

75318-7

6/06/2006

Page 1812

Amy Plato Roberts  
for B2E Biotech, LLC  
Technology Sciences Group  
1150 18<sup>th</sup> Street, NW, Suite 1000  
Washington, DC 20036

JUN 06 2006  
794176 | 332  
-----  
1285

RE: Product Name: B2E-07  
EPA Reg. No: 75318-7  
Application for Notification Dated: 13 Apr 2006

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received, but not reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mari Duggard at 703-308-0028 or email at [duggard.mari@epa.gov](mailto:duggard.mari@epa.gov).

Sincerely,

*Sheryl K. Reilly*

Sheryl K. Reilly, Ph.D.  
Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division

CONCURRENCES

SYMBOL	▶ 7511P							
SURNAME	▶ DUGGARD							
DATE	▶ 6 JUN 06							

2 8 12

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95

 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input checked="" type="checkbox"/> <b>Other</b>	OPP Identifier Number.
--	---	------------------------

**Application for Pesticide - Section I**

<b>1. Company/Product Number</b> 75318-7	<b>2. EPA Product Manager</b> Sheryl Reilly	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> B2E-07	<b>PM#</b> 91/Biochemical Pesticides Br/BPPD	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> B2E Biotech LLC 3030 Noyac Road, Bldg. D-2 Sag Harbor, NY 11963 <input type="checkbox"/> Check if this is a new address	<b>6. Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This notification is to add two alternate brand names per PR Notice 98-10 and is not subject to PRIA. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling of the Confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section - III**

**1. Material This Product Will Be Packaged In:**

<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>2. Type of Container</b> <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
<b>* Certification must be submitted</b> If "Yes" Unit Packaging wgt.    No. per container		If "Yes" Package wgt    No. per container	

**3. Location of Net Contents Information**  
 Label     Container

**4. Size(s) Retail Container**

**5. Location of Label Directions**

**6. Manner in Which Label is Affixed to Product**  
 Lithograph     Other \_\_\_\_\_  
 Paper glued     Stenciled

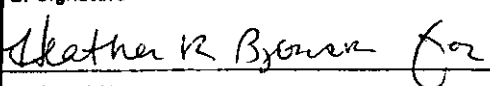
**Section - IV**

**1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)**

<b>Name</b> Amy Plato Roberts / aroberts@tsgusa.com	<b>Title</b> Regulatory Consultant	<b>Telephone No. (Include Area Code)</b> 202. 828-8964
--	---------------------------------------	---

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

<b>2. Signature</b> 	<b>3. Title</b> Regulatory Consultant to B2E LLC	<b>6. Date Application Received (Stamped)</b>
<b>4. Typed Name</b> Amy Plato Roberts	<b>5. Date</b> April 13, 2006	

3 8 12



**WASHINGTON**

1150 18th Street, N.W.  
Suite 1000  
Washington, D.C. 20036  
Telephone 202 223-4392  
Fax 202 872-0745

Sheryl Reilly  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511C)  
Office of Pesticide Programs, EPA  
1801 South Bell Street  
Arlington, VA 22202

April 13, 2006

**RE: B2E-07 (EPA Reg. No. 75318-7)**

**Notification to add alternate brand names per PR Notice 98-10**

**SACRAMENTO**

712 Fifth Street  
Suite A  
Davis, CA 95616  
Telephone 530 757-1298  
Fax 530 757-1299

Dear Dr Reilly:

Technology Sciences Group Inc., on behalf of B2E Biotech LLC, is submitting the enclosed notification to add two alternate brand names to the above referenced product.

You will find the following in support of this notification:

- 1) Application form;
- 2) One (1) copy of the redline label; and
- 3) Three (3) copies of the product label with the changes incorporated.

Please do not hesitate to contact me directly with any questions.

**CANADA**

275 Slater Street  
Suite 900  
Ottawa, Ontario  
K1P 5H9  
Telephone 613 247-6285  
Fax 613 236-3754

Sincerely,

Amy Plato Roberts  
Regulatory Consultant for B2E Biotech LLC  
Direct dial: (202) 828-8964; E-mail: [aroberts@tsgusa.com](mailto:aroberts@tsgusa.com)

cc: Dave Sjogren, B2E Biotech LLC

4 7 12

NOTIFICATION, Received,

~~Date~~ <sup>NOT</sup> Reviewed: 6 Jun 06

Reviewed By: m. Duggard

**B2E-07  
MASTER LABEL**

[Alternate Brand Names: Aquaprene XL Granules, Ultraprene Granules]

**Sublabel A: Commercial Use – Mosquitoes  
Sublabel B: Residential Use – Mosquitoes  
Sublabel C: Commercial Use – Filter Flies & Non-biting Midges  
Optional Label Claims**

**ACTIVE INGREDIENT:**  
(S)-Methoprene (CAS #65733-16-6)..... 2.8%  
**OTHER INGREDIENTS:**..... 97.2%  
**TOTAL:**..... 100.0%

EPA Reg No. 75318-7  
EPA Est. No.

