

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 14 2006

Exosect Ltd.  
c/o Technology Sciences Group, Inc  
4061 North 156<sup>th</sup> Drive  
Goodyear, AZ 85338

Subject: Product Name: Exosex CM  
EPA Reg. No: 79442-1  
Application for Notification Dated: January 31, 2006

Dear Dr. Weatherston:

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 Andrew Bryceland at (703)305-6928 or email at bryceland.andrew@epa.gov.

Sincerely,

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

CONCURRENCES

SYMBOL	75116	75116						
SURNAME	Bryceland	Reilly						
DATE	4/11/06	4/14/06						



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

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

### Application for Pesticide - Section I

1. Company/Product Number 79442-1	2. EPA Product Manager Dr. Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Exosect Ltd. / EXOSEX CM	PM# <u>91</u>	
5. Name and Address of Applicant (Include ZIP Code) Exosect Ltd., 2 Venture Road Chilworth Science Park Southampton, SO16 7NP United Kingdom <input type="checkbox"/> Check if this is a new address	6. Expedited Review. 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 _____	<b>NOTIFICATION</b> <i>Received</i>
<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. Date <u>4/12/06</u>	

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

Minor label verbiage change regarding assembly instructions for an improved autoconfusion station, does not impact application nor directions for product use. This notification is consistent with the provisions of PRN 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or 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 PRN 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

*Not Reviewed ACP*

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Iain Weatherston	Title Senior Regulatory Consultant	Telephone No. (Includes Area Code) 623-535-4060
<b>Certification</b> 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.		6. Date Application Received <b>(Stamped)</b>
2. Signature <i>Iain Weatherston</i>	3. Title Senior Regulatory Consultant	
4. Typed Name Iain Weatherston	5. Date January 31, 2006	

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NOTIFICATION *Received*

Date ~~██████████~~ 4/12/06.

~~Reviewed By~~  
*Not Reviewed KB*

[Front panel]

# EXOSEX<sup>®</sup> CM

A novel pheromone product for the control of codling moth (*Cydia pomonella*)  
on apples, pears and walnuts

This package contains: 50 x high impact polystyrene autoconfusion stations  
50 x codling moth autoconfusion trays and pheromone lures  
(in sealed packet)

## AUTOCONFUSION TRAY

[Net Weight: 2.5 g of pheromone impregnated wax powder]

ACTIVE INGREDIENT		
E,E-8,10-Dodecadien-1-ol [CAS# 33956-49-9]		0.10%
OTHER INGREDIENT		99.90%
	Total	100.00%

## SEX PHEROMONE LURE

[Net Weight: 714 mg (1 mg of pheromone in a rubber septum)]

ACTIVE INGREDIENT		
E,E-8,10-Dodecadien-1-ol [CAS# 33956-49-9]		0.14%
OTHER INGREDIENT		99.86%
	Total	100.00%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 79442-1

EPA Est. No. 79442-GBR-1  
Date of manufacture: mm/dd/yyyy

EXOSECT LTD.  
2 Venture Road  
Chilworth Science Park  
Southampton SO16 7NP  
United Kingdom

[Back panels]

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

**CAUTION**

Harmful if inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid breathing dust, wear a dust mask, protective eyewear and gloves (appropriate for applying product). Remove contaminated clothing and wash before reuse. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

**FIRST AID**

**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 poison control center or doctor for treatment advice.

**IF IN EYES**

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

**IF ON SKIN OR CLOTHING**

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

Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 for emergency medical treatment advice.

**ENVIRONMENTAL HAZARDS**

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

**STORAGE AND DISPOSAL STATEMENTS**

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

- PESTICIDE STORAGE:** Store in unopened package at temperatures below 40°F. Do not open until ready to use.
- PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.
- CONTAINER DISPOSAL:** Dispose of in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of the smoke.

**DIRECTIONS FOR USE**

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

Use within six months of manufacture

Check front panel for date of manufacture.

