

APR 5 1989

Wausau Chemical Corporation
2001 North River Drive
Wausau, WI 54401

Attention: James E. Cherwinka

Gentlemen:

Subject: Sanidet
EPA Registration No. 15265-1
Your Submission Dated December 18, 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. Revise the "Use Directions" heading to read:

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

- b. Include a 1-minute contact time for the sanitization section. The directions must also indicate how the product is to be removed from the surfaces after the recommended contact time. Include instructions to drain the use solution from the surface and air dry.
- c. Expand the sanitizing directions to include the method of application (e.g., immersion, flooding, spraying) to wet all surfaces thoroughly.
- d. Identify the types of hard surfaces or objects (glasses, dishes, silverware, etc.) intended for treatment for the sanitization section.

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CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- e. Include the necessity for removal of gross food particles and soil by a pre-rinse, or pre-scrape and, when necessary, pre-soak treatment. In addition, instruction must be provided for thoroughly washing the surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse prior to application of the sanitizing solution.
- f. For the disinfection section, include a 10-minute contact time. The directions must also indicate how the product should be removed from the surfaces after the recommended exposure period.
- g. Delete "Sodium Carbonate" and "Tetrasodium EDTA" from the active ingredient. They are now considered inert ingredients. Adjust your inert percentages accordingly.
- h. The correct signal word for this product is "DANGER." Therefore, replace the word "WARNING" with the word "DANGER" (center panel only).
- i. In the Physician section, delete the last sentence beginning with "Measures against circulatory"
- j. Delete the statement "No Rinse Required" from the sanitization section.
- k. Revise the sentence "a pre-cleaning step is recommended" to read "a pre-cleaning step is required."
- l. Delete the phenol coefficients section from the left panel.
- m. Revise your Storage and Disposal statement to read:

STORAGE AND DISPOSAL

PROHIBITIONS

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

BEST AVAILABLE COPY

CONTAINER DISPOSAL

(For metal containers)

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

(For plastic container)

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities, by burning. If burned, stay out of smoke.

The "STORAGE AND DISPOSAL" heading must be of the same type size as the child hazard warning statement.

- n. The child hazard warning statement "Keep Out of Reach of Children" must be placed immediately above the signal word "DANGER." The statement must be in a type size of 6-points or larger. Refer to the enclosure "THE LABEL" for labeling type size requirements (center panel only).
- o. Revise the referral statement to read:

See side panel for additional precautionary statements.

- p. Revise the precautionary statements to read:

**Precautionary Statements
Hazards to Humans and Domestic Animals
DANGER
Keep Out of Reach of Children**

Corrosive. Causes severe eye and skin damage.
Do not get in eyes, or skin, or on clothing.
Wear goggles or face shield and rubber gloves
when handling. Harmful if swallowed. Avoid
contamination of food.

- q. Revise the "FIRST AID" heading to read "Statement of Practical Treatment."
- r. Delete the word "milk" from the Statement of Practical Treatment.




- s. Revise the sentence ". . . controlling the hazard of cross-infection" to read ". . . controlling the hazard of cross-contamination."
2. Submit five (5) copies 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.

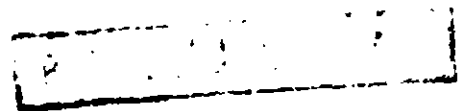
A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 557-6982.

Sincerely yours,

John H. Lee 
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7504C)

Enclosures



USE DIRECTIONS:

Use at 2 ounces per gallon. This product will be effective against *Pseudomonas aeruginosa* PRD-10 at this level. This has been substantiated by the AOAC Use Dilution Confirmation Test. At this level, the product is fungicidal against pathogenic fungi.

For best results, use Sanidet with a cloth or mop and apply to walls, floors and other hard surfaces.

Use for sanitization of food equipment or food contact items. Limit the level of active quaternary to 200 ppm (2.8 ounces per 5 gallons).

NO RINSE REQUIRED

For heavy soil or organic matter, a precleaning step is recommended.

PHENOL COEFFICIENTS

GUARANTEED
S. AUREUS
S. TYPHOSA

Minimum
32
27

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR - 5 1989

15285-1

Rinse empty container thoroughly with water and discard.

SANIDET

**CLEANER
DEODORIZER**

**DISINFECTANT
FUNGICIDE**

DESIGNED FOR HOSPITAL AND INSTITUTIONAL USE

ACTIVE INGREDIENTS:

n Alkyl (60% C ¹⁴ , 30% C ¹⁶ , 5% C ¹² , 5% C ¹⁸) dimethyl benzyl ammonium chlorides	2.25%
n Alkyl (68% C ¹² , 32% C ¹⁴) dimethyl ethylbenzyl ammonium chlorides	2.25%

INERT INGREDIENTS:

100.0%

EPA REG NO 15265-1 EPA EST NO 15265 WI-1

NET CONTENTS: _____ GALLON (S)

DANGER

Keep Out of Reach of Children. See right side panel for additional precautionary statements.

Wausau Chemical Corporation
Wausau, Wisconsin 54401

BEST AVAILABLE COPY

Sanidet is a cleaner, disinfectant and sanitizer designed for institutional use such as hospitals, nursing homes and institutions where housekeeping will be of prime importance in controlling the hazard of cross infection. Sanidet can provide the assurance of need in this area, when used as directed. For use on floors, walls, sink tops, garbage pails, telephones, rest rooms, bed pans and operating rooms. Effective against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Pseudomonas aeruginosa*. Also effective against pathogenic fungi, *Trichophyton interdigitale*.

DANGER

Keep Out of Reach of Children. Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Harmful or fatal 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 milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.