47371-35

10/09/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 9 2003

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

Subject:

Formulation HS-33A

EPA Registration Number 47371-35 Application Dated July 10, 2003 EPA Received July 14, 2003

Dear Mr. Sloan:

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

Proposed Amendment:

- revise first aid statement
- revise precautionary statements and storage and disposal

Major Deficiencies:

- 1. Delete the statement "Avoid contamination of food".
- 2. Under Food Processing Plant Use: replace the word "should" with "must". Refer to PR 2000-5 for mandatory language.

3. Under Dairy Use: replace the word "should" with "must". Refer to PR 2000-5 for mandatory language.

mandatory language.				CONCURRENCES				
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EPA Form 1320-1A (1/90)

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4. Under Restaurant and Bar Use: add this statement as per DIS/TSS 17:

It is necessity for removal of gross food particles and soil by a preflush, or pre-scrape and, when necessary, pre-soak treatment. In addition, instructions 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.

A stamped copy of the labeling accepted with conditions 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 or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerely.

Veľma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure

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, face shield, or safety glasses) and protective gloves (rubber or chemical resistant). Wash thoroughly with soap and water after handling. Harmful if swallowed. Avoid contamination of food. Remove and wash contaminated clothing before reuse.

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.

(For 5 gallon & larger only)

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.

FORMULATION HS-33A

- SANITIZER
- DEODORIZER

Active Ingredients:	
n-Alkyl (C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%)	
dimethyl benzyl ammonium chloride	5.0%
n-Alkyl (C ₁₂ 68%, C ₁₄ 32%)	
dimethyl ethylbenzyl ammonium chloride	5.0%
Other Ingredients:	90.0%
Total	. 100.0%

DANGER

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

EPA Reg. No. 47371-35 EPA Est. No. (insert EPA Est. No. here) Net Contents: (insert container size here)

> Manufactured by: H&S Chemicals Division c/o Lonza Inc. 17-17 Route 208 Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
FEPA Letter Dated:

OCT 9 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 4737/-35 This product fulfills the criteria of Appendix F of the Grade A Pasteurized Milk Ordinance 1965 recommendations of the U.S. Public Health Service in waters up to 500 ppm of hardness calculated as CaCO₃, when tested by the A.O.A.C. Germicidal and Detergent Sanitizer Test. Consult your milk inspector or health officer for recommendations on your local program.

Designed for use in sanitizing in dairy operations. Also used to sanitize bulk milk tanks, milk equipment and for use as a cow udder wash. Can be used as a no rinse sanitizer in federally inspected meat and poultry plants.

DILUTION:1:512

1 oz. per 4 gallons of water (195 ppm active quaternary)

DIRECTIONS FOR USE

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

GENERAL USE DIRECTIONS FOR SANITIZING

For use on precleaned hard nonporous surfaces such as milking equipment, pails, tubing, and bulk milk tanks. Wash equipment with a detergent cleaner, rinse with potable water and allow to drain. Sanitize immediately before reuse with 1 ounce per 4 gallons of water by applying with a mop, sponge, cloth, spray or soak to thoroughly wet the surfaces for at least 1 minute. Allow sanitizing solution to completely drain from the equipment and air dry before reusing. Do not rinse. Prepare a fresh solution for each use.

For mechanical applications, use solution may not be reused for sanitizing applications but may be used for other purposes such as cleaning.

FOOD PROCESSING PLANT USE:

Before use as a sanitizer in federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

Remove gross food particles and soil. Wash and rinse all surfaces, then apply a solution of 1 ounce in 4 gallons of water Thoroughly wet all surfaces. Surfaces should remain wet for at least one minute followed by adequate draining and air drying. Do not rinse.

ACCEPTED with COMMENTS
FEPA Letter Dated:

OCT 9 2003

DAIRY USE

The udders and teats of dairy cows are to be washed with a solution of 1 ounce in 4 gallons of warm water. Use a fresh towel for each cow. Avoid contamination of washing solution by dirt and soil. Do not dip used towel back into wash solution. A fresh wash solution should be prepared at least daily or more often if the solution becomes visibly dirty.

RESTAURANT AND BAR USE

For use as a sanitizer on dishes, glassware, silverware, cooking utensils, wash with detergent, rinse thoroughly and immerse in a solution of 1 ounce per 4 gallons of water for at least 1 minute. Allow to drain and air dry. Do not rinse.

(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

Open dumping is prohibited. Do not reuse empty container. 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 way of smoke.

(Metal Containers:) Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(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.

FORMULATION HS-33A Under the Federal Insecticide,
EPA REG. NO. 47371-35 Fungicide, and Redenticide Act as
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