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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

January 21, 2010

DP BARCODE: 371360

MRID: #478898-01, 478898-02

SUBJECT: WC Complete

REG. NO. OR FILE SYMBOL: 64240-AL

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use **OR** **End-use Product**

INGREDIENTS (PC Codes) L-Lactic Acid (128929)

CAS Number: 79-33-4

TEST LAB: The Dial Corporation

SUBMITTER: Combat Insect Control Systems (registrant)
Lewis & Harrison (agent)

GUIDELINE: OPPTS Guideline Series 830 Group A and B

REVIEWER: Alex Traska

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 1/20/10

COMMENT: New Product Registration



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MEMORANDUM

Subject: Review of EPA Reg. No. 64240-AL

From: Alexander W. Traska, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

ct. 01/21/2010

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

To: ShaRon Carlisle/Stacey Grigsby PM #34(Acting)
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Combat Insect Control Systems
Action Code: (A540) New Product, Non-Fast Track
Due out date: 09 March 2010

Formulation from Label

<u>Active Ingredient(s)</u>	<u>.....% by wt.</u>
Lactic acid.....	4.0
<u>Other Ingredients</u>	<u>96.0</u>
Total	100.0

I BACKGROUND

This new product registration, covering the subject end-use product for use as a hard, non-porous surface disinfectant and sanitizer, was submitted by Lewis & Harrison on behalf of the registrant, Combat Insect Control Systems.

On behalf of Combat Insect Control Systems, Lewis & Harrison, LLC has submitted an application for registration of a new end-use product, **WC Complete**. The product is for use as a disinfectant (bactericide, virucide), sanitizer, mildewstat, and deodorizer on hard, non-porous surfaces in household, institutional, industrial, commercial, animal care, and hospital or medical environments. The data package included a Confidential Statement of Formula (CSF) for the basic formulation and a CSF for one alternate formulation. The product is produced by a non-integrated system. The following products are sources of the active ingredient: Purac Sanilac (EPA Reg. No. 69132-1; 80% active) and Purac 88-T (File Symbol 69132-E; 88% active).

The following documents were submitted and examined in the chemistry review of this new product application: agent's cover letter and transmittal document both dated October 14, 2009, new product pesticide application dated October 14, 2009, Formulator's Exemption Statement dated October 14, 2009, Certification with Respect to Citation of Data dated October 14, 2009, End-Use Data Matrix 10/14/09, proposed new Basic CSF dated October 14, 2009, proposed new Alternate Formulation #1 dated October 14, 2009, proposed new product label dated 10/14/09 and a Summary of the Physical/Chemical Properties (PR Notice 98-1) dated October 14, 2009. Also submitted was Group A product chemistry data under MRID # 478898-01 dated 9/16/09 and MRID # 478898-02 August 26, 2009 and Group B product chemistry data under MRID # 478898-01 dated 9/16/09.

A preliminary chemistry review of this new product registration was made by CSC Systems & Solutions LLC (CSS). All relevant comments from the November 24, 2009 CSC review was incorporated into this final Product Chemistry Review.

II FINDINGS

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient, lactic acid, given in the proposed Basic CSF and Alternate Formulation #1, both dated October 14, 2009, agreed with the percentage declared on the product label.
2. The upper and lower certified limits for both the active and inert ingredients, utilized in the proposed basic and alternate formulations, were acceptable.
3. The active ingredient sources are EPA registered. The inert ingredients utilized in the proposed formulations are acceptable for use in pesticide formulations.

4. The Group A product chemistry data requirements, applicable to end-use products have been met

5. The 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).

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.

A statement of Good Laboratory Practice (GLP) compliance was provided for the study assigned MRID 478898-01. Studies were carried out in accordance with EPA GLP standards (40 CFR 160).

Information reported in the study assigned MRID # 478898-01 was summarized on EPA Form 8570-36 (Summary of the Physical/Chemical Properties (PR Notice 98-1)).

6. The following revision to the product label is recommended:

- 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.

7. The following revision to the Data Matrix is recommended:

- Under the "Ingredients" box, change "Lactic Acit" to read "Lactic Acid."

