

72642-2

10-30-2002

1/8

Please read instructions on reverse before completing form.

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



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72642-2	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Extinosad PSP	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly and Co. 2001 W. Main Street Greenfield, IN 46140 <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 _____	NOTIFICATION OCT 30 2002
<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.)
See attached page

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 32 oz, 250 mL		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued 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 Katherine M. Ehrenfried	Title Regulatory Manager	Telephone No. (include Area Code) (317)277-3362
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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Manager	
4. Typed Name Katherine M. Ehrenfried	5. Date 22 OCT 2002	

Research and Development
Elanco Animal Health
A Division of Eli Lilly and Company
2001 West Main St., P.O. Box 708
Greenfield, Indiana 46140



22 October 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22201-4501

RE: Notification for Extinosad PSP™ EPA Reg. # 72642-2

Please find attached, a notification for Extinosad PSP, EPA Reg. # 72642-2. Elanco Animal Health is submitting this notification as an "addition of tables, charts, or other graphics which present the same use directions already approved by the EPA in narrative form" under PR Notice 98-10, M(2). Text was added to the Application table (the added text is highlighted in gray) to make it easier for the user of the product to calculate the amount of product to mix and use. The added text represents the same use directions already approved by the EPA.

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 or the confidential statement of formula of this product. Elanco understands that it is a violation of 18 USC Sec 1001 to willfully make any false statement to the EPA. We 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 we may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please inform us that this notification is acceptable by providing us with the EPA-stamped label in the self-addressed stamped envelope included with this submission.

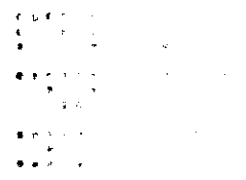
Please do not hesitate to contact me with any questions or concerns.

Sincerely,

ELANCO ANIMAL HEALTH

A handwritten signature in black ink, which appears to read "Katherine M. Ehrenfried", is written over the typed name.

Katherine M. Ehrenfried
Regulatory Manager
(317)277-3362
(317)277-4755 (fax)
Ehrenfried_k@lilly.com



Front Panel

EXTINOSAD PSP LOGO

Control of house flies, stable flies, darkling beetles and hide beetles in and around agricultural animal premises.

ACTIVE INGREDIENT	
Spinosad (A mixture of spinosyn A and spinosyn D).....	44.2%
OTHER INGREDIENTS.....	55.8%
TOTAL.....	100.0%

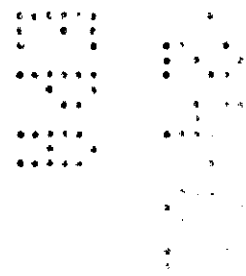
Keep Out of Reach of Children

CAUTION

Elanco Animal Health, A Division of Eli Lilly and Company
Indianapolis, IN 46285
www.elanco.com
Questions or comments call 1-800-428-4441

Net Contents: _____mL/oz

NOTIFICATION
OCT 30 2002



(Label Booklet: Page 1 through end)

EXTINOSAD PSP LOGO

Control of house flies, stable flies, darkling beetles and hide beetles in and around agricultural animal premises.

ENVIRONMENTAL HAZARDS

This product is highly toxic to molluscs. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning or disposing of equipment washwaters. Apply this product only as specified on this label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

Notice: Shake well before use. Avoid freezing.

MIXING FOR APPLICATIONS THAT REQUIRE DILUTION

Extinosad PSP is intended to be mixed with water and applied as a coarse, low-pressure spray. Fill the tank of the sprayer with water to about ½ of the total spray volume required. Start agitation and add the required amount of EXTINOSAD PSP. Continue mixing and agitation while filling the spray tank to the required spray volume. Maintain sufficient agitation during the application to ensure uniformity of the spray. Prepare spray fresh for each use.

GENERAL NOTICE

- Extinosad PSP may be applied as a general surface spray or a crack and crevice application. Applications may be made in and around poultry and livestock premises, including but not limited to poultry houses, beef and dairy barns, feedlots, stables, corrals and housing structures.
 - Control is enhanced when interior and exterior perimeter applications are made in and around livestock, poultry structures. Normal sanitation practices of the structure consistent with good animal husbandry should be followed to enhance effectiveness of insect control agents.
 - Do not apply dilutions for premise treatment directly onto poultry or livestock. When used in poultry and livestock premises, do not apply where animals are present. Allow treated surfaces to thoroughly dry before restocking/ reintroducing animals into facility. Horses not intended for human consumption may be present at the time of premise treatment.
 - Cover or remove exposed feed and water from the area being treated.
 - Do not use in milking rooms.
 - Do not apply as a fog or space spray.
-

APPLICATIONS

To Control:	Dilution			Application Rate
	Extinosad PSP	Water	Final Concentration	
House flies Stable flies	2 oz (60 mL)	10 gallons	0.08% (800 ppm)	1 gal/500-1000 sq. ft. (2 oz Extinosad PSP treats 5000-10,000 sq. ft.)
Darkling Beetles Hide Beetles	2 oz (60 mL)	10 gallons	0.08%* (800 ppm)	1 gal/ 500 sq. ft. (2 oz Extinosad PSP treats 5000 sq. ft.)