NET CONTENTS: \_\_\_\_\_

**KEEP OUT OF REACH OF CHILDREN  
CAUTION  
See (back panel) (side panel) (insert label) for additional precautionary  
statements**

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

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

<b>FIRST AID</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>o Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>o Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>o Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin</b>	<ul style="list-style-type: none"> <li>o Take off contaminated clothing.</li> <li>o Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>o Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>o Call a poison control center or doctor immediately for treatment advice</li> <li>o Have person sip a glass of water if able to swallow.</li> <li>o Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>o Do not give anything by mouth to an unconscious person.</li> </ul>
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-XXX-XXX-XXXX for emergency medical treatment information.</p>	

**ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of equipment washwaters or rinsate.

## Sublabel A: Commercial Use – Mosquitoes

**[Alternate Brand Names: Aquaprene XL Granules, Ultraprene Granules]**

### INTRODUCTION

**B2E-07** releases effective levels of S-Methoprene insect growth regulator for up to 35 days in mosquito breeding sites. Apply **B2E-07** prior to flooding (i.e. "pre-hatch") in known mosquito breeding areas, or post-hatch to sites containing mosquito larvae. Treated larvae will continue to develop normally to the pupal stage where they die. **B2E-07** prevents the emergence of adult mosquitoes from treated sites.

### DIRECTIONS FOR USE

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

### APPLICATION DIRECTIONS

Apply **B2E-07** to mosquito breeding at any time during the mosquito season. **B2E-07** is effective on 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and early 4<sup>th</sup> instar larval mosquitoes to prevent adult emergence. Under typical environmental conditions, one application will control for up to 35 days in water depths up to 6 inches. Continue treatments at regular intervals throughout the mosquito season.

Apply **B2E-07** prior to flooding (i.e. "pre-hatch") to known breeding sites that flood intermittently. In such areas, one application of **B2E-07** prevents adult mosquito emergence for several subsequent floodings. The actual length of control depends on the duration and frequency of flooding events.

Apply the granules in the lowest areas of each site to maintain continuous control as the site alternately floods and dries. Alternate wetting and drying will not reduce granule effectiveness.

**NOTE:** The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

### APPLICATION RATES

*Aedes, Ochlerotatus, Anopheles and Psorophora spp.*

Apply **B2E-07** at 2.5 – 5.0 lbs per acre.

### APPLICATION SITES

Apply **B2E-07** pre-hatch or post-hatch as directed above to temporary and permanent water sites which support mosquito larval development. Examples of typical sites are: freshwater and salt water marshes, cattail marshes, woodland pools and meadows, grassy swales, floodplains, irrigated croplands, pastures and rangeland, vineyards, rice fields (including wild rice), fruit and nut orchards, berry fields and bogs, water hyacinth beds, vegetation-choked phosphate pits, dredge spoil sites, storm drains, retention and detention ponds, drainage areas, roadside ditches, tree holes, log decks, tires, water-holding receptacles, and other natural and manmade depressions where mosquitoes may breed.

**NOTE:** Application of **B2E-07** to sites subject to water flow or exchange will diminish the product's effectiveness.

### STORAGE AND DISPOSAL

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

#### PESTICIDE STORAGE

Store in a cool, dry place.

#### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

#### CONTAINER DISPOSAL

Completely empty bag. Then dispose of empty bag in trash. Do not reuse container.

6 7 12

## **WARRANTY AND CONDITIONS OF SALE**

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. To the fullest extent permitted by law, buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Always read the label before using this product.

For information, call 1-XXX-XXX-XXXX or visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

**B2E Biotech LLC**  
**Sag Harbor, NY U.S.A.**

## Sublabel B: Residential Use – Mosquitoes

**[Alternate Brand Names: Aquaprene XL Granules, Ultraprene Granules]**

### DIRECTIONS FOR USE

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

### INTRODUCTION

**B2E-07**s an easy and effective way to kill developing mosquitoes in standing water before they become biting adults. Adult mosquitoes are both a nuisance and a serious health threat transmitting West Nile Virus and other viruses that can cause encephalitis in both people and pets. They may also transmit heartworm to dogs and cats. **B2E-07** slowly and continuously releases an Insect Growth Regulator into the water to prevent adult mosquito development for up to [35 days][4 weeks][1 month]. Mosquito larvae exposed to treated water will die in the pupal stage before they reach adulthood.

