

US EPA ARCHIVE DOCUMENT

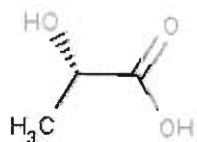


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

September 24, 2009

DP BARCODE: D362635
MRID: 476814-00, 476814-01, 476814-02
SUBJECT: Glyco-San
REG. NO. OR FILE SYMBOL: 42048-R
DOCUMENT TYPE: Product Chemistry Review
Manufacturing-use OR End-use Product
INGREDIENTS (PC Codes) L-Lactic acid (081407)



CAS Number: (79-33-4)
TEST LAB: Case Consulting Laboratories, Inc.
SUBMITTER: Celeste Industries Corporation
GUIDELINE: 830 Group "A & B"
COMMODITIES: Formulation
REVIEWER: Juan F. Negrón
ORGANIZATION: AD
APPROVER: Karen P. Hicks APPROVED DATE: 09/29/09
COMMENT:



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MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 42048-R.

From: Juan F. Negrón, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Sharon Carlisle / Stacey Grigsby
PM Team 34

APPLICANT: Celeste Industries Corporation
Action code: A500
Due date: 12/12/09

Product Formulation
Active Ingredient(s)

% by wt.

L-Lactic acid 12.0

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BACKGROUND:

On behalf of Celeste Industries Corporation, Lewis & Harrison has submitted an application for registration of a new end-use product, Glyco-San. This product is for use as a disinfectant for potable water supply use application in aircraft servicing. The product is produced by a non-integrated system. The registered product, Purac Sanilac (EPA Reg. No. 69132-1), is the source of the active ingredient.

The Product Chemistry Reviewer has received the following documents:

- A letter, dated 02/11/09.
- A label, dated 02/19/09 (pin punched).
- A study titled "Glyco-San, Product Identity and Composition; Description of Materials Used to Produce the Product and the Formulation Process; Discussion of Potential Impurity Formation; Preliminary Analysis; Certified Limits; Enforcement Analytical Method" (MRID 476814-01).
- A study titled "Physical and Chemical Characteristics of Glyco-San: Color, Physical State, Odor, pH, Viscosity and Relative Density" (MRID 476814-02).
- Certification with respect to citation of data, dated 02/11/09.
- Formulator's exemption statement, dated 02/11/09.
- Data matrix, dated 02/11/09.
- Confidential Statements of Formula (CSFs), dated 02/11/09 & 09/24/09, for the basic formulation.

FINDINGS:

1. Group "A" product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.1800 (Enforcement Analytical Method). See the "Recommendations" section of this report for deficiencies. See also Table A of this report.
2. The study assigned MRID 476814-01 appears to incorrectly identify proposed upper and lower certified limits for solvent. Limits identified on the CSF are assumed to be correct.
3. Group "B" product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics). See the "Recommendations" section of this report for deficiencies. See also Table B of this report.
4. A statement of Good Laboratory Practice (GLP) compliance was provided for the study assigned MRID 476814-02. The study was conducted in compliance with GLP standards set forth in 40 CFR Part 160.
5. The CSF, dated 02/11/09, for the basic formulation is obsolete.
6. The CSF, dated 09/24/09, for the basic formulation is revised.
7. The CSF and the label have the same nominal.

8. Certain information on the product label could be improved, as noted in the “Recommendations” section of this report.

CONCLUSIONS:

The CSF, dated 09/24/09, for the basic formulation is acceptable. The product chemistry package is acceptable, except for the storage stability and corrosion characteristic studies. The studies are currently in progress and will be made available to the Agency upon their completion.

RECOMMENDATIONS:

1. To satisfy OPPTS 830.1800 (Enforcement Analytical Method) the method must provide the following:
 - Section “1.0.” should provide to the analyst basic information on what to expect through out the assay.
 - A copy of the standardization for both chemicals mentioned in page 13 of 13 from the MRID #47681-01.
2. To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. The concentration of the active ingredient in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year. Storage and disposal information on the product label must be revised if product composition (or packaging) deteriorates over time. EPA Form 8570-1 (Application for Pesticide) indicates that the product container may be metal or plastic.
3. The following revisions to the product label are recommended:
 - a. Under the “Precautionary Statements” section of the product label, change “before eating, drinking, or using tobacco” to read “before eating, drinking, chewing gum, using tobacco, or using the toilet.”
 - b. Under the “Pesticide Storage” section of the product label, add instructions that specify what to do if the product leaks or spills from the product container.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAIs used registered? Yes [] No [X]
- Integrated formulation system []
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [x] No []

c. Physical state of product:

Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [] No [X]

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredient(s)

<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
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L-Lactic acid

12.0	11.4	12.6
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g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No []

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [] No [X]
- 1.0% or more of methyl alcohol: Yes [] No [X]
- sodium nitrite at any level: Yes [] No [X]
- a toxic List 1 inert at any level: Yes [] No [X]
- arsenic in any form: Yes [] No [X]

c. If “yes” to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [] No [] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label. Yes [] No [] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses. Yes [X] No []

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information). Yes [] No []

Note: Results for a minimum of 1 year from a GLP-compliant storage stability study must be provided.

**Table A:
Product Chemistry (830 Series, Group A)**

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	476814-01
830.1600 Description of Materials	A	476814-01
830.1620 Production Process ²	NR [<i>Not required for products produced by a non-integrated system.</i>]	
830.1650 Formulation Process ³	A	476814-01
830.1670 Formation of Impurities ⁴	A	476814-01
830.1700 Preliminary Analysis ⁵	NR [<i>Not required for products produced by a non-integrated system.</i>]	
830.1750 Certified Limits ⁶	A – Standard certified limits were proposed.	476814-01
830.1800 Analytical Method ⁷	U See recommendations	476814-01
830.1900 Submittal of Samples	[<i>Samples are to be provided on a case-by-case basis for end-use products.</i>]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product is clear at 22°C, based on visual inspection. CCL SOP 10.11 was referenced. Testing was conducted in compliance with GLP.	476814-02
830.6303 Physical State	A	The product is a liquid at 22°C, based on visual inspection. CCL SOP 10.12 was referenced. Testing was conducted in compliance with GLP.	476814-02
830.6304 Odor	A	The product has a sweet odor at 22°C. CCL SOP 10.13 was referenced. Testing was conducted in compliance with GLP.	476814-02
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	<i>[Not required for end-use products.]</i>	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	The product does not contain any oxidizing or reducing agents.	
830.6315 Flammability/Flame Extension	A	The product does not contain any flammable ingredients.	
830.6316 Explodability	A	The product does not contain any explosive ingredients.	
830.6317 Storage Stability	G	A storage stability study is currently underway. Results will be provided to EPA once the study is complete.	
830.6319 Miscibility ¹	A	The product is not to be diluted with petroleum solvents.	
830.6320 Corrosion Characteristics	G	A corrosion characteristics study is currently underway. Results will be provided to EPA once the study is complete.	
830.6321 Dielectric Breakdown Voltage	A	The product is not for use around electrical equipment.	
830.7000 pH ²	A	The pH of the product was reported to be 2.87 at 25°C. A 1% w/w mixture of the product in deionized water was tested. CCL SOP 10.17, which is based on ASTM E 70, was referenced. Testing was conducted	476814-02

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		in compliance with GLP.	
830.7050 UV/Visible Absorption	NR	[Not required for end-use products.]	
830.7100 Viscosity	A	The mean kinematic viscosity of the product was reported to be 1.36 mm ² /s at 23°C (as determined using an Ubbelohde viscometer). Two determinations were made. Testing was not conducted at another temperature (e.g., 20°C higher), although OPPTS 830.7100(d) notes that this is preferable. ASTM D445 and D446 were referenced. Testing was conducted in compliance with GLP.	476814-02
830.7200 Melting Point/Melting Range	NR	[Not required for end-use products.]	
830.7220 Boiling Point/Boiling Range	NR	[Not required for end-use products.]	
830.7300 Density/Relative Density/Bulk Density	A	The relative density of the product was reported to be 1.05 at 22°C. CCL SOP 10.16, which is based on ASTM D 891 Method B, was referenced. Testing was conducted in compliance with GLP.	476814-02
830.7370 Dissociation Constants in Water	NR	[Not required for end-use products.]	
830.7550/830.7560/830.7570 Partition Coefficient	NR	[Not required for end-use products.]	
830.7840/830.7860 Water Solubility	NR	[Not required for end-use products.]	
830.7950 Vapor Pressure	NR	[Not required for end-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid

²If product is dispersible with water