NOTE: One capful of Extinosad PSP equals 2 ounces. Rinse cap after use and pour rinsate into spray tank.

*For severe infestations, a concentration of 0.16% at 1 gal/ 500 sq. ft. may be used (4 oz/10 gal or 4 oz Extinosad PSP treats 5000 sq. ft)

Poultry Houses

House Flies and Stable Flies: Treat areas where flies rest: pay attention to side walls, the ends of buildings, upper sides of posts, and crossbeams. Spray in early morning when flies are resting. Use enough water in a directed spray to contact flies and their resting surfaces thoroughly, but do not allow run-off to occur. Do not apply where birds are present; allow treated surfaces to dry completely before restocking. Do not contaminate feedstuffs, water or watering and feeding equipment with premise treatment. Re-application may occur every 7 to 10 days as needed, or when fly populations reach nuisance levels.

Darkling Beetles and Hide Beetles: Apply to floor area, especially to litter around feed and water lines and to walls and support beams, but do not allow run-off to occur. Application should also be made into cracks and crevices around insulation, and where pests have been seen or can find harborage. Do not apply where birds are present; allow treated surfaces to dry completely before restocking. Reapply after each grow-out or sanitation procedure. Indoor control can be enhanced by making perimeter treatments to the outside of building foundations to prevent migrating adult beetles.

Livestock Housing

House Flies and Stable Flies: Apply to vertical and overhead surfaces where flies may congregate. Feeders, waterers and feedcarts should be covered before application to prevent contamination. Do not contaminate feedstuffs or water with premise treatment. Pay attention to animal areas including fence railings, alleyways, stanchions, pipes, windows and doors, and other areas where flies congregate. Spray in early morning when flies are resting. Do not apply where livestock are present and allow treated surfaces to dry completely before restocking or reintroducing livestock. Re-application may occur every 7 to 10 days as needed, or when fly populations reach nuisance levels.

INTEGRATED PEST AND RESISTANCE MANAGEMENT

EXTINOSAD PSP is a member of a new unique class of insect control agents (spinosyns) with no pre-existing levels of resistance to any other insect control agents and can be rotated with all other classes, such as synthetic pyrethroids and organophosphates. House flies, stable flies and other insects have demonstrated the ability to develop resistance to insect control products. Continual exposure of flies and other insects to a single class of insecticide may lead to the development of resistance to that class of insecticide. The following resistance management strategy will help ensure the prolonged usefulness of EXTINOSAD PSP, as well as other conventional insecticides:

- Apply EXTINOSAD PSP and other insect control agents only according to label directions
- Do not use less than the labeled rate of any insect control product
- Include multiple control tactics (cultural and/or biological controls) within an Integrated Pest Management Program
- Rotate EXTINOSAD PSP with other classes of insecticides (synthetic pyrethroid, organophosphate) during a fly season

For advice concerning integrated pest management practices in relation to specific local conditions, consult resources in resistance management programs, your Cooperative Agricultural Extension Service, or your Elanco Animal Health representative (800-428-4441).

STORAGE AND DISPOSAL

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

Storage: Store in original container only. In case of leak or spill, remove with absorbent materials and dispose of as waste.

Disposal: Wastes resulting from the use of this product may be disposed of on site according to label use directions 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 incinerator, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

INHERENT RISKS OF USE

It is impossible to eliminate all risks associated with the use of this product. Lack of performance or other unintended consequences may result because of such factors as use of the product contrary to label instructions, abnormal conditions, presence of other materials, the manner of application, or other factors which are beyond the control of Elanco Animal Health or the seller. All such risks are assumed by the buyer.

LIMITATIONS OF REMEDIES

The exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Elanco Animal Health's election, one of the following:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used

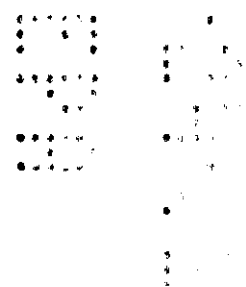
Elanco Animal Health shall not be liable for losses or damages resulting from the handling or use of this product unless Elanco Animal Health is promptly notified of such loss or damage in writing. In no case shall Elanco Animal Health be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Elanco Animal Health or the seller is authorized to vary or exceed the terms of Warranty Disclaimer of this Limitation of Remedies in any manner

Elanco Animal Health, A Division of Eli Lilly and Company
Indianapolis, IN 46285
www.elanco.com
Questions or comments call 1-800-428-4441

EPA Reg. No.: 72642-2
EPA Est. No.: 37429-GA-02

*Elanco®, EXTINOSAD™ PSP, and the diagonal color bar are trademarks of Eli Lilly and Company.



(Label Booklet Cover-Back Panel)

EXTINOSAD PSP LOGO

Control of house flies, stable flies, darkling beetles and hide beetles in and around agricultural animal premises.

Environmental Hazards

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Notice: Shake Well Before Use. Avoid Freezing. Read the entire label before using. Use only according to label directions. See Directions for Use including storage and disposal inside label booklet.

EPA Reg. No: 72642-2
EPA Est. No.: 37429-GA-02

Peel Back Logo