### HOW TO APPLY

Apply **B2E-07** to standing water where mosquitoes breed. One scoop (included) treats 200 square feet (10 feet x 20 feet) of water surface. **B2E-07** offers long-lasting mosquito control for up to 35 days in water up to 6 inches. **B2E-07** will not adversely affect humans, animals, fish or vegetation when used as directed.

Amount of Product (Scoop provided in container)	Treatment Surface Area
½ scoop	up to 100 Square Feet
1 scoop	up to 200 Square Feet
1 ½ scoops	up to 300 Square Feet
2 scoops	up to 400 Square Feet
3 scoops	up to 600 Square Feet

Do not use measuring scoop for food purposes after use.

### APPLICATION SITES

**B2E-07** controls mosquitoes in water holding receptacles and standing water sites around your home. Apply **B2E-07** as a preventative measure to mosquito breeding sites before they fill with water. Also use **B2E-07** in sites that intermittently fill with water. The active ingredient is released when in contact with water, and will remain effective for up to [35 days][4 weeks][1 month]. Do not apply to waters that drain into public waterways such as lakes or streams.

Examples of application sites include, but are not limited to:

Bird Baths	Roof Gutters	Animal Watering Troughs
Ornamental Fountains	Old Tires	Man-made depressions
Ornamental fish ponds	Tree Holes	Other water holding
Flower Pots or planters	Pool Covers	containers
Urns	Unused Swimming Pools or	
Rain Barrels	Spas	

### APPLICATION TIMING

For best results, apply **B2E-07** before the beginning of the mosquito season, and reapply every 35 days throughout the entire mosquito season.

8 8 12

### **STORAGE AND DISPOSAL**

**Storage:** Store closed containers of B2E-07 in a cool dry place. **Disposal: If empty:** Do not reuse this container. Place in trash or offer for recycling if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

### **WARRANTY AND CONDITIONS OF SALE**

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. To the fullest extent permitted by law, buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Always read the label before using this product.

For information, call 1-XXX-XXX-XXXX or visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

**B2E Biotech LLC**  
**Sag Harbor, NY U.S.A.**



9 7 12

**Sublabel C: Commercial Use – Filter Flies & Non-biting Midges**

[Alternate Brand Names: Aquaprene XL Granules, Ultraprene Granules]

**INTRODUCTION**

B2E-07 is a unique product that controls filter flies (*Psychodidae*) and midges (*Chironomidae*) infesting waste water treatment facilities and aquatic habitats. B2E-07 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-07 does not control adults but prevents the larval stage from developing into flying adults. For best results, maintain regular treatment of pest populations to prevent the development of nuisance fly levels.

**DIRECTIONS FOR USE**

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

**GENERAL DIRECTIONS**

B2E-07 releases effective levels of an Insect Growth Regulator for up to 35 days under typical environmental conditions. Continue treatments on regular intervals through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die. **NOTE:** This insect growth regulator has no effect on midges or filter flies that have reached the pupal or adult stage prior to treatment.

**APPLICATION SITES AND RATES**

MIDGE HABITAT	RATES (LB/ACRE)
Midge larvae occur in permanent and temporary natural and manmade aquatic habitats. Examples include ponds, natural and man made lakes, golf course water hazards, homeowner association lakes and ponds. Apply granules uniformly to the water surface. Repeat application as necessary.	2.5 - 5 lbs.
FILTER FLY HABITAT	RATES (LB/ACRE)
Filter flies are waste water treatment pests that inhabit sludge drying beds, clarifiers, holding tanks or ponds, sewage lagoons, evaporation ponds, paper or food waste ponds, stagnant or standing water, or other standing wastewater treatment areas where midges, filter flies, and other nuisance aquatic insect pests are a problem.	2.5 - 5 lbs.

Within these ranges, use lower rates when water is shallow (<2 ft) and vegetation and/or organic matter is minimal. Use higher rates when water is deep (>2 ft) and when vegetation and/or organic matter is heavy. Application of B2E-07 to sites subject to water flow or exchange will diminish the product's effectiveness and require higher application rates and/or more frequent applications.

**APPLICATION METHODS**

**MIDGES**

Apply B2E-07 Granules up to 15 days prior to flooding, or at any stage of larval development. Use fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 5 lbs/acre to apply B2E-07. The granules can also be applied using ground equipment, such hand or motorized spreaders and backpack blowers that will deliver the above rates. Even coverage over the water surface will provide best product performance.

**FOOD AND PAPER PROCESSING PLANTS**

To prevent food and paper contamination by aquatic midges and filter flies, identify all water holding areas that can breed these insects such as waste water ponds, sewage lagoons, food waste ponds, floor drains, catch basins, sludge drying beds, etc. Treat all potential breeding areas. Place particular emphasis on treating all highly organic water areas.

