

75497-2

03-03-2004

413

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR - 3 2004

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

SUBJECT: BioShield AM500 I
EPA Registration Number: 75497-2
Application Dated: December 1, 2003
Receipt Date: December 9, 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

A number of the label comments identified in the Notice of Registration for this product dated 10/13/98 have not been addressed. Make all the revisions listed below to the label for this product.

The following comments apply to the Master Label.

1. 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.
2. Revise the "Precautionary Statements" to include: "So not get in eyes or on clothing."

CONCURRENCES							
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SURNAME	J. Lark						
DATE	3/2/04						

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3. So that this label will be in agreement with other similar products already in the market place, add the following statements below the heading: "Directions for Use":

"For use in Formulating, Manufacturing, and Fabricating of Treated Article Products Specified under "approved uses."

AM 500 I may be used in materials that are incorporated into manufactured products listed on this label. The final article may contain from 0.1 to 1.0 % by weight active ingredient."

Add this same language to the collateral label.

4. Add the following two statements directly below the heading "Approved Uses"

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

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

5. Revise the use site beginning: "AM500 I can be used in paints and coatings as an in can preservative for..." by correcting the spelling of preservative. In addition, add this site to the collateral labeling of this product.

6. Add the following statements immediately prior to the Storage and Disposal statements such that this label agrees with the last stamped for this product:

"EPA REGISTRATION REQUIREMENTS:

The applications for which is product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products."

7. Make the following revisions to the "Storage and Disposal" statements:

A. Delete the bracketed information regarding homeowner use as this product is an MUP and not for sale to or use by homeowners.

B. Revise the Container Disposal statement to read exactly as follows such that the appropriate language is used for metal containers: "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."

The following comments apply to the collateral label.

1. On the first page, revise the statement which begins as follows: "As an active ingredient for formulating microbiocides..." to read "As an active ingredient for formulating microbiostats..." as per the Registration Notice for this product.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2. In the description section of the labeling, revise the name of the active ingredient to be in agreement with that listed on the first panel of the Master Label.

3. Also in the description section of the labeling, correct the name of this product to read: *BioShield AM 500 I*.

4. Correct the wording in the fifth bullet under Benefits as follows: "...by resisting the growth of odor-causing *bacteria and imparts odor resistance*."

5. Revise to read "Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton..." by correcting the spelling of fiberfill and deleting the "etc."

6. Add the following site to the collateral labeling such that it is in agreement with the Master Label: "*Exterior walls (such as stone, concrete, brick)*"

7. Add the following clarification to the collateral label: "Polyurethane and cellulose foam for household, industrial and institutional sponges and mops."

8. Add the following statement to the Directions for Use as per the Registration Notice for this product: "*It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.*"

9. As per the Registration Notice for this product, revise the Precautionary Statements as follows: 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 "*Avoid contact with skin and avoid breathing vapor.*"

10. As per the Registration Notice for this product, revise the Storage and Disposal, Pesticide Storage statement to 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 and feed. AM 500 I has a..."

11. The Agency suggests that your collateral labeling include a "First Aid" statement which is in agreement with the Master Label for this product.

12. Correct the word "REFRENCES" to read "REFERENCES."

CONCURRENCES

SYMBOL								
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4/13

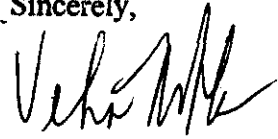
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

General Comments

A stamped copy of the accepted labeling, including technical bulletin, 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 & Technical Bulletin
7510C:T.Lantz:3/1/04:75497-2a

CONCURRENCES							
SYMBOL							
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DATE							



BIOSHIELD® AM 500 I
MICROBIOSTATIC AGENT
 A Silicone Quaternary Ammonium Salt
 (For Manufacturing Use Only)

ACCEPTED
 WITH COMMENTS
 In EPA Letter dated

MAR 3 2004

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

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

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KEEP OUT OF REACH OF CHILDREN

WARNING

EPA Reg. No. 75497-2

EPA EST. xxxxx-Ga-xxxx

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

Lot No.

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria.

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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. Avoid contact with skin and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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 may be required during clean up if a spill occurs. De-activation of AM 500I can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of AM 500I.

DIRECTIONS FOR USE

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

AM500I can be incorporated directly into formulations used to make the end products listed under "approved uses"

For formulating use into end use products.

