AGENCY

STATES ENVIRONMENTAL PROTECT: AGE

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OCT 2 2 2003

Mr. Robert Sloan H&S Chemicals Division c/o Lonza Inc. 17-17 Route 208 Fair Lawn, NJ 07410

SUBJECT:

Formulation HS-96

EPA Registration Number: 47371-143 Application Dated: July 24, 2003

Received Date: July 25, 2003

Dear Mr. Sloan:

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

- revise label language
- update to comply with PR Notices

# **Conditions**

Revise the label as follows:

- 1. Revise the Precautionary Statements to include the following statements: "Wear protective eyewear (goggles, safety glasses or face shield) protective gloves (rubber or chemical resistant) and protective clothing when handling..." and "Wash thoroughly with soap and water after handling." Delete the following statement from this section: "Avoid contamination of food, water, or feed."
- 2. At a dilution of 1 ½ ounces per gallon, this product is diluted at a ratio of 1:85. Revise the language on page two to read: "DILUTION: 1:85 1½ oz. per gallon."

		CONCURRENCES				
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EPA Form 1320-1A (1/90)

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- 3. Revise the directions "To Disinfect Toilet Bowls and Urinals" to read begin as follows: "Preclean surfaces to remove heavy soil prior to application of the disinfectant. Flush to wet surfaces. Use..."
- 4. Revise the Disinfection directions by changing this section to read as follows: "...with a cloth, mop, or coarse (mechanical) spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. Thoroughly wet surfaces..." In addition, add the following statement to the end of this section: "Wipe dry with a cloth, sponge or mop or allow to air dry."
- 5. Revise the section on page two beginning: "Rinse all surfaces that..." to end as follows: "Do not use on utensils, glassware, dishes or appliance interior surfaces as a disinfectant."
- 6. Revise the one gallon "Storage and Disposal" statement to include the following: "Wrap and discard in trash or recycle."
- 7. Revise the "Pesticide Storage" statement to include: "Store in area inaccessible to children."
- 8. Revise the "Pesticide Disposal" statement to include the following language: "...pesticide, spray mixture or rinsate is a..." such that your language is in agreement with PR Notice 83-3.

# **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.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely.

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure: Stamped Label

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PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER CORROSIVE: Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, safety glasses or face shield) and protective gloves (rubber or chemical resistant) when handling. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Avoid contamination of food, water, or feed.

#### FIRST AID

**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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

**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.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(For container sizes of 5 gallons & larger)

#### **ENVIRONMENTAL HAZARDS**

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 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.

ACCEPTED with COMMENTS in EPA Letter Dated:

OCT 2 2 2003

Under the Fedoral Insecticide.
Pangicida, and Rodenticide Act as amended, for the pesticide,

registered under EPA Reg. No. 47371-143

# HS-96 DISINFECTANT BOWL CLEANER

#### Cleaner - Deodorant - Disinfectant

Active ingredients:	
n-Alkyl (C <sub>14</sub> 60%, C <sub>16</sub> 30%, C <sub>12</sub> 5%, C <sub>18</sub> 5%)	
dimethyl benzyl ammonium chloride	2.4%
n-Alkyl (C <sub>12</sub> 50%, C <sub>14</sub> 30%, C <sub>16</sub> 17%, C <sub>18</sub> 3%)	ı
dimethyl ethylbenzyl ammonium chloride	2.4%
Other Ingredients:	<u>95.2%</u>
Total:	100.0%

# DANGER

See (side) (left) (right) (back) panel for Precautionary Statements and First Aid.

EPA Reg No. 47371-143

EPA Est No. (insert EPA Establishment No. here)

Net Contents: (insert container size here)

H&S CHEMICALS DIVISION

c/o Lonza Inc.

17-17 Route 208

Fair Lawn, New Jersey 07410

HS-96 DISINFECTANT BOWL CLEANER EPA REG NO. 47371-143 EPA DRAFT LABEL 7-21-03 An excellent, multi-purpose germicide formulation that disinfects, cleans and deodorizes.

Designed for institutional use such as hospitals and nursing homes, schools and colleges, motels and hotels, and the household.

Effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis. \*Virucidal against HIV-1 (AIDS virus).

**DILUTION: 1:96** 

1½ oz. per gallon

#### **DIRECTIONS FOR USE**

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

# TO DISINFECT TOILET BOWLS AND URINALS:

Preclean surfaces prior to application of the disinfectant.

Flush to wet surfaces and remove heavy soil. Use 1 oz. of concentrate in the toilet bowl. Brush over exposed surfaces and under the rim. Leave for 10 minutes, swab and flush. Close safety cap after use.

#### **DISINFECTION DIRECTIONS:**

Remove gross filth and heavy soil deposits. Preclean all surfaces prior to disinfection. Use 1½ oz. per gallon of water. Apply to exterior bowl surfaces, walls, floors, garbage cans, and other hard nonporous surfaces such as tables, chairs, countertops, sinks, bathroom fixtures and bed frames with a cloth, mop, sponge or coarse (mechanical) spray device so as to thoroughly wet surfaces for a contact time of 10 minutes.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

Frepare fresh solution daily or more often if the solution becomes visibly diluted or soiled.

(Note to reviewer: Only One of the following two statements will be used:)

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.

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This product is not for use on medical device surfaces.

**KITCHEN:** Kitchen floors collect both traffic dirt and germs. Use 1½ oz. per gallon of water or full strength where greasy dirt is a problem. Follow disinfection directions.

**BATHROOM:** Excellent for cleaning and deodorizing basins, tub and tiles. Leaves everything bright and clean. Kills odor-causing household germs. Use 1½ oz. per gallon of water, or full strength where odors are a problem. Follow disinfection directions.

MILDEWSTATIC INSTRUCTIONS: Will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces at a dilution rate of 1½ oz. per gallon of water. Allow to dry on surface and repeat weekly or more often if mildew growth returns.

HS-96 DISINFECTANT BOWL CLEANER EPA REG NO. 47371-143 EPA DRAFT LABEL 7-21-03 \*Kills H1V-1 (AIDS virus) on precleaned environmental surfaces / objects previously soiled with blood / body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects likely to be soiled with blood or body fluids can be associated with transmission of Human potential for immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

**Personal Protection:** Disposable protective gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

Contact Time: Leave surfaces wet for 5 minutes. Use a ten (10) minute contact time for disinfection against all other bacteria, claimed.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

(If container size is 1 gallon or less, the following storage and disposal statements will be used:)

#### **STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than gallon, the following storage and disposal statements will be used:)

#### STORAGE AND DISPOSAL

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

#### Pesticide Storage

Do not store on side. Avoid creasing or impacting of side walls.

#### Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of 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.

#### Container disposal

(Plastic containers:) 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.

(Fiber drums with liners): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

(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.

