UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 3, 2009

MEMORANDUM

Subject: Efficacy Review for Glyco-San;
EPA Reg. No. 42048-R; DP Barcode: D362640

From: Marcie Tidd, Microbiologist
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8/3/09

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To: Sharon Carlisle, Acting PM 34 / Stacey Grigsby
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Applicant: Celeste Industries Corporation
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Formulation from the Label:

Active Ingredient(s)	% by wt.
L-Lactic Acid	12.0%
Other Ingredients	88.0%
Total	100.0%

I. BACKGROUND

The product, Glyco-San, is a new product. The applicant is submitting data to support the use of the product as a disinfectant in potable water supply use applications in aircraft servicing. Testing was conducted by ATS Labs located at 1285 Corporate Center Drive, Suite 110 in Eagan Minnesota.

The data package contained a letter from the applicant's representative to the Agency (dated February 11, 2009), the Confidential Statement of Formula, the Data Matrix, the proposed label (dated February 19, 2009), and two studies (MRID's 476814-09 and 476814-10) with Statements of No Data Confidentiality and Good Laboratory Practice for each.

II. USE DIRECTIONS

The product, Glyco-San, is intended for use as a cleaner and disinfectant for potable water supply use applications in aircraft servicing. Use directions vary by use site. To disinfect aircraft water trucks, water closet and line the directions indicate to mix one part of product to 3 parts water, let soak for 30 minutes to 4 hours, then rinse with potable water. To disinfect aircraft faucets, directions indicate to soak faucets undiluted for 30 minutes, then open taps to rinse. For on-board aircraft tanks, instructions indicate to mix one part product to 3 parts water and circulate through system for one minute. Soak for 30 minutes to 4 hours for maximum "cleaning." For on-board aircraft water tanks, disinfect with one part of product to 7 parts water, flush for one minute, and soak for 30 minutes. For aircraft coffee makers, mix one part product to 5 parts water and make a full pot. Continue to make pots of hot water until water does not foam when shaken.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

General or broad-spectrum Disinfectants for Use on Hard Surfaces
Claims of effectiveness as a "general disinfectant" or representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative bacteria. These claims must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella choleraesuis* ATCC 10708 (for effectiveness against Gram-negative bacteria) and *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria). [120 carriers per sample; a total of 360 carriers] To pass performance requirements, tests must result in killing in 59 out of each set of 60 carriers to give a 95% confidence level.

Aircraft Drinking Water Guidance
There are no efficacy guidelines developed specifically for the use of a disinfectant in these areas. Standards for broad spectrum disinfectants will be used, and EPA

Guidance for Aircraft Drinking Water will be referenced, as it is specifically mentioned on the product label.

Supplemental Recommendations
Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. SUMMARY OF SUBMITTED STUDIES

1. MRID 476814-09 "AOAC Use Dilution Method" against Glyco-San by Joy Salverda. Study conducted by ATS Labs, Laboratory Project Number A06835. Study completed October 21, 2008.
This test was conducted against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708) following ATS Labs protocol LEH09091508.UD.1 (included) according to AOAC Use-Dilution Tests, Official Methods of Analysis of the AOAC, 15th Edition (1990). Three lots of the product were tested (Lot Nos. 7317 (>60 days old), 8030, and 8163). Fetal bovine serum was added to the bacterial inoculum to achieve a 5% organic soil load. A 1:8 dilution of the test substance was prepared adding 160.0 mL of test substance to 1120 mL of filter sterilized tap water. Stainless steel penicylinders were placed into 48-54 hour old cultures (at a ratio of one penicylinder per one mL of inoculum). Carriers were dried for 40 minutes at 35-37C and 47% relative humidity then exposed to the test agent (10 mL per cylinder) for 30 minutes at 20.0C. Following exposure, carriers were transferred to individual tubes containing 10 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 then incubated for 46 hours at 35-37C. Subcultures were stored at 2-8C for approximately 2 days prior to examination. Cultures were evaluated visually for the presence or absence of growth. Subcultures showing growth were subcultured onto appropriate agar to determine the presence of the test organism. Controls included those for purity, neutralizer effectiveness, viability, sterility, and carrier population.

2. MRID 476814-10 "AOAC Use Dilution Method" against Glyco-San by Joy Salverda. Study conducted by ATS Labs, Laboratory Project Number A06836. Study completed October 21, 2008.

