

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

MAY 18 2005

SUBJECT: Formulation 362 No Rinse Cleaner/Sanitizer
EPA Registration Number: 70799-8
Application Dated: November 12, 2004
Receipt Date: November 19, 2004

Dear Ms. Julee Kasprisin:

The following amendment, submitted in connection with registration under section 3 (c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to revise the labeling is acceptable subject to the conditions listed below:

- Addition of public health pests

Conditions

Make the following changes to your labeling:

1. Revise the "Disinfection" directions to read as follows: "...and then let air dry, Remove gross filth from heavily soiled surfaces prior to applying disinfectant solution. To disinfect toilet bowls..."

2. Add the following statement to the disinfection section of the label: "This product is not to be used as a disinfectant on glassware, dishes, and eating utensils."

3. The cited data (MRID 00133899) to support food contact sanitizing data is unacceptable. These studies were performed on a Manufacturing Use Product which by definition does not include end use directions nor specific efficacy claims. Your claims for food contact sanitizing may continue to be included on this label at this time. This letter will serve to put you on notice that at the time of re-registration, you will be expected to submit a study performed in accordance with DIS/TSS/4 which shows a five log reduction in 30 seconds.

MSOL							
SURNAME	J. Kasprisin						
DATE	5/18/05						

At the present, revise this section exactly as follows such that the directions for use are in agreement with DIS/TSS 17 as follows:

“Sanitization: Remove gross food particles and soil by a preflush, or prescrape and, when necessary, pre-soak treatment. Then thoroughly wash surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse prior to the application of the sanitizing solution. Prepare a 200 ppm active quaternary solution by adding 2.8 ounces of this product per 5 gallons of water. **To sanitize immobile items** (such as tanks, chopping blocks, counter tops) flood the area with a 200 ppm solution, or apply with a cloth or sponge making sure all surfaces remain wet for at least 60 seconds. Then drain excess solution from surface and allow to air dry. Prepare a fresh solution for each use. **To sanitize mobile items:** Immerse in a solution of 200 ppm active quaternary solution for at least 60 seconds. Remove and let air dry. Prepare a fresh solution daily or more frequently if solution becomes soiled or diluted. Do not add dishwashing liquid to this sanitizing solution.”

4. Revise the following statement: “Disinfection: At 2 ounces per gallon *with a 10 minute contact time*, State Formula 362 No Rinse Cleaner/Sanitizer exhibits effective disinfectant activity against the organisms...”

5. Revise to read as follows: “At this level the product is also fungicidal against the Pathogenic fungus *Trichophyton mentagrophytes* when used on hard non-porous surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.”

6. Revise the HIV instructions to include the following phrases:

“...with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (*associated with AIDS*)...” and “CONTACT TIME: Allow surfaces to remain wet for 10 minutes *with a solution of 2 ounces product per gallon of water*. Disposal...and disposed of according to *federal, state and local regulations* for infectious...”

7. Revise label to read: “*Listeria monocytogene*”.

8. The submitted Confidential Statement of Formulation for the Basic Formula dated 11/12/04 is acceptable and will be made part of the record for this file.

9. The submitted labeling was very difficult to read and review. All copies of the label must be legible and should be of suitable quality for making legible photocopies. When submitting labels to the Agency, make certain that the type size is at least 12 characters per inch or a font size of at least 6 points.

CONCURRENCES							
ABOL							
SURNAME							
DATE							

EPA Form 1320-1A (1/00) Printed on Recycled Paper **OFFICIAL FILE COPY**

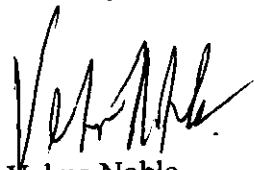
General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
 Product Manager (31)
 Regulatory Management Branch I
 Antimicrobials Division (7510C)

Enclosure: Stamped Label
 7510C:T.Lantz:5/16/05:70799-8b

CONCURRENCES							
MSOL							
SURNAME							
DATE							

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 18 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 70799-8

FOR INFO

Do not com
PESTICIDE
temperature
CONTAINER
dispose of it
stay out of
For caustic
in trash.
PESTICIDE I
mixture, or
label instruc
reservative

STATE FORMULA
schools where ho
Provides assuranc
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In addition, this pr
lines and cans, tal
Disinfectant: At 2
by against the org:
Pseudomonas
Streptococcu
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Staphylococc
Methicillin Re.

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Virucidal * Activity
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sensitive of the Pto
Efficacy tests have
virucide* in the pro
KILLS HIV-1, HBV
FLUIDS in health ca
surfaces/objects w
ated with the potent
HCV).
SPECIAL INSTRUCT
SOILED WITH BLOO
latex gloves, gowns,
surfaces and object
INFECTIOUS WASTE
waste disposal.
Mold and Mildew:
fates.

PRECAUTIONARY STATEMENTS

DANGER

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Keep out of reach of children. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves and protective clothing. Hazard if swallowed. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

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.

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.

This product is not to be used as a terminal disinfectant/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.

