study included a positive control DNCB study carried out within six months of the current study and the results were appropriate.

In this study, Wash `N Bleach Extra was not a dermal sensitizer.

This study is classified as acceptable (guideline). This study satisfies the guideline requirement for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. **Test Material:** Wash `N Bleach Extra

Description:	White, solid, waxy soap
Lot/Batch #:	C061
Purity:	11.90% w/w tetraacetylethylenediamine and 7.32% hydrogen peroxide; a.i.
CAS # of TGAI:	10543-57-4 for tetraacetylethylenediamine 7722-84-4 for hydrogen peroxide

2. **Vehicle and/or positive control:** Deionized water (induction); 1-chloro-2,4-dinitrobenzene (DNCB) (historical data)

3. **Test animals:**

Species:	Guinea pig	
Strain:	Hartley	
Age/weight at start:	Age not given, assumed to be young adults; males: 357-413 g, females: 355-385 g	
Source:	Charles River Laboratories, Wilmington, MA	
Housing:	1-4 animals per sex per suspended, wire bottom, stainless steel cage	
Diet:	PMI Feeds, Inc.™ Guinea pig Diet No. 5025, *ad libitum*	
Water:	Municipal water, *ad libitum*	
Environmental conditions:	**Temperature:**	20±3°C
	Humidity:	30-70%
	Air changes:	10-12/hr
	Photoperiod:	12 hrs dark/12 hrs light
Acclimation period:	5 days	

B. STUDY DESIGN and METHODS:

1. **In life dates** - Start: March 28, 2001; End: April 27, 2001

2. **Animal assignment and treatment** - On the day prior to each treatment, the back of the animals (20 test animals and 10 naive control animals) were clipped free of hair. The inductions were conducted once each week for three weeks. For the first induction, 0.4 g of the test material was applied beneath a 2.5 x 2.5 cm surgical gauze patch moistened with deionized water under occlusion for approximately six hours. For the second and third inductions, the same amount of test material was used but with a dry gauze patch at naive sites. Guinea pigs were left untreated for two weeks before challenge. The test animals were challenged with 0.4 g of the non-moistened test material under a dry gauze patch under occlusion at naive sites for 6 hours. A naive control group was treated with 0.4 g of the non-moistened test material at challenge only. Reactions were scored 24 hours after the inductions and challenge. In addition, reactions were scored 48 hours after the first induction and challenge.

II. RESULTS AND DISCUSSION:

A. INDUCTION REACTIONS AND DURATION - Faint usually confluent to strong erythema with or without edema were noted on all test animals 24 hours after the first induction that persisted on 18/20 animals by 48 hours. One animal had faint usually confluent erythema 24 hours after the third induction, all other animals had no reaction after the second and the third inductions.

B. CHALLENGE REACTIONS AND DURATION - No test animals or naive control animals had any reaction after challenge.

Wash `N Bleach Extra was a not dermal sensitizer.

C. POSITIVE CONTROL - The study included a positive control DNCB study carried out within six months of the current study and the results were appropriate.

D. It is the reviewer's opinion that the study was conducted in a manner suitable to detect the sensitization potential of the test material. No additional testing is needed.

E. REVIEWER'S CONCLUSIONS: Wash `N Bleach Extra was a not dermal sensitizer. These conclusions are in agreement with the study author.

F. DEFICIENCIES - None

G. COMMENT - A report titled "Wash `N Bleach Extra[2], solid laundry detergent/disinfectant, toxicity data, acute toxicity" (MRID 45479002) included the summary of this current study as reported by the author/editor. The test material was not a sensitizer.