

73499-2

10-10-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Keller and Heckman LLP
c/o American Biotech Laboratories, LLC
1001 G Street NW
Washington, DC 20001

OCT 10 2009

Attention: John Dubeck
Regulatory Manager

Subject: ASAP-AGX-32
EPA Reg. No. 73499-2
Application dated January 1, 2009

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Please submit two copies of your final printed labeling before you release the product for shipment. A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,


Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

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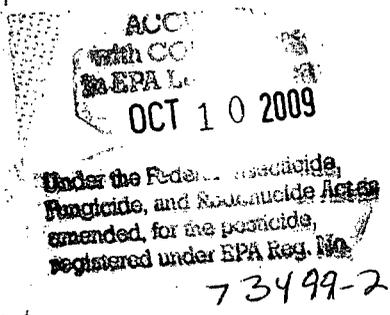
ASAP-AGX-32®

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

SilverSol Technology®

Bactericidal – Disinfectant – Antimicrobial – Cleaner – Bacteriostat

Active Ingredients	
Silver	0.0032%
Other Ingredients	99.9968%
Total	100.000%



CAUTION

KEEP OUT OF REACH OF CHILDREN

EPA Establishment No. 073499-UT-001
 EPA Reg. No. 73499-2
 Net Contents: _____

Manufactured for:
 American Biotech Labs, LLC
 80 West Canyon Crest Road
 Alpine, UT 84004
 (801) 756-1000
 E-mail: abl@americanbiotechlabs.com

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*, *Escherichia coli*; and *Klebsiella pneumoniae*)
- Gram positive bacteria (i.e., *Staphylococcus aureus* and *Streptococcus pyogenes*)
- Nosocomial bacterial pathogen, *Pseudomonas aeruginosa*
- Yeast (*Candida albicans*)
- Environmental Fungi, including black mold (*Stachybotrys chartarum*)

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 yeast (*Candida albicans*), gram negative bacteria (i.e., *Salmonella choleraesuis*, *Escherichia coli*, and *Klebsiella pneumoniae*), gram positive bacteria

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(i.e., *Staphylococcus aureus* and *Streptococcus pyogenes*), 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 as a Hard Surface Disinfectant

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

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. Add 8 oz. 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. Apply the **Reminder Card** to the chair to prevent use of the dental unit water line system while the cleaning dose is in the system. Allow product to remain in lines for at least 12 hours. Before chair use, completely drain ASAP-AGX-32 from dental unit chair reservoir and prepare maintenance treatment (see Maintenance Treatment section). **After initial cleaning, drain the reservoir and then fill it with the maintenance dose and flush dental hand-piece before using.**

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.

ACCEPTED
with COMMENTS
in EPA Letter Dated
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Fungicide, and Rodenticide Act as
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Storage and Disposal of Unused Product

Store in a cool place out of direct sunlight. Do not contaminate water, food, or feed by storage and disposal.

Disposal of Unused Product

Empty container by using product according to label directions.

Container Disposal

Discard empty container in trash collection.

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ASAP-AGX-32®

This text will be printed on a placard that will be placed on dental chairs when the cleaning dose is in the reservoir.

Placard language:

"Initial cleaning dose is in the dental unit reservoir.
Drain reservoir and fill with maintenance dose of ASAP AGX-32,
and flush dental hand piece."

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