US EPA ARCHIVE DOCUMENT

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

MEMORANDUM:

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: EPA File Registration Number 1677-90
Mandate

From: Mary L. Waller, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

Mary Waller
6/13/94

To: Ruth Douglas, PM 32
Antimicrobial Program Branch
Registration Division (7505C)

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

FORMULATIONS FROM LABELS:

EPA Registration Number 1677-90

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: In a company letter dated 6/28/93, the registrant has requested a reconsideration of the data waiver denial for the acute inhalation toxicity study. This submission is in response to the Citric Acid RED. No products were batched in the Citric Acid RED. In a previous PRS review (M. Waller dated 4/27/93), a waiver was granted for the dermal sensitization study and the waiver request for the acute inhalation toxicity study was denied.

In the company letter dated 6/28/93, the registrant states that the company will be submitting particle sizing data to demonstrate that the product does not result in inhalable material. As of this review, this data has not been presented.

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

RECOMMENDATION: RSB/PRS findings are as follows:

1. PRS has reconsidered the waiver request for the acute inhalation toxicity study and has decided that the waiver request is denied. The registrant states that the corrosive nature of the product will be measured rather than the systemic effects. While this may be true, it is important to provide appropriate respiratory protection for pesticide users who may suffer respiratory damage as a result of product corrosivity rather than product toxicity.

   As stated in the 4/27/93 review, if the registrant is willing to accept toxicity category I for the acute inhalation toxicity study then the study can be waived. If the registrant does accept toxicity category I for the acute inhalation study and wants to obtain reduced inhalation precautionary labeling and personal protective equipment (PPE) for pesticide applicators handling the diluted product, then the registrant can submit acute inhalation toxicity data on the most concentrated use dilution. If supported by the data, the precautionary labeling and PPE for pesticide applicators handling the diluted product will be modified according to the data.

2. The acute dermal, primary eye irritation, and primary skin irritation study are waived based on the product's pH as reported on the confidential statement of formula (pH = 2).

3. The registrant must submit an acute oral toxicity study on the product to support reregistration.

4. Attached is a copy of the acute tox data waiver policy. This is simply to provide the registrant with an understanding of the circumstances or situations where data requirments might be waived.

LABELING:

Labeling will be reviewed upon submission of data.

Page 3 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

__✓__ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.