General Cleaning: Apply this product to soiled area with mop, cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer. This product can be diluted at 2 ounces per gallon of water or applied full strength. Thoroughly wet soiled surface and scrub as necessary. Rinse surface with potable water and wipe dry with a dry paper towel or lint-free cloth.

Disinfection: To disinfect hard pre-cleaned, non porous inanimate surfaces add 2 ounces per gallon water. Apply solution with mop cloth, sponge or hand pump coarse fog 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. Remove gross filth from heavily soiled surfaces. Prepare a fresh solution for each use.

Mildewstat: To control mold and mildew on pre-cleaned, hard nonporous non-load 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.

Sanitization: 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 trays, chopping blocks, counter tops), flood the area with a 200 ppm solution or apply with a cloth or sponge making 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. (Disinfectant describes the sanitizing ingredients.)

State
Since 1911 **Formula 362**

No Rinse Cleaner/Sanitizer

Cleaner-Disinfectant-Detergent-Fungicide-Virucide*
Sanitizer-Mildewstat on hard inanimate surfaces
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 chloride.....	2.25%
n-Alkyl (68% C ₁₂ , 32% C ₁₄)	
dimethyl ethylbenzyl ammonium chlorides.....	2.25%
OTHER INGREDIENTS	95.50%
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.



State Chemical
3100 Hamilton Avenue,
Cleveland, OH 44114
To Order Call: 1-800-782-2436
www.statechemical.com

Peoria Rice
Royal Industrial Park, Bldg "M"
Local #5, Carr #68, km 1.5 Palmas,
Cataño, PR, 00962
To Order Call: 1-800-782-2436

State Chemical is a Division of State Industrial Products.

Net Contents:

40R11 - 500391

4/5

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

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep product under locked storage inaccessible to children in a dry place no lower in temperature than 50°F or higher than 120°F.

CONTAINER DISPOSAL: 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 burned, stay out of smoke.

For each gallon 1 gallon or less: Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

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.

STATE FORMULA 302 NO RINSE CLEANSER-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 by environmental bacteria. Provides assurance you need in this area when used as directed. For use on inanimate hard surfaces such as walls, floors, sink tops, latrine bowls, tables, chairs and telephones as a disinfectant.

In addition, this product disinfects 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.

Dilution: At 2 ounces per gallon dilution **STATE FORMULA 302 NO RINSE CLEANSER-SANITIZER** exhibits effective disinfectant activity against the organisms:

- *Pseudomonas aeruginosa* PRO10
- *Streptococcus faecalis*
- *Salmonella schubertwinkels*
- *Staphylococcus aureus*
- *Methicillin Resistant Staphylococcus Aureus (MRSA)*
- *Brevibacterium aeroviridigenes*
- *Klebsiella pneumoniae*
- *Enterobacter aerogenes*
- *Streptococcus salivarius*
- *Neisseria meningitidis* (Meningococcus meningitidis)
- *Escherichia coli*
- *Shigella dysenteriae*
- *Salmonella choleraesuis*
- *Listeria monocytogenes*

At this level the product is also fungicidal against the Parasitic fungi *Microsporum canis*.

Virucidal Activity: The product when used on environmental (hard) surfaces at 2 ounces per gallon of water and a contact time of 10 minutes, exhibits effective virucidal activity against (a) 25 types representative of the cyprinid fish virus, Herpes Simplex 1 (a causative agent of fever blisters), Adenovirus type 2 (causative agent of upper respiratory tract infections), Influenza virus (responsible of the flu virus group), Human Immunodeficiency Virus (HIV-1), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). Efficacy tests have demonstrated that **STATE FORMULA 302 NO RINSE CLEANSER-SANITIZER** is an effective bactericide, fungicide and virucide in the presence of organic soil (5% blood serum).

KILLS HIV-1, HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS IN HEALTH CARE SETTINGS (HOSPITALS, NURSING HOMES) OR OTHER SETTINGS IN WHICH THERE IS AN EXPECTED RISK OF CONTACT WITH BLOOD/BODY FLUIDS. The product when used on environmental (hard) surfaces at 2 ounces per gallon of water and a contact time of 10 minutes, exhibits effective virucidal activity against (a) 25 types representative of the cyprinid fish virus, Herpes Simplex 1 (a causative agent of fever blisters), Adenovirus type 2 (causative agent of upper respiratory tract infections), Influenza virus (responsible of the flu virus group), Human Immunodeficiency Virus (HIV-1), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). Efficacy tests have demonstrated that **STATE FORMULA 302 NO RINSE CLEANSER-SANITIZER** is an effective bactericide, fungicide and virucide in the presence of organic soil (5% blood serum).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, or eye coverings. **CLEANING PROCEDURES:** Blood and other body fluids should be thoroughly cleaned from surfaces and objects before application of this product. **CONTACT TIME:** Allow surfaces to remain wet for 10 minutes. **DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Hold and Mixture: This product prevents and controls mold and rot and the odors they cause in hard inanimate surfaces.

To order call 1-800-782-2436 • FAX: (216) 931-7717

Questions about pesticides? Call 1-800-858-7378

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