US EPA ARCHIVE DOCUMENT

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

APR 27 1993

Subject: EPA Registration Number 1677-90
Mandate Acid Sanitizer

From: Mary L. Waller, Biologist Mary L. Waller
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

To: Ruth Douglas, PM 32
Antimicrobial Program Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Head E 4/27/93
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

Applicant: Ecolab Inc.
370 Wabasha St. Ecolab Center
St. Paul, MN 55102

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Phosphoric Acid	22.5%
Citric Acid	20.5%
Octanoic Acid	6.0%
Decanoic Acid	2.0%
Inert Ingredient(s):	49.5%
Total:	100.0%

BACKGROUND: The registrant has requested a waiver for the acute inhalation toxicity and dermal sensitization studies. These data waiver requests are in response to the RED issued for citric acid.

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

RECOMMENDATIONS: RSB/PRS findings are as follows:

The dermal sensitization study is waived on the basis of the registrant's statement that the pH is < 2 for this product. It would not be feasible to test such a product. The registrant provided documentation of the product's pH in an attachment to the Requirements Status and Registrant's Response Form. A pH of 2 for a 1% solution was reported on the CSF.

The request for a waiver of the acute inhalation toxicity study is denied. The registrant's statement that the product "is not applied in such a manner to generate particles of inhalable size (15 microns or less)" is unsupported by any information. According to the product label, the product is a liquid which is used to clean dairy and food processing equipment, tanks, vats, pails, pipelines and closed systems. While the closed system may not result in any exposure, the other methods of application are likely to expose any person using this product to respirable droplets or vapor.

If the registrant is willing to accept toxicity category I labeling for the inhalation exposure and possible classification as restricted-use (based on PM decision), then the requirement for an acute inhalation toxicity study can be waived. However, if the registrant is not amenable to this option, then an acute inhalation toxicity study must be submitted on the product as formulated.

Note to PM: If the registrant submits any exposure data to substantiate the claim that inhalation exposure is not actually a hazard, this data should be submitted to HED/OREB for review.

LABELING: Comments will be made upon submission of outstanding data.