



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 26, 2003

MEMORANDUM

Subject: Data Package D289767
WASH 'N BLEACH EXTRA2, EPA File Symbol 16930-L

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11/26/2003

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BACKGROUND

NorAmTech Corporation (as represented by an agent) has submitted a revision to a registration application for WASH 'N BLEACH EXTRA2. Included is a 3/28/2003 letter requesting waivers for eye and skin irritation data. The letter requests assignment to no acute Toxicity Category for eye or skin irritation but proposes a label in which the irritation precautions refer only to skin irritation resulting only from contact with the product concentrate in the presence of water.

WASH 'N BLEACH EXTRA2 is a commercial-use peroxy laundry bleach containing two active ingredients:

<u>Active Ingredient</u>	<u>Percent w/w</u>
Sodium percarbonate	22.53
Ethane, bis-1,2-([N,N-diacetyl]amino-)	11.90

The latter chemical above, also called tetracetyl ethylenediamine (TAED), is a New Chemical.

The applicant has revised the Confidential Statement of Formula to amend some notation, but it appears the formulation has not changed.

In a 4/30/2002 Product Science Branch (PSB) review (D277999), data for acute oral and acute inhalation toxicity was waived. Submitted studies for acute dermal toxicity, skin irritation, and skin sensitization were accepted.

In the 4/30/2002 PSB review, a request for assignment to Tox Category IV for eye irritation was denied. However, PSB indicated that the requested eye irritation waiver could be granted if the applicant accepts Tox Category I.

The 4/30/2002 PSB review placed the product in Tox Category I for skin irritation based on the submitted study. However, the review indicated that another option would be to assign no Tox Category but to require human-hazard and first-aid statements that refer to product in the presence of water.

DISCUSSION AND RECOMMENDATION

Eye irritation

The eye irritation waiver request is unacceptable unless the applicant is willing to have eye-irritation Tox Category I labeling.

Although the applicant's unsuccessful attempts to achieve suitable test substance appear credible, the material could still be tested as tiny cut shavings. Although this form of test substance might not be considered representative of product use situations, it could still be used to characterize the hazard in case of exposure to product in the presence of water. Should an employee rub his/her eyelids after inadvertently scratching the product tablet or handling it with warm wet hands, then eye damage may occur. Although this is an unlikely exposure situation, PSB does not view it as unlikely enough to justify a waiver.

It appears that eye exposure by other means is less likely. This opinion is based on engineering controls, means of delivery, and nature of product. (These things are discussed in applicant's 3/28/2003 letter and elsewhere in the product registration file.) With this in mind and because the unsuccessful attempts to achieve suitable test substance appear credible, if the applicant wishes to place the required precaution "causes irreversible eye damage" in the same sentence as the proposed skin-irritation wording which only applies to contact with product in the presence of water, PSB has no objections.

Skin irritation

The 4/30/2002 PSB review gave the option of not assigning a skin irritation Tox Category but instead requiring the human-hazard and first-aid statements to refer to product in the presence of water. The proposed label does this. The proposed skin-irritation precautionary statements are acceptable.

The applicant has requested assignment to no Tox Category for skin irritation. This is not acceptable. PSB assigns Category I. In the previously submitted study, the applicable animal set was the more conservative one, the one with the worse case result, Tox Category I with corrosion evident. Besides, skin irritation studies are supposed to be conducted using a vehicle, and the animal set in which a vehicle (water) was used was the one that resulted in Tox Category I. Based on this Category, the label signal word must be "Danger".

Clarification

In response to a question from Team 33 staff, PSB notes that in the previous PSB review, no Tox Category was assigned for acute oral or acute inhalation toxicity. This has the same regulatory outcome as assigning Tox Category IV. If a Tox Category assignment is needed for the record, it should be Category IV.

Summary

The acute toxicity regulatory profile for WASH 'N BLEACH EXTRA2, with updated skin irritation entry, appears below:

Data Requirement	Means of Support	Status
Acute Oral Toxicity	Waiver request	Waived Tox Category IV
Acute Dermal Tox.	MRID 454790-03 (submitted)	Acceptable Tox Category IV
Acute Inhalation Tox.	Waiver request	Waived Tox Category IV
Eye Irritation	Request for Waiver and Tox Category IV	Unacceptable. Can be waived if applicant accepts Category I
Skin Irritation	MRID 454790-05 (submitted)	Acceptable. No Tox Category assigned; Category I labeling required but may refer to product in presence of water
Skin Sensitization	MRID 454790-04 (submitted)	Acceptable/Non-sensitizer

Product labeling – precautionary statements

If the applicant chooses to let eye irritation data be waived and to have eye-irritation Tox Category I labeling, then PSB's comments on the human-hazard precautionary statements in the proposed label (the label included with 3/28/2003 submission of EPA Received date 3/31/2003) are as follows:

- The eye irritation Tox Category is I. Therefore, the signal word "Danger" must replace the word "Caution" on the label front panel. Also, it should be placed below the "Keep Out of Reach of Children" precaution (because the signal word is not meant to define or modify the child hazard warning).
- The proposed skin irritation precautionary statements are acceptable.
- However, regarding eye irritation, the label should add the precaution, "Causes irreversible eye damage." PSB has no objection to the placement of this wording in the same sentence as the skin-irritation wording (as explained in the *Eye Irritation* section above).
- The label should also indicate protective eyewear ("Wear [*specify appropriate protective eyewear such as goggles, face shield, or safety glasses*]").
- There should be a period (".") after the word "Corrosive". (On the proposed label, "Corrosive" is followed by a statement about skin effects. The word "corrosive" is applicable to eye effects, so it should not appear that it's limited to skin effects.)

Product labeling – first aid statements

The following comments apply to the proposed first aid statements (as per Pesticide Registration [PR] Notice 2001-1 and the Label Review Manual third edition):

- The following general statement is required to be included with the First Aid statements, at the beginning or the end: "Have the product container or label with you when calling a poison control center or doctor, or going for treatment."
- A Note to Physician is also required and should appear close to the First Aid section and should include the statement, "Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

The first-aid statements above should be used unless the applicant considers them medically incorrect for the product, in which case a rationale for alternative statements should be submitted for review.

On the front panel, the applicant should expand the reference statement to refer to the first aid statements: "See back panel for additional precautionary and first aid statements." (40 CFR §156.68 says: "*The first aid statement must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as 'See first aid statement on back panel' appears on the front panel.*")