



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.