Approved Uses

AM500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

- 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
- Exterior walls (such as stone, concrete, brick)
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
- Fiberglass ductboard
- Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Mens underwear and outerwear

Under the Federal
Pesticide Act
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- Non-woven disposable diapers
- Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- AM500I can be used in paints and coatings as an in can preservative for protection of paint film and coating film. Types of paints and coatings include : latex indoor/outdoor paints and stains, woodstains, architectural paints, laquer and maintenance coatings, films, laminates and finishes including alkyd, urethane, enamel, epoxy, siloxaline , amino resins, textile coatings, extrusion coatings, architural coatings and overlays, anti-corrosion coatings, fire-resistant coatings, aliphatic coatings, vinylester and polyester coatings, gel coatings, amino resins, resins used as additive mixes for cement, epoxy laminating resins, and blends and copolymers thereof;
- Polyurethane and cellulose 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, 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 or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
- Women's hosiery
- Women's intimate apparel

ACCEPTED
WITH COMMENTS
In EPA Register Label:
MAR 3 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by the Pesticide
Control Act of 1972, under EPA Reg. No.

75497-2

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: 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 homeowner use statement will read: "Container Disposal: Securely 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 obtain from our website 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 SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY

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MAR 3 2004

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

75497-2



Collateral Labeling

NovaBioGenetics Inc.
8601 Dunwoody Place, Suite 338
Atlanta, GA 30350

Information About

Microbiostatic Agents

AM500 I- FOR MANUFACTURING USE ONLY

U.S. Environmental Protection

Agency Registration Number.....75497-2
 Type.....Silicone quaternary ammonium salt
 Physical Form.....Low-viscosity liquid
 Special Properties.....Surface bond ability
 Primary Uses.....As an active ingredient for
 Formulating microbiocides for use in laundry additives,
 Carpet treatment products, upholstery and
 Drapery treatment products to give a
 Bacteriostatic, fungistatic, 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 StabilityStable to 230C

REGISTERED
 PESTICIDE
 OTHER DATA:
 MAR 3 2004
 General Insecticide,
 and Rodenticide Act as
 the pesticide,
 under EPA Reg. No.

75497-2

Specification Writers: Please contact NovaBioGenetics for information regarding specifications

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DESCRIPTION

AM500 I is NovaBioGenetics field's designation for 3-(trimethoxysilyl) propyloctdimethyl 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).

AM500 I offers users the following features:

- Good durability - NOVABIOGENETICS AM500 I imparts biostatic activity to the surface of a wide variety of substrates
- Increased efficiency-through proper application, durable bacteriostatic, fungi static and algistatic surfaces can be attained with a minimum amount of AM500I.

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 an 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 growth and imparts odor resistance.
- Product performance with little degradation up to 375 F

Materials treated with formulations containing the microbiostatics agent AM500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM500 I inhibit 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. AM500 I forms a coating on a wide variety of substrates and microbiostatic action is exhibited on contact.

ACCEPTED
with COMMENTS
in EPI Letter

MAR 3 2004

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

75497-2

APPROVED USES

AM500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

The active ingredient in AM500 I is an effective agent against fungi (including mold and mildew) and algae as a static agent.

AM500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculation air handling systems;
- Air filters/materials;
- Aquarium filter materials;
- Bed sheets, blankets, and bedspreads;
- Buffer pads(abrasive and polishing);
- Carpets and draperies;

- Fiberfil led for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fire hose fabric;
- Fiberglass duct board;
- 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 Air float Systems;
- Polyurethane foam for household, industrial, and instructional 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;
- Sandbags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, and 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, polyolefin's, 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 or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery;
- Women's imitate apparel.

REGISTERED
 WITH THE U.S. ENVIRONMENTAL PROTECTION AGENCY
 in Full Accordance with
 MAR 3 2004

DIRECTIONS FOR USE

AM500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

PRECAUTIONARY STATEMENTS

Warning Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or 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 contained clothing and wash clothing before reuse.

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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 AM500 I may be accomplished by one of the following methods:

- Addition of an anionic surfactant or detergent in quantity equivalent to that of AM500 I in solution;
- 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 AM500 I.

Every effort should be made to contain accidental spills of AM500 I 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 3 C (86 F) and above 0 C (32 F). AM500 I have minimum shelf life of 12 months from the date of shipment from NovaBioGenetics

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

ACCEPTED
WITH COMMENTS
in EPA Letter Dated:

MAR 3 2004

Container Disposal: [plastic] Triple rinse (or equivalent). Then offer for recycling or recondition, 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.

75497-2

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

Nova Biogenetics 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.

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

REFERENCES

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2. Johancs, O.K., Stark, F.O., Voguel, G.E., and Fleischmann, R.M. "Evidence for Chemical Bond Formation at Silane Coupling Agent Interfaces." J. Compos. Mater. 1967,1:278-292.
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15. Hales, M.G. and White, W.C. "Antimicrobial Treatments, Part 3: Methods for Determining Their Effectiveness." Cleaning and Restoration", 1986. May, 18-20.
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.

NovaBioGenetics Inc.
 8601 Dunwoody Place. Suite 338
 Atlanta, GA 30350

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
 MAR 3 2004

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

75497-2