

75497-8

3-11-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 11 2004

Mr. Timothy C. Moses  
President, Antimicrobials & Biocides Division  
Nova BioGenetics, Inc.  
8601 Dunwoody Pl., Suite 338  
Atlanta, GA 30350

SUBJECT: BioShield AM3651P  
EPA Registration Number: 75497-8  
Application Dated: December 8, 2003  
Receipt Date: December 16, 2003

Dear Mr. Timothy C. Moses:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below.

- Correct name of Active Ingredient as per Agency request

**Conditions**

1. The Agency has reviewed your justification and is in agreement that the name of the active ingredient does not require a change at this time.
2. In future submissions to the Agency, list all packaging sizes on the Application for Pesticide such that the application is in agreement with the label for this product.
3. Correct the percentage of "Other Ingredients" to read "48.40%" such that all percentages are carried out to the same decimal place.
4. On the final printed label, the skull and cross bones as well as the word "POISON" must appear in red ink on a contrasting background.

CONCURRENCES

SYMBOL	75100							
SURNAME	S. J. [Signature]							
DATE	3/9/04							

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5. Reorder the "First Aid" statements as on the last stamped label such that "IF SWALLOWED" precedes the "IF ON SKIN" statement.

6. Revise the "Precautionary Statements" by deleting the phrase "or fatal" such that the statement reads as follows: "...Harmful if swallowed or inhaled..."

7. Revise the first section in the "Directions for Use" by deleting "Dry treated areas and articles such as clothing before use." This statement does not agree with the use pattern for this product. Replace this statement with "Allow treated areas and surfaces to dry before use." as per the last stamped label.

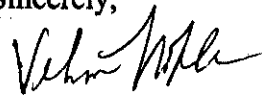
8. Revise the listing of surfaces to read as follows: "Exterior surfaces of appliances and refrigerators."

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

Enclosure: Stamped Label  
7510C:T.Lantz:3/9/04:75497-8a

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 11 2004

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 75497-8



**BIOSHIELD® AM 3651 P**  
**DISINFECTANT and ANTIMICROBIAL AGENT**  
A Silicone Quaternary Ammonium Salt

Active Ingredients:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	36.60%
	n-alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>10</sub> ) dimethyl benzyl ammonium chloride.....	6.40%
	Octyl decyl dimethyl ammonium chloride.....	4.80%
	Dioctyl dimethyl ammonium chloride.....	1.92%
	Didecyl dimethyl ammonium chloride.....	2.88%
Other Ingredients:	.....	48.4%
<b>TOTAL</b>	.....	<b>100.0%</b>
<b>INGREDIENTS:</b>	.....	
Contains over 6% methanol		

<b>EPA Reg. No. 75497-8</b>	<b>KEEP OUT OF REACH OF CHILDREN</b>	<b>EPA EST - XXXXX-GA-XX</b>
<b>DANGER &amp; POISON</b>		

**NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 1, 5, 55, 150, or 300 gal.** Lot No. \_\_\_\_\_

<b>FIRST AID</b>
Have the product container or label with you when calling the poison control center or doctor, or going for treatment.
<p><b>IF IN EYES:</b></p> <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>• Call poison control center or doctor for treatment advice.</li> </ul>
<p><b>IF INHALED:</b></p> <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<p><b>IF ON SKIN:</b></p> <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>IF SWALLOWED:</b></p> <ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> <li>• Methanol may cause blindness.</li> </ul> <p style="text-align: center;"><b>NOTE TO PHYSICIAN: Probably mucosal damage may contraindicate the use of gastric lavage.</b></p>

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**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER! Corrosive:** Methanol may cause blindness. Causes irreversible eye damage. Harmful or fatal if swallowed or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTABLE.** Do not use or store near heat or open flame. De-activation of AM 3651P can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of AM 3651P.

**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 may be required during clean up if a spill occurs. De-activation of AM 3651P can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of AM 3651P.

**DIRECTIONS FOR USE**

**For use in homes, offices, and institutions (schools, daycare centers, churches, correctional facilities)**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application

AM 3651P is an effective disinfectant against *Salmonella choleraesuis*, and *Staphylococcus aureus*. AM 3651P is also effective against odor causing bacteria, bacteria that causes staining and discoloration, fungi (mold and mildew) and algae as a static agent.

AM 3651P may be used for treatment of the following hard non porous surfaces to impart disinfection (*Salmonella choleraesuis* and *Staphylococcus aureus*), bacteriostatic/fungistatic/algaestatic, and deodorizing activity:

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	Pest controlled	Dilution Rate	Method of Application
<ul style="list-style-type: none"> <li>Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garage cans, appliances, refrigerators (exterior)</li> </ul>	Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), Salmonella choleraesuis, and Staphylococcus aureus	0.5 oz./gallon	<b>SPRAY:</b> Dilute AM 3651P in water; mix well. Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. <b>For Disinfecting:</b> Let stand for 10 minutes then wipe surface dry.

**MOLD, MILDEW, ODOR PROTECTOR, ODOR INHIBITOR, AND GERM KILLER**

AM 3651P is an antimicrobial agent effective against common household germs and helps prevent the spread of harmful germs on treated hard, non-porous surfaces in kitchen, bathroom, and household.

AM 3651P is an antimicrobial agent effective against microorganisms that cause offensive odors on hard, non-porous surfaces.

AM 3651P is an antimicrobial agent effective against odor causing bacteria and germs in the kitchen and bathroom.

AM 3651P is an antimicrobial agent effective in controlling mold and mildew, and inhibiting the growth of mold and mildew.

AM 3651P, an antimicrobial agent, disinfects hard, non-porous surfaces and kills *Salmonella choleraesuis*, and *Staphylococcus aureus*.

AM 3651P, an antimicrobial agent, can be used in and around bathtubs and showers stalls to prevent the growth of mold and mildew.

AM 3651P, provides an invisible barrier to inhibit the growth of odor causing bacteria.

AM 3651P, provides a invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

AM 3651P, provides a invisible barrier to inhibit the growth of fungi (mold and mildew).

AM 3651P, provides a invisible barrier to inhibit the growth of algae.

AM 3651P, prevents deterioration caused by bacteria and fungi (mold and mildew).

AM 3651P, resists development of microbial odors.

AM 3651P, resists development of stains and discoloration due to bacteria.

AM 3651P, resists development of stains due to fungi (mold and mildew).

AM 3651P, resists stains due to algae.

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**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.

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Containers 1 gallon or less:** Wastes resulting from the use of this product may be disposed of on site.

**Container Disposal:** (plastic) 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. (metal) Triple rinse(or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (glass) Triple rinse (or equivalent), then dispose of in a sanitary landfill or by approved State and local procedures.

**Containers 1 gallon or less:** Security wrap original container in several layers of newspaper and discard in trash.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING Nova BioGenetics Inc., 8601 Dunwoody Place, Suite 338, Atlanta, Georgia 30350, or by visiting our website: [www.novabiogenetics.com](http://www.novabiogenetics.com).

**IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION**

Nova BioGenetics 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.

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