

72642-5

11-2-2006

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 72642-5
Date of Issuance: 11/02/06

Term of Issuance:
Conditional

Name of Pesticide Product:
StandGuard Pour On Insecticide

NOTICE OF PESTICIDE:
 Registration
 Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Elanco Animal Health
2001 W. Main St.
Greenfield, IN 46140

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following labeling changes before you release the product for shipment:
 - a. Revise the EPA Registration Number to read: "EPA Registration No. 72642-5"

Signature of Approving Official:

George LaRocca
Product Manager (RM 13)
Insecticide Branch
Registration Division (MC 7505P)

Date:

November 2, 2006

- b. You may delete the precautionary statements "*Harmful if inhaled; Avoid breathing vapors or spray mist*" and the associated first aid statement "*If inhaled*" (Acute inhalation toxicity of category IV).
 - c. Delete the statement "Avoid contact with eyes" – 4th line in the PL box and directly before the statement "Wear rubber . . . this product. This sentence is repeated on the 2nd line.
 - d. Capitalize the word "D" in the sent "Data indicate . . . allergenic" – 5th line in the PL box.
 - e. Revise the statement "Wash thoroughly with soap and water after handling" to read "*Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco*".
3. Submit to the Agency, data on one year storage stability testing (830.6317), conducted concurrently with the corrosion characteristics study (830-6320) at 0, 3, 6, 9 and 12 months of warehouse storage.
 4. Submit two (2) copies of the final printed label bearing the above stated revisions prior to releasing this product for sale.

If you fail to comply with the above stated conditions, this registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the stamped label is enclosed for your records. If you have any questions concerning this action, please contact Dr. B. A. Akinlosotu at (703) 605-0653.

Enclosure

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[Draft label]

STANDGUARD POUR ON INSECTICIDE

FOR CONTROL OF HORN FLY AND LICE ON BEEF CATTLE AND CALVES

SEASON LONG CONTROL OF LICE WITH A SINGLE APPLICATION

ACTIVE INGREDIENT

Gamma cyhalothrin [CAS# 76703-62-3] 0.50%

INERT INGREDIENTS

99.50%

TOTAL

100.00%

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

NOV 2 2006

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
72642-5**

Squeeze-N-Measure Bottle (this will go on 30 fl. oz. label only)

May be used with an automatic dosing system

Treats 60 cattle at maximum application rate (on 30 fl. oz. label)

Treats 120 cattle at maximum application rate (on 60 fl. oz. label)

Treats 333 cattle at maximum application rate (on 5 liter label)

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENT

CONTENTS: 30 fl. oz. (900 ml)

CONTENTS: 60 fl. oz. (1.8 liter)

CONTENTS: 1 gal. 41 fl. oz. (5 liter)

Elanco Animal Health
A Division of Eli Lilly & Company
2001 West Main Street
Greenfield, IN 46140

EPA Reg No.: 72642-?

EPA Establ. No. xxxxx-xx-x

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PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed, absorbed through the skin, or inhaled. Causes moderate eye irritation. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before re-use. Wash thoroughly with soap and water after handling. Avoid contact with eyes. Wear rubber or non-permeable protective gloves when applying this product. data indicate this product to be a contact allergenic. Do not apply this product to the face of cattle.

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 a poison control center or doctor for further treatment advice.

If on skin or clothing:

- 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 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 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 to an unconscious person.

Have product container label container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-428-4441 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish. Do not apply directly to water, or areas where surface water is present, or to intertidal areas below the mean water mark. Do not contaminate water when disposing of equipment wash waters. Apply the product only as specified on this label.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or an open flame.

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DIRECTIONS FOR USE

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

READY TO USE. No dilution necessary. Do not apply to lactating or dry dairy cows. Do not apply this product to the face of beef cattle and calves.

Apply to	Target Insects	Dosage				
Beef Cattle	Horn flies, Lice	Apply product along the backline at the rate of: <table border="0"> <tr> <td><u>Less than 600 lbs</u></td> <td><u>More than 600 lbs</u></td> </tr> <tr> <td>10 mls (1/3 fl.oz.)</td> <td>15 mls (1/2 fl. oz.)</td> </tr> </table>	<u>Less than 600 lbs</u>	<u>More than 600 lbs</u>	10 mls (1/3 fl.oz.)	15 mls (1/2 fl. oz.)
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For horn flies, repeat treatment as needed, however do not apply more than once every two weeks and do not apply more than four times within any 6-month period.

SPECIAL NOTE: StandGuard Pour On Insecticide is not recommended for veal calves. StandGuard Pour On Insecticide is not effective in controlling cattle grubs. Therefore, this product can be used on cattle at any time of the year without fear of host-parasite reactions commonly associated with grub treatments.

StandGuard Pour On Insecticide should be used in an integrated pest management system which may involve repeat treatments and the use of other pest control practices. Continual exposure of horn flies to a single class of insecticide (eg. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance, it is important to rotate, on a seasonal basis, the class of insecticide used and/or the method of horn fly control. For advice concerning current control practices with relation to specific local conditions, consult resources in resistance management programs, your Cooperative Agricultural Extension Agent or your Elanco Animal Health Representative at 1-800-428-4441.

STORAGE AND DISPOSAL

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

STORAGE: Keep container sealed when not in use. Do not store near 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.

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TERMS AND CONDITIONS OF USE

If terms of the following Warranty Disclaimer, Inherent Risks of Use and Limitation of Remedies are not acceptable, return unopened package at once to the seller for a full refund of purchase price paid. Otherwise, use by the buyer or any other user constitutes acceptance of the terms under Warranty Disclaimer, Inherent Risks of Use and Limitation of Remedies.

WARRANTY DISCLAIMER

Elanco warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. ELANCO ANIMAL HEALTH MAKES NO OTHER EXPRESSED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

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.

LIMITATION 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 the buyer or user of the product bought, or
- (2) Replacement of the 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. To the extent permitted by law, Elanco Animal Health shall not 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.