III CONCLUSIONS

This new product registration, which requested approval to register the new end-use disinfectant and sanitizer, **WC Complete**, has partially met guideline requirements. The registrant is requested to address data gaps, comments and recommendations noted in the Findings.

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 []
- Integrated formulation system []
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inert ingredients for non-food or food use:

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

Note: All inert ingredients, with the exception of the fragrance, are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated on January 27, 2009 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

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 [X] No []

e. The NCs and CLs are acceptable. Yes [X] No []

f. Active ingredient(s)	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
Lactic acid	4.0	3.80	4.20

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: Storage stability studies are ongoing and have not been completed.

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

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	478898-01 and CSFs
830.1600 Description of Materials	A	478898-01
830.1620 Production Process ²	NA	
830.1650 Formulation Process ³	A	478898-01
830.1670 Formation of	A	478898-01

Data Requirements	Acceptance of Information	MRID No.
Impurities⁴		
830.1700 Preliminary Analysis ⁵	<i>[Not required for products produced by a non-integrated system.]</i>	
830.1750 Certified Limits ⁶	A – Standard certified limits were proposed. A – A signed certification statement was provided, as requested under OPPTS 830.1750(g).	478898-01
830.1800 Analytical Method ⁷	A – A copy of a validated HPLC method was provided for determining lactic acid content.	478898-01 and 478898-02
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 product is nearly white in color, based on visual inspection. A Munsell Color of N 9.25/ was reported. SOP1544 was referenced. Testing was conducted in compliance with GLP.	478898-01
830.6303 Physical State	A	The product is a liquid, based on visual inspection. Testing was conducted in compliance with GLP.	478898-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6304 Odor	A	The product has a pungent citrus odor. Testing was conducted in compliance with GLP.	478898-01
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	<i>[Not required for end-use products.]</i>	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	The product contains no oxidizing or reducing agents. Note: The product label includes a "Physical or Chemical Hazards" section, which instructs the user to not mix the product with chlorine bleach or other household chemicals.	478898-01
830.6315 Flammability/Flame Extension	A	The product is an aqueous-based system.	478898-01
830.6316 Explodability	A	The product contains no shock-sensitive materials.	478898-01
830.6317 Storage Stability	G	Data are being developed.	Data Matrix
830.6319 Miscibility ¹	A	The product is not meant for dilution.	478898-01
830.6320 Corrosion Characteristics	G	Data are being developed.	Data Matrix
830.6321 Dielectric Breakdown Voltage	A	The product is not intended for use around electrical equipment.	478898-01
830.7000 pH ²	A	The mean pH of the product is calculated to be 2.54. Three determinations were made. SOP1611 was referenced. Testing was conducted in compliance with GLP.	478898-01
830.7050 UV/Visible Absorption	NA	<i>[Not required for end-use products.]</i>	
830.7100 Viscosity	A	The mean viscosity of the product is calculated to be 4 cps at 24.8°C (as determined using a Brookfield viscometer). Three determinations were made. Testing was not conducted at another temperature (e.g., 20°C higher), although OPPTS	478898-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		830.7100(d) notes that this is preferable. SOP1543 was referenced. Testing was conducted in compliance with GLP.	
830.7200 Melting Point/Melting Range	NA	<i>[Not required for end-use products.]</i>	
830.7220 Boiling Point/Boiling Range	NA	<i>[Not required for end-use products.]</i>	
830.7300 Density/Relative Density/Bulk Density	A	The density of the product was reported to be 1.0125 g/mL. The specific gravity of the product was reported to be 1.0144. Three determinations were made. SOP1712 was referenced. Testing was conducted in compliance with GLP.	478898-01
830.7370 Dissociation Constants in Water	NA	<i>[Not required for end-use products.]</i>	
830.7550/830.7560/830.7570 Partition Coefficient	NA	<i>[Not required for end-use products.]</i>	
830.7840/830.7860 Water Solubility	NA	<i>[Not required for end-use products.]</i>	
830.7950 Vapor Pressure	NA	<i>[Not required for end-use products.]</i>	

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* 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