

Ambion Corporation
37 Naugatuck Drive
Naugatuck Industrial Park
Naugatuck, CT 06770

OCT 17

Attention: Peter Schuyler

Gentlemen:

Subject: Ambicide Disinfectant Cleaner
EPA Registration No. 34770-1
Your Submission Dated November 23, 1987

The amendment referred to above, submitted in connection with the Label Improvement Program Notice for Antimicrobial Products Used as Food Contact Surface Sanitizers, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
 - a. On the right panel, change "Use Directions" to "Directions For Use." Add the following misuse statement:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
 - b. On the front panel, delete the entire Phenol Coefficient claim.
 - c. On the left panel, replace "First Aid" with "Statement of Practical Treatment."
 - d. Delete the following ingredients. They are now considered inert ingredients.

Tetrasodium ethylenediamine tetraacetate
Sodium carbonate
Sodium metasilicate, anhydrous

50212:I/C:Lee:L-15:KENCO:9/2/88:10/17/88:CB:psr:rw

CONCURRENCES

SYMBOL	SURNAME	DATE						

- e. Refer to PR Notice 83-3 for acceptable storage and disposal statements. Include the heading Storage and Disposal and add the following subheadings, Pesticide Disposal and Container Disposal.
- f. The statement "Keep Out of Reach of Children" must appear directly above the signal word "Warning" (front panel only).
- g. Change "cross-infections" to "cross-contamination" (two locations).
- h. On the left panel above the word "Warning" place the following headings:

Precautionary Statements
Hazard to Humans and Domestic Animals

- 2. Submit five copies (5) of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please call Martha DeLaney at (703) 557-3675.

Sincerely yours,

John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosure

Cross infection is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. **AMBICIDE DISINFECTANT CLEANER** is formulated for this problem area. It both cleans and disinfects effectively and is virucidal when used as directed. Its hard surface disinfecting action will reduce the hazard of cross-infection.

Two ounces of **AMBICIDE DISINFECTANT CLEANER** per gallon of water will deodorize bathrooms, garbage storage areas, and other areas where bacterial growth can cause mal odors.

WARNING

Keep out of reach of children. May cause severe eye irritation or eye damage. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. Avoid contamination of food.

FIRST AID:

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink promptly a large quantity of water. Avoid alcohol. Call a physician immediately.

AMBICIDE DISINFECTANT CLEANER
 Cleaner—Disinfectant—Deodorizer—Fungicide—Virucide
 [REDACTED] for Hospital and Institutional Use

AOAC Phenol Coefficients

Staph. aureus (ATCC No. 6538)	100
Salmonella typhosa (ATCC No. 6539)	50

Active Ingredients

Didecyl dimethyl ammonium chloride	4.5%
[REDACTED]	

Inert Ingredients

ACCEPTED
with 95% [REDACTED]
in EPA Letter Dated: 100.0%

EPA Registration No. 007 17 1503 34770-1

Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended, for the purpose of registered under EPA Reg. No. 34770-1

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 NAUGATUCK, CONNECTICUT 06770

WARNING

KEEP OUT OF REACH OF CHILDREN. SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

Apply **AMBICIDE** to walls, floors, tables, chairs and... For heavily soiled may be required. For Hospitals & per gallon of water. At two ounces **DISINFECTANT** Pseudomonas, Salmonella, Shigella, Staphylococcus aureus, Streptococcus, etc. At 2 ounces per gallon of **AMBICIDE** is shown by its following additional: Brevibacterium, Enterobacter, Proteus, Streptococcus, Staphylococcus, Salmonella, Streptococcus, Shigella. At two ounces **DISINFECTANT** Herpes Simplex causes Infectious representative of the causative virus, influenza A2 as recalled the Hong Kong Virus, on human **FOR SCHOOLS TRIAL USES**. At one ounce **DISINFECTANT** cleaning and disinfecting Staphylococcus, Escherichia coli, athlete's foot, etc. above to disinfect hospitals were used.

Rinse empty container.