

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1 of 13

PM 31

70871-1

10-13-98



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (M7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
70871-1

Date of Issuance:
OCT 13 1998

NOTICE OF PESTICIDE:
 X Registration
 Reregistration

Term of Issuance:
CONDITIONAL

(under FIFRA, as amended)

Name of Pesticide Product:
BioShield AM 500

Name and Address of Registrant (include ZIP Code):

BioShield Technologies, Inc.
4405 International Boulevard, Suite B 109
Norcross, GA 30093

Note: Changes in labeling differing in substance that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

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

2. Add the phrase EPA Registration Number "EPA Reg. No. 70871-1".

Signature of Approving Official:

Velma Noble

Velma Noble
Regulatory Management Branch 1
Antimicrobial Division (7510W)

Date:

OCT 13 1998

CONCURRENCES

SYMBOL	7510W						
SURNAME	<i>J. Lopez</i>						
DATE	10/9/98						

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3. This product has been registered as a microbiostatic agent for materials preservation only; neither this product, nor articles treated with this product, may state or imply any public health claims.

4. Articles or substances treated with this product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) only if the intended use for incorporating this material into the treated article or substance is for protection of the article or substance itself.

The following comments apply to the master label.

1. On page one, increase the font size of the signal word "WARNING".

2. On page one, revise the phrase "microbiostatic agent & protectant" to read as follows "microbiostatic agent".

3. On page two in the "Precautionary Statements" section, increase the font size of the signal word "WARNING" and change the statement which reads "Avoid contact with skin or clothing and avoid breathing vapor." to read as follows "Avoid contact with skin and avoid breathing vapor."

The following comments apply to the collateral label.

1. On page four in the "Directions for Use" section include the statement "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."

2. On page four in the "Precautionary Statements" section, increase the font size of the signal word "WARNING" and change the statement which reads "Avoid contact with skin or clothing and avoid breathing vapor." to read as follows "Avoid contact with skin and avoid breathing vapor."

3. On page five in the "Storage and Disposal" section the Pesticide Storage statement should begin as follows "Store in original, tightly closed containers below 30 C (86 F) and above 0 C (32 F) in a secure area inaccessible to children and away from food or feed. AM 500 has a minimum..."

4. The Agency suggests that your collateral label include a "Statement of Practical Treatment" which is in agreement with the master label.

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Refer to PR Notice 92-5 for Agency requirements regarding the Storage Stability study.

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 master label is enclosed for your records. Since the collateral label should remain in agreement with the master label, the Agency will not stamp the collateral label. Submit one (1) copy of the final printed label prior to the release of the product for shipment.

If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL	Enclosure						
SURNAME	7510W:T.Lantz:10/5/98:70871-1						
DATE							

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109
Norcross, GA 30093

BioShield AM 500

MICROBIOSTATIC AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt

Active Ingredient:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	5.0%
Inert Ingredients:	95.0%
TOTAL		
INGREDIENTS:	100.0%

**KEEP OUT OF REACH OF CHILDREN
WARNING**

Lot No. _____

EPA Reg. No. xxxx-xx

EPA EST. xxxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 0.5, 1, 5, 55, 150, or 300 gal.

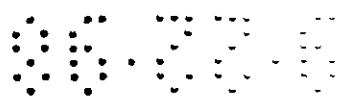
STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol.



ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 13 1998 OCT 13 1998

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Warning. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on clothing. Avoid contact with skin or clothing, and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation of AM 500 can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500.

DIRECTIONS FOR USE

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

Solutions can be prepared by simply adding AM 500 to solvent with stirring. AM 500 can also be diluted by adding 0.2 to 2 fluid ounces of AM 500 per cup (3.2 to 32 fluid ounces of AM 500 per gallon) of water or other solvents (for example, alcohol and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the microbiostatic agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

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APPROVED USES

The active ingredient in AM 500 is effective against fungi (including mold and mildew) and algae as a static agent.

AM 500 can be used for treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;

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- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed. AM 500 has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.



