

42048-1

06/10/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUN 10 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Christina M. Swick
Agent for Celeste Industries Corporation
Lewis & Harrison
122 C Street, NW, #740
Washington, DC 20001

Subject: Notification per PR Notice 2007-4
Glyco-San
EPA Registration Number: 42048-1
Application Date: May 12, 2010
Receipt Date: May 13, 2010

Dear Ms. Swick:

This letter acknowledges receipt of the following notification, submitted under the provisions of FIFRA section 3(c) 9 and PR Notice 98-10.

Proposed Notification

Label revisions per Container Rule, PR Notice 2007-4.

General Comments

Based on a review of the submitted materials, your notification to update the container disposal statements per PR Notice 2007-4 is acceptable and apart of the records on file.

If you have further questions concerning this letter, then please contact me by telephone at 703-308-6416 or by email at campbell-mcfarlane.jacqueline@epa.gov or Killian Swift by telephone at 703-308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline Campbell-McFarlane
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

34

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Please read instructions on reverse before completing form.

Form Approved MB No. 2070-0060, Approval expires 05-31-98



EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other NOTIFICATION**

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 42048-1	2. EPA Product Manager Jaqueline Campbell-McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Glyco-San	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Celeste Industries Corporation 8221 Teal Drive, Suite 405 Easton, MD 21601 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		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: _____

Section – II

- | | |
|--|--|
| <input type="checkbox"/> Amendment – Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification – Explain below. | <input type="checkbox"/> Other – Explain below |

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

NOTIFICATION OF LABEL CHANGE PER PR NOTICE 2007-4

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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: Christina M. Swick Date: 5/12/10

THIS SUBMISSION IS NOT SUBJECT TO PRIA FEES

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
				<input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input 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 Christina M. Swick, Lewis & Harrison 122 C Street, NW, Suite 740, Washington DC 20001	Title Agent	Telephone No. (Include Area Code) 202-393-3903 x16
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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 (Stamped)

2. Signature <u>Christina M. Swick</u>	3. Title Agent	
4. Typed Name Christina M. Swick, Lewis & Harrison, LLC	5. Date May 12, 2010	

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

May 12, 2010

HAND DELIVERED

Antimicrobials Division (Mail Code 7504P)
Office of Pesticide Programs
Document Processing Desk [NOTIFY]
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**ATTN: Jaqueline Campbell-McFarlane
Product Manager, Team 34**

**SUBJECT: Celeste Industries Corporation
Glyco-San (EPA Reg. No. 42048-1)
Notification of Label Changes per PR Notice 2007-4**

Dear Ms. Campbell-McFarlane:

On behalf of Celeste Industries Corporation, we are notifying the Agency of changes to the *Glyco-San* label. The changes are in accordance with PR Notice 2007-4. All of the language has been added verbatim from the aforementioned PR Notice. No other changes have been made to the label.

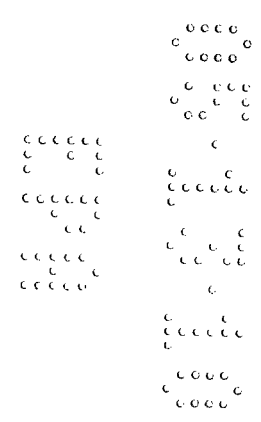
Please find enclosed the following documents to support this notification:

- 1) Pesticide Application Form;
- 2) One (1) copy of the proposed product label with the changes marked; and,
- 3) Three (3) copies of the proposed product label.

If you have any questions or comments, please contact me at 202-393-3903 ext. 16 or cswick@lewisharrison.com.

Sincerely,

Christina M. Swick
Agent for Celeste Industries Corporation



GLYCO-SAN
Disinfectant and Cleaner
For Use with Aircraft Drinking Water Systems

<u>Active Ingredient</u>	
L-Lactic Acid.....	12.0%
<u>Inert Ingredients</u>	88.0%
Total	100.0%

NOTIFICATION
Date Reviewed: 6/10/10
Reviewed By: K. Swift

KEEP OUT OF REACH OF CHILDREN
CAUTION

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. Call a poison control center or doctor for treatment advice.

