



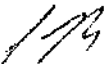
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460


OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

April 09, 2009

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 83315-E

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

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

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobial Division (7510P)

TO: Marshall Swindell / Shirley Madison
PM Team 33

Applicant: Sterisil, Inc.

Action code: A540
Due date: 05/17/09

Product Formulation
Active Ingredient(s):

% by wt.
Silver.....17.5



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DP BARCODE: D361824

MRID: None

SUBJECT: Sterisil Dental Water Microbiological Cartridge

REG. NO. 83315-E

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use OR End-use Product

INGREDIENTS (PC Codes) Silver (072501)
Ag

CAS Number: (7440-22-4)

TEST LAB: Evergreen Analytical, Inc.

SUBMITTER: Sterisil, Inc.

GUIDELINE: None.

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 04/09/09

COMMENT:

BACKGROUND:

The registrant, Sterisil, Inc., has submitted an application for registration of a new integrated end-use product, Sterisil Dental Water Microbiological Cartridge. This product is a technical grade product, contained in a filter-cartridge housing, for use in cleaning and maintaining dental unit water lines. The data package included a Confidential Statement of Formula (CSF) for the basic formulation (dated August 14, 2008). The product is produced by an integrated formulation system (i.e., the product contains an active ingredient that is not an EPA-registered product). The Product Chemistry Reviewer has received the following documents:

- Confidential Statement of Formula (CSF), dated 08/14/08, for the basic formulation.
- A study titled "Sterisil Silver Impregnated Resin Product Chemistry" (MRID 475124-01).
- A letter, dated 08/14/08, MRID # 475124-00.
- A label, dated 08/15/08 pin punched.
- Summary of the physical/chemical properties, dated 08/14/08 (EPA Form 8570-36).

FINDINGS:

1. The laboratory report describes studies conducted for the product, Sterisil Silver Impregnated Resin. It appears that this name is an alternate name for the product, Sterisil Dental Water Microbiological Cartridge.
2. Studies supporting Group B product chemistry data requirements were not provided in this data package. However, a summary of the physical/chemical properties (EPA Form 8570-36) was provided.
3. The reported density and pH on the CSF could not be confirmed with the studies.
4. The CSFs, dated 01/12/09, for the basic and alternate formulations are revised.
5. The CSF and the label have the same nominal.

CONCLUSION:

The CSFs, dated 01/12/09, for the basic and alternate formulations are acceptable. The product chemistry package is acceptable. Storage Stability and Corrosion Characteristic studies are in progress.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system []
- Are all TGAs used registered? Yes [] No []
- Integrated formulation system [X]
- 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 [] No [X]

c. Physical state of product:

Solid (resin)

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

Yes [] No [X]

Note: The density does not match with the document.

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredient(s)

	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
Silver	17.5	16.63	18.38

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 No

b. The formula contains one of the following:

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

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

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

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 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: Studies supporting Group B product chemistry data requirements were not provided in this data package.

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

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	475124-01
830.1600 Description of Materials	A	475124-01
830.1620 Production Process ²	A	475124-01
830.1650 Formulation Process ³	NA	
830.1670 Formation of Impurities ⁴	A	475124-01
830.1700 Preliminary Analysis ⁵	A	475124-01
830.1750 Certified Limits ⁶	A	475124-01
830.1800 Analytical Method ⁷	A	475124-01
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 TGA1 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	NR	[Not required for end-use products.]	
830.6303 Physical State	A	The product is a solid (resin).	
830.6304 Odor	NA	[Not required for end-use products.]	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	[Not required for end-use products.]	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	React with strong acids or divalent minerals.	
830.6315 Flammability/ Flame Extension	NA	The product is a solid.	
830.6316 Explodability	A	Formulation does not contains explosive components.	
830.6317 Storage Stability	G		
830.6319 Miscibility ¹	A	Resin insoluble in water, silver soluble to 0.6 ppm in distilled water.	
830.6320 Corrosion Characteristics	G		
830.6321 Dielectric Breakdown Voltage	A	Is not designed to be near electric outlet.	
830.7000 pH ²	A	6.8	
830.7050 UV/Visible Absorption	NR	[Not required for end-use products.]	
830.7100 Viscosity	NA	The product is a solid.	
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	1.2	
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.]	

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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