This test was conducted against *Escherichia coli* (ATCC 11229) following ATS Labs protocol LEH09091508.UD.2 (included) according to AOAC Use-Dilution Tests, Official Methods of Analysis of the AOAC, 15th Edition (1990). Two lots of the product were tested (Lot Nos. 8030 and 8163). Fetal bovine serum was added to the bacterial inoculum to achieve a 5% organic soil load. A 1:8 dilution of the test substance was prepared adding 15.0 mL of test substance to 105.0 mL of filter sterilized tap water. Stainless steel penicylinders were placed into 48-54 hour old cultures (at a ratio of one penicylinder per one mL of inoculum). Carriers were dried for 40 minutes at 35-37C and 41% relative humidity then exposed to the test agent (10 mL per cylinder) for 30 minutes at 19.0C. Following exposure, carriers were transferred to individual tubes containing 10 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 then incubated for 46 hours at 35-37C. Subcultures were stored at 2-8C for approximately 2 days prior to examination. Cultures were evaluated visually for the presence or absence of growth. Subcultures showing growth were subcultured onto appropriate agar to determine the presence of the test organism. Controls included those for purity, neutralizer effectiveness, viability, sterility, and carrier population.

V. RESULTS

MRID Number	Organism	Dried Carrier Count CFU/Carrier	No. Exhibiting Growth/Total No. Tested		
			Lot 7317	Lot 8030	Lot 8163
476814-09	*Staphylococcus aureus* ATCC 6538	2.03×10^7	0/60	1/60	0/60
	Salmonella enterica ATCC 10708	2.02×10^7	0/60	0/60	0/60
476814-10	*Escherichia coli* ATCC 11229	2.03×10^7	-	0/10	0/10

VI. CONCLUSIONS

1. The submitted data (MRID's 476814-09 and 476814-10) support the use of the product, Glyco-San, as a hard surface disinfectant with bactericidal activity against the following organisms at a 1:8 dilution in the presence of light organic soil at room temperature with a contact time of 30 minutes*. Adequate killing was demonstrated on all carriers per lot tested (at least 59/60 for *S. aureus and S. enterica*, and 10/10 for *E. coli*). Controls were acceptable for a valid test.

Staphylococcus aureus ATCC 6538
Salmonella enterica ATCC 10708
Escherichia coli ATCC 11229

*Note: A contact time of 30 minutes exceeds the 10 minute limit typically afforded to disinfectant products. This contact time will only be applicable to situations where surfaces are soaked with or submerged in the solution.

VII. RECOMMENDATIONS

1. The proposed label claims that the product are unacceptable regarding the use of the product, Glyco-San, as a **disinfectant** in the presence of moderate organic soil (5% serum) in at least a 1:8 (product to water) dilution with a contact time of 30 minutes on **hard, nonporous surfaces associated with aircraft drinking water**. The Agency is concerned about the use of the product in existing potable water systems were biofilm is ubiquitous. Additionally, the proposed contact time of 30 minutes to 4 hours extends beyond the 10 minute contact time associated with disinfection claims.

When the Agency's concerns have been adequately addressed, the following label modifications are required:

- Currently, several different dilutions and contact times are recommended for each use site. **Use directions need to be clarified such that one main dilution and contact time for disinfection is specified**. Understandably, each use site will require unique instructions, and additional time for cleaning or separate cleaning steps, along with heightened concentrations can be listed for each, following general instructions.

- **Directions for cleaning (buildup removal) and disinfection must be kept separate** and clearly marked.

- The product was only tested in moderate organic soil. These use sites can harbor grime/buildup/bioload prior to treatment. Therefore **an additional pre-cleaning step must be specified to remove gross soil if the surfaces are visibly soiled** (or believed to be, since this may not be verifiable in closed-tank or hose situations). The applicant has not submitted data to support the belief that increased concentrations and contact times will be efficacious in heavily soiled conditions.

- The section, "Aircraft coffee maker cleaner & disinfectant (in shop cleaning)" does not list a contact time. Surfaces will not be considered to be disinfected unless a 30 minute contact period occurs. The applicant must either add the 30 minute direction, or change the section to indicate cleaning only.

- The proposed label does not list the organisms against which the product was tested as a disinfectant. The label must list the following microorganisms: *Staphylococcus aureus, Salmonella enterica, Escherichia coli.*

- Page one of the label states that the product "Complies with EPA regulations for treatment of airline potable water. Follow EPA Guidance for Aircraft Drinking Water."

This statement is misleading as it implies that the Guidance sets standards for disinfectant products, or that products can comply with the Guidance, which is not the case. The Draft Technical Guidance Manual for the Proposed Aircraft Drinking Water Rule requires each aircraft water system to develop Operations and Maintenance Plans which include routine and corrective disinfection and flushing. This product is a disinfectant which may be used in the process. The applicant must change the statement to read, "For use in conjunction with EPA Guidance for Aircraft Drinking Water," or similar.