Use experience with this product dictates a minimum treatment area of 7.5 acres

1. CROP: Apples, pears and walnuts
2. PEST: Codling moth [*Cydia pomonella*]
3. APPLICATION: Deploy Exosex Autoconfusion Stations at the rate of at least between 10 - 12 stations per acre. Place the stations as high in the trees as possible, but at least in the upper third of the canopy. Assemble the autoconfusion station by popping it into a delta shape (triangle cross section) and folding up one of the tray retaining flaps at one end of the station. Remove the plastic coverlid of the autoconfusion tray and slide it into the autoconfusion station so that the tab at the far end of the tray slots into the slot hole cut in the tray retaining flap which has been folded up. Then fold up the tray retaining flap at the open end of the autoconfusion station so that the tab at the near end of the tray slots into the slot hole cut in the tray retaining flap when folded up. The station is affixed to the tree with the provided ties which push-fit into the holes in the top ridge of the station.
4. TIMING: Deploy the stations prior to the onset of codling moth emergence in the spring (Biofix). The stations are active for an extended period of time, depending on the temperature. Make a second application prior to the emergence of the second moth flight but not later than August 1.
5. NOTES: If the treated orchard borders another orchard where codling moth is not controlled, migration of these moths can reduce the level of control achieved. To counteract this effect treat entire blocks of orchards and not just sections of conventionally treated areas. Double the number of stations along such borders in a strip of 4 - 6 rows of trees. Alternatively treat this strip with insecticide. Monitor the occurrence of codling moth in an orchard using weekly pheromone traps catches. If monitoring traps show an extremely high infestation in early spring, consider a pre-application treatment of insecticide. If monitoring traps indicate an extended period of infestation (longer than 8 weeks), replace the Exosex stations, to coincide with subsequent codling moth flights. Supplementary applications of insecticide are advised when Exosex CM is used to control high populations of codling moth. All pests must be monitored on a regular schedule so that timely intervention with insecticides is possible. As with equivalent products, high pest levels in the previous cropping season indicate that an early pre-season clean up pesticide application may be required.

**WARRANTY**

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, unfavorable temperatures, presence of other materials, weather, watering practices, nature of the soil, disease problems, condition of the crop, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

Technology Sciences Group Inc.  
Arizona: Regulatory Division  
4061 North 156<sup>th</sup> Drive  
Goodyear, AZ 85338  
Phone: (623) 535-4060  
FAX (623) 535-4061  
E-Mail: jazkatz@qwest.net



Iain Weatherston, Ph.D.  
Senior Regulatory Consultant  
Pesticide Division

Notification Coordinator  
Biopesticide and Pollution Prevention Division  
U.S. EPA - Office of Pesticide Programs  
Crystal Mall #2, 9<sup>th</sup> Floor  
1801 South Bell Street  
Arlington, VA 22202

January 31, 2006

SUBJECT: Notification of Minor Label Verbiage Change

COMPANY: Exosect Ltd.  
2 Venture Road  
Chilworth Science Park  
Southampton

CONTACT: Iain Weatherston  
Technology Sciences Group Inc.  
[contact information as per letterhead]

PRODUCT: EXOSEX<sup>®</sup> CM [EPARN 79442-1]

Dear Sir/Madam:

I enclose for your information a notification of a minor verbiage change to the label of EXOSEX<sup>®</sup> CM.

Accompanying this letter is:

- a fully executed application for registration form [EPA 8570-1].
- One copy of the current stamped approved label for this product
- Two copies of the draft label, one of which is highlighted to show the text changes.

Recently (August 17, 2005) we submitted a previous notification on the label of this same product, BPPD as is their right determined that the action was an amendment rather than a notification, however they did not comply with PRN 98-10 which states in Section IV A 3(b) the Agency should *notify the registrant within 30 days of receipt of the notification if the application does not qualify as an notification and state the reasons why.* In the case of the August 17, 2005 notification the Agency did not notify the registrant within 30 days (almost 100 days), did not do it in writing and did not give the reason for considering it as an amendment.

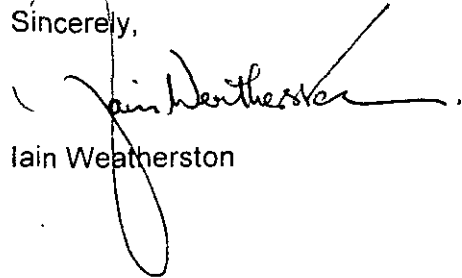
In this 2005 case the registrant did not incur any expenses or time loss due to the Agency failure to comply with its own mandates, however in this current application, the product is required in the

United States in early March and we request that BPPD comply with the above designated section of PRN 98-10 if they decide to designate this action as an amendment.

The verbiage change is related to how to assemble the autoconfusion station and does not impact on the application or directions of use of the product, and is hence a notification.

If there are any questions, or further information is required please do not hesitate to contact me at [jazkatz@qwest.net](mailto:jazkatz@qwest.net) or by phone at 623-535-4060.

Sincerely,

A handwritten signature in black ink, appearing to read "Iain Weatherston", with a large, stylized flourish extending downwards and to the left.

Iain Weatherston