

6836-91

10/8/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Joanna Holcombe
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

OCT - 9 2010

SUBJECT: Hyamine 1622 Crystals
EPA Registration Number: 6836-91
Application Dated: September 03, 2010
Receipt Date: September 08, 2010

Dear Ms. Holcombe:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

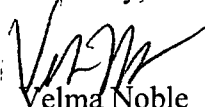
- Propose to add an advisory statement

Based on a review of the submitted information, this notification is acceptable. A copy has been inserted in your file for future reference.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,



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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Environmental Protection Agency Washington, DC 20460	United States <input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section 1

1. Company/Product Number 6836-91	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hyamine 1622 Crystals	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 90 Boroline Road Allendale, NJ 07401	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	

Check if this is a new address

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application

Notification - Explain below. Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Not Subject to PRIA

Label Notification to add an advisory statement. Please see cover letter for details.

This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: *Joanna Holcombe* Date: 9-3-10

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(s) Retail Container 1 oz. to bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name Joanna Holcombe	Title Sr. Commercial Regulatory Services Associate	Telephone No. (include Area Code) 201-316-9297
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamp)

2. Signature <u><i>Joanna Holcombe</i></u>	3. Title Sr. Commercial Regulatory Services Associate	Date Application Received (Stamp) o o o o o o o o o o o o
4. Typed Name Joanna Holcombe	5. Date September 3, 2010	



Via FedEx

Lonza Inc
Allendale
90 Boroline Road
Allendale, NJ 07401, USA

Ms. Velma Noble, PM-31
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2227 S. Crystal Drive
Arlington, VA 22202

Joanna Holcombe
Lonza Life Science Ingredients
Commercial Regulatory Services

Tel 201-316-9297
Fax 201-696-3470
joanna.holcombe@lonza.com

September 3, 2010

**SUBJECT: Hyamine 1622 Crystals, EPA Reg. No. 6836-91
Application for Label Notification**

Dear Ms. Noble:

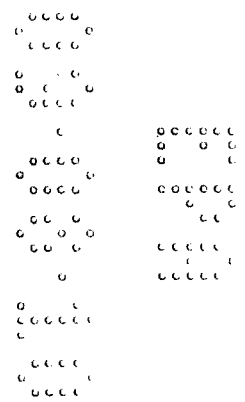
I am submitting an application to add an advisory statement, "This product is not intended for use in Pharmaceutical Applications" to the Hyamine 1622 Crystals label. Please find the enclosed documents in support of this notification:

- Application for Notification;
- One copy of the proposed label with changes highlighted; and
- Two copies of the proposed label

If you have any questions or need any additional information, please feel free to contact me at 201-316-9297.

Sincerely,

Joanna Holcombe
Sr. Commercial Regulatory Services Associate
Lonza Inc.



LONZA

LONZA INC.
90 BOROLINE ROAD
ALLEDALE, NJ 07401
EMERGENCY TEL. NO. 309-697-5400

HYAMINE® 1622 CRYSTALS

For Use By Manufacturers Only In Formulating Antimicrobial Products For The Uses Indicated On The Label

Active Ingredient: Diisobutylphenoxyethoxy Ethyl Dimethyl Benzyl Ammonium Chloride Monohydrate98.8%
Other Ingredients:1.2%
100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

CAS. NO. 121-54-0
EPA Reg. No. 6836-91
EPA EST No. 48210-JP-01

HEALTH	3
FLAMMABILITY	1
REACTIVITY	0
PERSONAL PROTECTION	

DOT
NOT REGULATED
(NON-HAZARDOUS)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled, swallowed or absorbed through the skin. Do not breathe dust. Do not get in eyes, on skin or on clothing. Wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Wear goggles or face shield, 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.
IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable by mouth-to-mouth if possible. 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.

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!

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 and Swimming Pools. This product is not intended for use in Pharmaceutical Applications. 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 mixtures may be explosive. Do not use in conjunction with soap or any anionic wetting agent. In preparing packaging mixes containing Hyamine 1622 Crystals use normal precautions for handling powdered materials likely to create dust. Use an exhaust fan to keep dust away from operators.

(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses. Chapter 13, Table 6 of the Label Review Manual states that for "All products in containers that could be burned," the registrant has the option to "Remain silent on burning;" therefore, no incineration language is provided for plastic containers.)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

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.

(Note to reviewer: This Container Statement will be used only for containers 5 gallons or less:)
Container Disposal:

Nonrefillable container. Do not reuse or refill this container.
(Plastic and Metal Containers:) Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.
(For metal containers only: DO NOT cut or weld metal containers.)
(For Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

FOR HELP IN A CHEMICAL
EMERGENCY CALL
CHEMTREC 1-800-424-9300.

BEFORE USING
CONSULT MATERIAL
SAFETY DATA SHEET.

CODE NO. (P)

LOT NO. (S)

WEIGHT. (Q)

lb. kg.

NUMBER:

(Note to reviewer: This Container Statement will be used for containers over 5 gallons:)

Container Disposal:

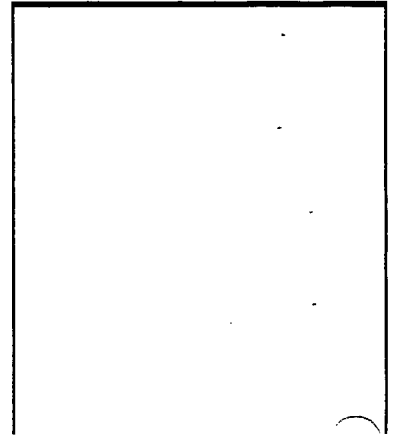
Nonrefillable container. Do not reuse or refill this container.

(Plastic and Metal Containers:) Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For metal containers only: DO NOT cut or weld metal containers.)

(Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed 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.



S/S