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COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109
Norcross, GA 30093

**Information About
Microbiostatic Agents:**

AM 500

U.S. Environmental Protection Agency Registration Number.....
 Type Silicone quaternary ammonium salt
 Physical Form Low-viscosity liquid
 Special Properties..... Surface bondability
 Primary Uses As a microbiostat for use on the sites detailed on page three of this collateral labeling to provide bacteriostatic, fungistatic, and mildewstatic activity

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications

Structure.....
$$\begin{array}{c} \text{CH}_3 \\ | \\ [(\text{CH}_3\text{O})_3\text{Si}(\text{CH}_2)_3\text{N}-\text{C}_{18}\text{H}_{37}]^+\text{Cl}^- \\ | \\ \text{CH}_3 \end{array}$$

 Concentration..... 5.0%
 Appearance..... Colorless Liquid
 Solubility..... Miscible in all proportions with water, ethanol, and methanol
 Thermal Stability °C (°F)..... Stable to 30°C (86°F)

Specification Writers: Please contact BioShield for information regarding specifications

DESCRIPTION

AM 500 is BioShield's designation for 3-(trimethoxysilyl)propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 offers users the following features:

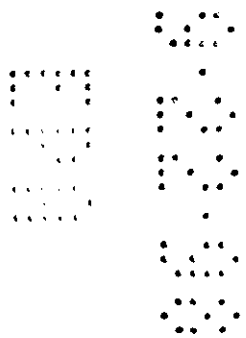
- Good durability—BIOSHIELD AM 500 imparts biostatic activity to the surface of a wide variety of substrates.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides freshness and combats deterioration caused by bacteria, fungi, and algae.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the microbiostatic agent AM 500 are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500 forms a coating on a wide variety of substrates and microbiostatic action is exhibited on contact.



APPROVED USES

The active ingredient in AM 500 is effective against fungi (including mold and mildew) and algae as a static agent.

AM 500 can be used for treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
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- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting of washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

DIRECTIONS FOR USE

Solutions can be prepared by simply adding AM 500 to solvent with stirring. AM 500 can be diluted by adding 0.2 to 2 fluid ounces of AM 500 per cup (3.2 to 32 fluid ounces of AM 500 per 1 gallon) of water or other solvents (for example, alcohol, and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the microbiostatic agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

PRECAUTIONARY STATEMENTS

Warning. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on clothing. Avoid contact with skin or clothing, and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

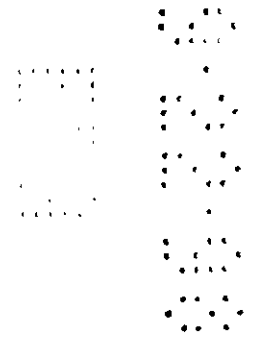
This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Inactivation of solutions containing AM 500 may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 in solution; or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500.

Every effort should be made to contain accidental spills of AM 500 to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.



STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 30°C (86°F) and above 0°C (32°F). AM 500 has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

REFERENCES

1. Hough, J.S. and Lyons, T.P. "Coupling of Enzymes Onto Microorganisms" *Nature*. London, 1972, 235: 389.
2. Johannsen, O.K., Stark, F.O., Vogel, G.E., and Fleischmann, R.M. "Evidence for Chemical Bond Formation at Silane Coupling Agent Interfaces." *J. Compos. Mater.*, 1967, 1:278-292.
3. Plueddemann, E.P. "Adhesion Through Silane Coupling Agents." *J. Adhesion*, 1970, 2:184-201.
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6. Isquith, A.J., Abbott, E.A., and Walters, P.A. "Surface-Bonded Antimicrobial Activity of an Organosilicon Quaternary Ammonium Chloride." *Appl. Microbiol.*, 1972, 24:859-863.
7. Gettings, R.L. and Triplett, B.L. "A New Durable Antimicrobial Finish for Textiles." *AATCC Book of Papers—1978 Nat. Tech. Conf.*, 1978, 259-261.
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16. Battice, D.R. and Hales, M.G. "A New Technology for Producing Stabilized Foams Having Antimicrobial Activity." *Journal of Cellular Plastics*, 1985, Vol. 21, Num. 5, 332-337.

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