



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 10 2006

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Ms. Elizabeth A. Heger  
Regulatory Agent for,  
American Biotech Labs, LLC  
80 West Canyon Crest Road  
Alpine, Utah 84004

Mail to: Elizabeth A. Heger  
Keller and Heckman  
1001 G Street, NW  
Suite 500 West  
Washington, D.C. 20001

Subject: ASAP-AGX-32  
EPA Registration Number 73499-2  
Your Amendment Dated September 30<sup>th</sup>, 2005  
EPA Received Date October 24<sup>th</sup>, 2005

The amendment, submitted in connection with registration under the FIFRA sec. 3(c)(7)(A), to amend the product labeling by adding claims to control the odor in dental water unit lines (DUWL), is acceptable, provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec.3(c)(5) and sec.4 when the Agency requires all registrants of similar products to submit such data.

2. Submit two(2) copies of final printed labeling before you release the product for shipment.

Add some form of labeling to be attached to the dental unit chair reservoir to remind the dental technician to flush out the DUWL before the patients are examined/treated. This approach would likely eliminate, or minimize, exposure of dental patients to initial treatment solution.

The following statement should appear on some type of adhesive plaque which is attached to the side of the dental unit chair to read as follows:

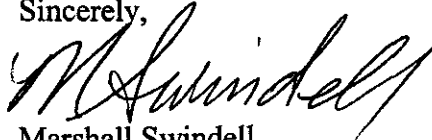
Remember to flush the dental water line unit each morning before patients are examined and treated.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division(7510C)

**ASAP-AGX-32**

Master Label

A Ready To Use Surface Disinfectant  
A Broad Spectrum Disinfectant  
A Hospital and Medical Disinfectant  
A Dental Unit Water Line Cleaner

Bactericidal – Disinfectant – Antimicrobial – Cleaner - Bacteriostat

ACCEPTED  
with COMMENTS  
EPA Letter Dated

Active Ingredient  
Silver.....0.0032%  
Inert Ingredients...99.9968%  
Total.....100.000%

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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

73499-2

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**

EPA Reg. No. 73499-2

EPA Establishment No. 073499-UT-001

Net Contents: 16.0 fluid ounces

**PRECAUTIONARY STATEMENTS**

Silver is toxic to fish and aquatic invertebrates. Chronic long-term ingestion of silver or silver salts may cause argyria.

Effective as a hard, non-porous surface disinfectant against the following microorganisms with 10-minute contact time:

- Gram negative bacteria, (i.e. *Salmonella choleraesuis*)
- Gram positive bacteria (i.e., *Staphylococcus aureus*)
- Nosocomial bacterial pathogen, *Pseudomonas aeruginosa*

Hard, Non-porous Surface Disinfectant Description

This product is a broad spectrum surface disinfectant and a hospital and medical environment disinfectant. This product is ready to use on hard, non-porous surfaces of inanimate objects. It is intended for use in commercial, residential, industrial, and medical settings. This product is not for use on food contact surfaces.

The product will be effective against gram negative bacteria (i.e., *Salmonella choleraesuis*), gram positive bacteria (i.e., *Staphylococcus aureus*), and nosocomial bacterial pathogen, *Pseudomonas aeruginosa*, with a 10-minute contact time when used as directed on hard, non-porous surfaces, including walls, urinals, floors, tables, chairs, light fixtures, and bathroom surfaces. This includes those surfaces made of glass, porcelain, metal, glazed ceramic, enameled, and painted surfaces.

Directions for Use

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

**DRAFT**

Application to disinfect the hard, non-porous surfaces in commercial, residential, industrial, and hospital and medical environments, listed on this label: Apply product by spray, mop, sponge or cloth to the pre-cleaned surface, thoroughly wetting the area to be disinfected. Surface must remain visibly wet for a full 10 minutes at 20 degrees C (68 degrees F). Follow by wiping surface using a clean paper or cloth towel. Discard used towel.

**Effective as a cleaner and a bacteriostat against odor-causing bacteria in dental unit water lines**

**Cleaner and Bacteriostat Description**

This product is a general purpose cleaner and bacteriostat against odor-causing bacteria for use in stand alone dental unit water line systems. As a cleaner at 22 ppm silver, ASAP-AGX-32 will remove odor-causing bacteria in the dental unit water lines. As a bacteriostat at 0.5 ppm silver, ASAP-AGX-32 will inhibit the regrowth of odor-causing bacteria. Efficacy of ASAP-AGX-32 as a cleaner and a bacteriostat may be affected by water quality used with solution.

**Directions for Use in Dental Unit Water Line as Initial Cleaner**

For initial cleaning of dental unit water line to remove odor-causing bacteria, drain system of all liquid. Empty 8 oz (or 1/2 bottle) of ASAP-AGX-32 into empty dental chair water bottle. Add 1/2 cup (4 oz or 0.12 L) of distilled or deionized water to dental chair water bottle to achieve a 22 ppm silver solution. Run all lines connected to the dental unit water bottle for approximately 5 minutes to ensure even distribution of ASAP-AGX-32 throughout the dental unit water line system. Allow product to remain in lines for at least 2 hours. Before chair use, completely drain ASAP-AGX-32 from dental unit chair reservoir, and prepare maintenance treatment (see below).

**Directions for Use in Dental Unit Water Lines as a Maintenance Treatment**

For maintenance of the dental unit water line to inhibit the regrowth of odor-causing bacteria, add 2 oz of ASAP-AGX-32 solution to 1 gallon (128 oz or 3.75 L) of distilled or deionized water to achieve a 0.5 ppm solution. Mix thoroughly. Fill drained dental chair water bottle to operating capacity. Store unused solution in a cool place out of direct sunlight. Run all lines connected to the dental unit water bottle for approximately 5 minutes to ensure even distribution of ASAP-AGX-32 throughout the dental unit water line system. Use continuously in dental water line systems with distilled or deionized water.

**Storage and Disposal of Unused Product**

Store in a cool place out of direct sunlight.

**Disposal of Unused Product**

Empty container by using product according to label directions.

**Container Disposal**

Discard empty container in trash collection.

ACCEPTED  
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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

73499-2

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October 18, 2005

Manufactured for:  
American Biotech Labs. LLC  
80 West Canyon Crest Road  
Alpine, UT 84004  
(801) 756-1000

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