**WASTE WATER NUISANCE PESTS**

To control waste solids areas, such as sludge and retention ponds, apply an initial rate of 5 lbs/acre. Uniformly apply B2E-07 to the surface of sludge drying beds immediately after filling to prevent midge and

10 7 12

filter fly emergence. Application of **B2E-07** to solids will prevent the emergence of adult insect pests thereby keeping infestations under control. For applications in aquatic habitats, including waste water treatment facilities, evaporation ponds, sewage lagoons, manure runoff areas, retention ponds, and holding tanks, apply the granules as uniformly as possible over the pond surface. When the ponds are large, make applications as a 20-40 foot perimeter band out from the pond bank using the highest rate.

**WHAT TO EXPECT IN WASTE WATER FACILITIES**

A gradual reduction in the number of adult pests will be seen over a 7-10 days period after initial applications of **B2E-07**. Reduction in adult populations will be noticeable within 14 days following the application. Due to varying conditions such as heavy infestations or cool temperatures, the period required to achieve control can be longer.

**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE**

Store in a cool, dry place.

**PESTICIDE DISPOSAL**

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL**

Completely empty bag. Then dispose of empty bag in trash. Do not reuse container.

**WARRANTY AND CONDITIONS OF SALE**

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. To the fullest extent permitted by law, buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Always read the label before using this product.

For information, call 1-XXX-XXX-XXXX or visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

**B2E Biotech LLC**  
**Sag Harbor, NY U.S.A.**

<b>OPTIONAL LABEL CLAIMS</b>
------------------------------

- An Insect Growth Regulator to prevent the emergence of [adult] mosquitoes.
- An Insect Growth Regulator to prevent the emergence of [adult][nuisance] filter flies and midges.
- A sustained release granular product – prevents adult mosquito emergence for up to 35 days [(including those which may transmit West Nile Virus)].
- A controlled [sustained] release granule that prevents adult mosquito emergence [(including those which may transmit West Nile Virus)].
- Prevents Adult Mosquito Emergence (including those which (may) transmit West Nile Virus).
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) (before they hatch) including those which may (can) transmit (carry) West Nile Virus (and encephalitis) (and equine encephalitis).
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) before they become breeding, biting adults, including those which may (can) transmit (carry) West Nile Virus (and encephalitis) (and equine encephalitis).
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) (before they hatch) including those which may (can) transmit [West Nile virus] [and heartworm disease] [and heartworm disease to dogs and cats].
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) (before they hatch) including those which may (can) transmit heartworm disease to dogs and cats.
- Just place in standing water.
- Won't harm humans, animals, fish or vegetation when used as directed.
- When used as directed, B2E-07 [will not][won't] harm humans, animals, fish or vegetation.
- Can be applied to areas that contain aquatic life, fish and plants.
- Kills mosquitoes in standing water where they breed.
- Mosquito Larvicide Granule.
- Mosquito Larvicide – [35 day][4 weeks][1 month] Protection.
- Concentrated Formula Treats Over 4,000 sq. ft. (0.5 lb container)
- Concentrated Formula Treats Over 8,000 sq. ft. (1.0 lb container)
- Concentrated Formula Treats Over 12,000 sq. ft. (1.5 lb container)
- Highly selective larvicide.
- Effectively reduces mosquito populations.
- Biochemical mosquito larvicide.
- A (highly selective) insect growth regulator effective against mosquitoes in a variety of habitats.
- Easy to use.
- Easy to apply granules.

12 8 12

- Will not float away.
- Won't discolor water.
- No unsightly debris.
- Quick, clean and simple to use.
- Prevents the development of adult mosquitoes.
- Prevents immature mosquitoes from developing into adults.
- Prevents emergence of breeding, biting adult mosquitoes.
- Prevents the development of mosquito larvae.
- Nothing to mix or spray.
- An alternative to chemical sprays.
- Treat (standing) water, avoid chemical sprays.
- Treat mosquitoes at the source.
- (Use) (Apply) in standing water (where mosquitoes may breed); see label for specific use sites.
- (Use) (Apply) in containerized or private standing water (where mosquitoes may breed); see label for specific use sites.
- Kills mosquito(es) [larvae] in [stagnant] standing water [before they are able to bite][where they breed]. Apply to standing [stagnant] water in your yard.
- For use in all water-holding receptacles [containers] where mosquitoes may breed including water gardens [and animal [horse] watering troughs]
- Sustained release larvicide for long term control of mosquito larvae.
- Mosquito Larvicide with [35 day][4 weeks][1 month] protection.
- [35 days][4 weeks][1 month] protection.
- Effective [controls][protects] for up to [35 days][4 weeks][1 month].
- A Sustained Release [35 day][4 week][1 month] Mosquito Larvicide Granule.
- Kills developing mosquito larvae.