

SEP 26 2003

Mr. Robert Sloan
Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: HYAMINE 35000 W/E-80% CONC
EPA Registration No. 6836 -106
Amendment Date: June 27, 2003
EPA Receipt Date: June 30, 2003

Dear Mr. Sloan,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the following conditions listed below.

Proposed Amendment

- Update First Aid Statements, Precautionary Statements, Storage and Disposal Statements as required by the applicable PR Notices and the Label Review Manual.

Conditions

Revise the label as follows:

1. The Agency has completed risk assessments to characterize the chemical, Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC). During this process, the acute toxicology profile was determined for Manufacturing Use Products (MUP) with an active ingredient concentration ranging from 40% to 80% and End-Use Products (EP) that are formulated repackages of MUPs in the aforementioned concentration range. According to this data, this product is classified as tox. II for acute inhalation, so the "Precautionary Statements" must be revised by adding the following statements:

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

May be fatal if inhaled. Do not breathe vapor. Wear a dust mist filtering respirator (MSHA/NIOSH approval # prefix TC-21C).

2. Revise the "First Aid" statements by adding "**If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.**"
3. Under "First Aid," bold the subheadings, If swallowed/If in eyes/If on skin or clothing, so the statements stand out on the label.
4. Under the "Directions for Use, delete the use sites, "Residential and Public access premise, Antifouling Coating, Materials and Preservatives, Swimming Pools and Aquatic areas . These sites are not supported by this active ingredient.

General Comments

A stamped copy of the labeling accepted with conditions 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 Velma Noble at (703) 308-6233.

Sincerely,



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

LONZA

17-17 ROUTE 208
FAIR LAWN, NEW JERSEY 07410
EMERGENCY TEL. NO. 309-697-5400

HYAMINE® 3500 W/E-80% CONC.

For Formulation Into Antimicrobial Products

Active Ingredients: Alkyl (C₁₄-50%, C₁₂-40%, C₁₆-10%) Dimethyl Benzyl Ammonium Chloride..... 80.0%

Other Ingredients:..... 20.0%

..... 100.0%

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP 26 2003
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-106

CAS. NO. 68391-01-5
Net Weight

KEEP OUT OF REACH OF CHILDREN
DANGER

EPA Reg. No. 6836-106
EPA EST No. 6836-IL-1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash 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. 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. 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.

PHYSICAL OR CHEMICAL HAZARDS

DO NOT USE OR STORE NEAR HEAT OR FLAME!

FOR HELP IN A CHEMICAL EMERGENCY CALL CHEMTREC 800-424-9300
BEFORE USING CONSULT MATERIAL SAFETY DATA SHEET

DIRECTIONS FOR USE

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

This product is a concentrate for formulating purposes only. This product for formulation into antimicrobial products for use in/on Agricultural premises and equipment, Food Handling/storage establishment premises and equipment, Commercial, institutional and industrial premises and equipment, Residential and public access premises, Materials and Preservatives, Medical Premises and equipment, Industrial processes and water systems, Antifouling Coatings, Wood preservatives, Swimming Pools and Aquatic Areas. Formulators using this product are responsible for providing data for the EPA registration of their formulated products. This product may be used to formulate products for specific use(s) not listed on this label if the formulator or primary registrant has complied with U.S. EPA data requirements regarding the support of such use(s).

NOTE: This product should not be used or compounded with any reducing or oxidizing agents (such as calcium hypochlorite, solid perchlorate, or nitric acid) since such admixtures may be explosive. Do not use in conjunction with soap or any anionic wetting agent.

Provide goggles, gloves and respirators. Under certain conditions, the use of protective creams may be advisable.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Do not store on side.

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.

CONTAINER DISPOSAL

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

FAIR LAWN, NJ

MAPLETON, IL

PASADENA, TX

LONG BEACH, CA

WILLIAMSPORT, PA

PAINSEVILLE, OH