

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 16, 2001

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 72674-5 / Vantocil IB
DP Barcode: D268352
Case No: 023188

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

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

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

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

Applicant: Nalco Chemical Company

FORMULATION FROM LABEL:

| <u>Active Ingredient(s):</u> | <u>% by wt.</u> |
|--|-----------------|
| Poly(iminoinidocarnoyliminoimidocarbonyliminohexanethylene) hydrochloride | 20 |
| <u>Other Ingredient(s):</u> | 80 |
| Total: | 100% |

BACKGROUND: Nalco Chemical Company has submitted a dermal sensitization study in support of their product "Vantocil IB". This study is a Magnusson-Kligman (Guinea Pig Maximization) study conducted in humans. The study was conducted by Ivy Laboratories (KGL, Inc.). The MRID Number is 451877-05.

RECOMMENDATIONS: PSB findings are:

MRID Number 451877-05: This study was conducted using a modification of the Magnusson-Kligman method for determining dermal sensitization. However, the lab tested this product in *humans*. The Agency does not endorse the use of humans in acute toxicity studies. Apparently, this study was conducted to override a previous dermal sensitization where sensitization was found using Vantocil IB in guinea pigs. However, this study does appear to demonstrate that this product is not a dermal sensitizer.

The acute toxicity profile for Reg. No. 72674-5 is currently*:

| | | |
|---------------------------|---------------|------------|
| acute oral toxicity | | |
| acute dermal toxicity | | |
| acute inhalation toxicity | | |
| primary eye irritation | | |
| primary skin irritation | | |
| dermal sensitization | nonsensitizer | acceptable |

*-PSB/AD could not find acute toxicity data for 72674-5. A complete acute toxicity profile could not be compiled for this product.

LABELING:

The registrant may remove labeling pertaining to dermal sensitization from its label.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 34
MRID No.: 451877-05

Reviewer: I. Blackwell
Study Completion Date: 9/22/95
Project ID: #KS950101

Testing Laboratory: Ivy Laboratories
Author: K. Baidbey

Quality Assurance (40 CFR §160.12): NO.

Test Material: Cosmocil CQ (#S2082001)
Positive Control Material:

Species: HUMANS
Weight: not reported
Source: not applicable

Age: ranged from 18-55 years (Table 1)

Method: Guinea Pig Maximization Study

Summary:

- 1. This Product is not a dermal sensitizer.**
- 2. Classification:** acceptable

Procedure (Deviation From §81-6):

Procedure:

Results: No dermal sensitization was observed in any of the 25 human test subjects.