

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 29 2003

Ms. Julee Kasprisin
Regulatory Affairs Specialist
State Industrial Products
3100 Hamilton Avenue
Cleveland, OH 44114

Subject: Formula 362 No Rinse Cleaner/Sanitizer
EPA Registration No. 70799-8
Application Date: 8/12/03
Receipt Date: 8/19/03

Dear Ms. Kasprisin:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comments:

Update PR Notice 2001-1

LABEL COMMENTS

1. The Memorandum of Understanding (MOU) language must be added to your label because your product is a hospital use: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.
2. You must submit separate deodorizing directions.
3. According to PR Notice 84-1 and 83-3, you must update the Storage and Disposal statements for containers one (1) gallon or less and for containers more than one gallon, since your label have one gallon or less and above one gallon.
4. Under the Directions for Use, insert the words "non porous" between hard surfaces.
5. Under the Precautionary Statements, revise the statement to include the word "Corrosive" between "children and Causes". The following categories are used for the "First Aid" statement:

CONCURRENCES

SYMBOL	SURNAME	DATE					
15100	J. Kasprisin	10/29/03					

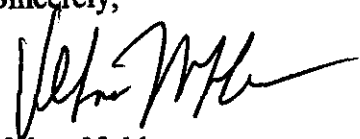
Primary Eye	Tox I
Primary Skin	Tox I
Acute Oral	Tox III

GENERAL COMMENTS

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 29 2003
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY.
NOT FOR HOUSEHOLD USE OR RESALE.

PRECAUTIONARY STATEMENTS

DANGER

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Keep out of reach of children. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Protect eyes and skin when handling concentrates. Harmful if swallowed. Avoid contamination of food. Remove and wash contaminated clothing.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage, measures against circulatory shock. Respiratory depression and convulsion may be needed.

ENVIRONMENTAL HAZARDS: For 5 gallon containers and larger: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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

Disinfection: To disinfect hard inanimate surfaces add 2 ounces per gallon water. Apply solution with mop cloth, sponge or mechanical sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air dry. To disinfect toilet bowls, flush toilet, add 2 ounces concentrate directly to the bowl water. Scrub the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush. For heavily soiled areas, a pre-cleaning step is recommended. Prepare a fresh solution for each use.

Mildewstat: To control mold and mildew on pre-cleaned, hard nonporous non-food contact surfaces (such as floors, walls, table tops) add 2 ounces concentrate per gallon of water. Apply solution with a cloth mop or sponge, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears.

Sanitizer: To sanitize previously cleaned and rinsed nonporous food contact surfaces, prepare 200 ppm active quaternary solution by adding 2.8 ounces per 5 gallons of water. At this level no potable water rinse is required. To sanitize immobile items (such as tanks, shopping baskets, cooler tops), flood the area with a 200 ppm solution or apply with a cloth or sponge rubbing sure to wet all surfaces completely for at least 60 seconds. Let air dry. Prepare a fresh solution for each use.

To sanitize previously cleaned mobile items (such as drinking glasses, eating utensils), immerse in a 200 ppm solution (2 ounces of product per 3 1/2 gallons of water) for at least 60 seconds making sure to immerse completely. Remove and let air dry. Prepare a fresh solution daily or more frequently as soil is apparent. DO NOT add dishwashing detergent to the sanitizing solution. (Detergent deactivates the sanitizing ingredients.)



Formula 362

No Rinse Cleaner/Sanitizer

Cleaner-Disinfectant-Deodorizer Detergent-Fungicide-Virucide*
Sanitizer-Mildewstat on hard inanimate surfaces
Designed for Hospital and Institutional Use

ACTIVE INGREDIENTS:

n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈)
dimethyl benzyl ammonium chloride.....2.25%
n-Alkyl (68% C₁₂, 32% C₁₄)
dimethyl ethylbenzyl ammonium chlorides.....2.25%

OTHER INGREDIENTS95.50%
Total.....100.00%

EPA Reg. No. 70799-8

EPA Est. No. 70799-OH-1

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
AND STATEMENTS OF PRACTICAL TREATMENT.

Net Contents:

State Industrial Products
World Headquarters
3100 Hamilton Ave
Cleveland, OH 44111
Puerto Rico
Cataño, P.R.
Call for work environments • 1-800-782-2436

30R08 - 500391

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 29 2003

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

70799-8

STORAGE AND DISPOSAL

STORAGE: Store this product only in its original container and place in a locked storage area out of the reach of children. Keep container closed when not in use. Store at temperatures above 32°F

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of outside or at an approved waste disposal facility.

CONTAINER DISPOSAL:

55 and 36 gallon drums: 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.

20 gallon and 7 gallon (6 gallon) drums and pails: Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burning stay out of smoke.

1 gallon and 1 pint container: Do not reuse empty container. Wrap container and put in trash.

STATE FORMULA 362 NO RINSE CLEANER/SANITIZER has been designed for institutional use, such as hospitals, nursing homes and schools where housekeeping will be of prime importance in controlling the hazard of cross contamination from environmental surfaces. Provides assurance you need in this area when used as directed. For use on inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs and telephones as a disinfectant.

In addition, this product deodorizes those areas which are hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, toilet bowls, and any other areas which are prone to odors caused by microorganisms.

Disinfection: At 2 ounces per gallon dilution STATE FORMULA 362 NO RINSE CLEANER/SANITIZER exhibits effective disinfectant activity against the organisms:

Pseudomonas aeruginosa PRD10	Brevibacterium ammoniagenes	Escherichia coli
Streptococcus faecalis	Klebsiella pneumoniae	Shigella dysenteriae
Salmonella schottmuller	Enterobacter aerogenes	Salmonella choleraesuis
Staphylococcus aureus	Streptococcus salivarius	

At this level the product is also fungicidal against the Pathogenic fungi Trichophyton mentagrophytes. **Virucidal * Activity:** - The product when used on environmental inanimate hard surfaces at 2 ounces per gallon of water exhibits effective virucidal activity against influenza A2-Asian (representative of the common flu virus), Herpes simplex 2 (causative agent of fever blisters and mononucleosis), Adeno virus type 2 (causative agent of upper respiratory infections), and Vaccinia virus (representative of the pox virus group). Efficacy tests have demonstrated that STATE FORMULA 362 NO RINSE CLEANER/SANITIZER is an effective bactericide, fungicide and virucide* in the presence of organic soil (5% blood serum).

Mold and Mildew: This product prevents and controls mold and mildew and the odors they cause on hard nonporous inanimate surfaces.

Sanitization: This product is an effective sanitizer when diluted in water up to 250 ppm hardness (CaCO3).

To order call 1-800-782-2436 • FAX: (216) 931-7717
Questions about pesticides? Call 1-800-858-7378
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