If on skin: 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.

Hot Line Number

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.

EPA Reg. No. 42048-1
EPA Est. No. 42048-MD-001

Net Weight: [32 fl. oz. (946 mL)] [1 US Gallon (3.78 Litres)] [5 US Gallon (18.93 Litres)] [55 US Gallon (207.9 Litres)]

Manufactured By: Celeste Industries Corporation, 8221 Teal Drive, Suite 405, Easton, MD 21601

Precautionary Statements

Hazards to Humans and Domestic Animals

Caution. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear protective eyewear and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

Environmental Hazards

[If container size is 5 gallons or greater the following statement will be used:]

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.

Directions for Use

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

Use Glyco-San to disinfectant on-board potable water storage tanks and components associated with these tanks such as pipes, plumbing fixtures, aircraft water trucks and carts, and hoses. Glyco-San is an effective disinfectant against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708) and *Escherichia coli* (ATCC 11229).

Application Instructions:

Prior to disinfection, pre-clean water storage tanks and associated components with Glyco-San by preparing a use-solution consisting of 1 part Glyco-San to 3 parts of water (1:4). Prepare the Glyco-San cleaning solution by either pumping the appropriate amount of water into the water storage tank or system followed by Glyco-San addition, or by making up the Glyco-San cleaning solution in a tank, drum or water cart and then pumping the Glyco-San cleaning solution into the potable water tank. Pre-clean for a minimum of 30 minutes and, when necessary, up to 4 hours. After the pre-cleaning period is completed, thoroughly rinse the storage tank and associated components with potable water.

To disinfectant, prepare a use-solution of 1 part of Glyco-San to 7 parts of water (1:8) by either pumping the appropriate amount of water into the potable water tank followed by Glyco-San addition, or by making up the Glyco-San disinfectant solution in a tank, drum or water cart and then pumping the disinfectant use-solution into the potable water tank. After the disinfectant use-solution has filled the potable water tank, flush through the potable water system for 1 minute by opening all taps, including the coffee maker and vacuum toilets (where appropriate). This will allow the disinfectant use-solution to come into contact with all surfaces that contact potable water. Flush the lavatory 1-2 times. Allow the use-solution to soak in-place for at least 30 minutes and then flush to a sanitary sewer drain. Once drained, flush the potable water system with water to remove any traces of the disinfectant use-solution. In order to determine whether the system is completely flushed, half-fill a small jar with the rinse water, cap and shake. If the water in the jar DOES NOT FOAM, the system has been thoroughly flushed.

Glyco-San can also be use to disinfectant the aircraft coffee maker during shop cleaning. If heavily soiled, pre-clean the coffee maker with a suitable detergent or a 1:4 dilution of Glyco-San. To disinfectant, prepare a use-solution of 1 part of Glyco-San to 7 parts of water (1:8). Make a full pot of hot water using the Glyco-San use-solution and allow to soak in-place for at least 30 minutes. Continue to make pots of hot water using only tap water until hot water DOES NOT FOAM when shaken in a small, capped jar. Absence of foam indicates that the disinfectant solution has been flushed from the coffee maker.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry, well-ventilated area inaccessible to children. If leak or spill occurs – ventilate area of leak or spill. Remove all sources of ignition. Dilute with water and mop-up or absorb with an inert material (e.g., vermiculite, dry sand, earth) and place in a chemical waste container.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on-site or at an approved waste disposal facility.

[If container size is 5 gallons or less the following statement will be used:]

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or dispose of in a sanitary landfill.

[If container size is greater than 5 gallons the following statement will be used:]

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip the container on its side and roll it back and forth ~~several times~~, ensuring at least one complete revolution, for 30 seconds. Stand container on its end and tip 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 the procedure two more times. Then offer for recycling or dispose of in a sanitary landfill.

[Optional Marketing Language]

- Disinfectant for Potable Water Tanks
- For use in conjunction with EPA guidance for Aircraft Drinking Water
- Eliminates slimy buildup and removes scale.
- Kills bacteria in potable water tanks.