

70585-2

09-02-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 2, 2010

Ms. Rebecca Barnes
Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408

Subject: Label Notification(s) for Pesticide Registration Notices 2007-4
Updating the Container Disposal Language

Dear Ms. Barnes:

The Agency is in receipt of your Application(s) for Pesticide Notification under
Pesticide Registration Notice PRN 2007-4 dated August 9, 2010 for the following product(s):

Larvadex 1% Premix	EPA Reg. No. 70585-1
Larvadex 2SL	EPA Reg. No. 70585-2
Novartis Cyromazine Technical Spec Ground	EPA Reg. No. 70585-6
Neporex 2SG	EPA Reg. No. 70585-7

The Registration Division (RD) has conducted a review of this request for applicability under
PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label
has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or
other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable
containers. The code may appear either on the label (and can be added by non-notification/PR Notice
98-10) or durably marked on the container itself.

If you have any questions, please contact Regina Foushee'-Smith at 703-605-0780.

Sincerely,

Richard J. Gebken
Product Manager
Insecticide Branch
Registration Division (7505P)



August 9, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Paul Mastradone

**LARVADEX 2SL
EPA REG. NO. 70585-2
NOTIFICATION OF LABEL CHANGE PER PR NOTICE 2007-4**

Novartis Animal Health US, Inc. is submitting this Notification for Larvadex 2SL, EPA Reg. No. 70585-2. Novartis is amending the Storage and Disposal section of the label by Notification according to the directions stated in PR Notice 2007-4.

Contents of Submission

- One copy of the label with the changes clearly marked
- One unmarked copy of the label
- Completed EPA Form 8570-1

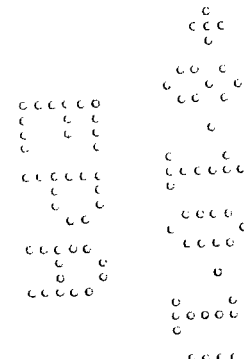
Our consultant representative, Richard L. Conn, of Conn & Smith, Inc, assisted us with preparing this notification. If you have any questions or if you need any further information, you may contact him directly. You may also call me toll free at (800) 447-2391 or directly at (336) 387-1674. Mr. Conn can be reached at (703) 339-4199.

Sincerely,

Rebecca Barnes
Regulatory Affairs Manager
Novartis Animal Health US, Inc. (Greensboro, NC)

Enclosures

cc: Richard L. Conn, Conn & Smith, Inc.



Marked

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(Pages 1-6 constitute the label booklet)

NOTIFICATION

SEP 2 2010

Larvadex®
2SL
LIQUID LARVICIDE
One Gallon
U.S. Standard Measure

For fly control in and around chicken layer and breeder operations only

Active Ingredient: Cyromazine: N-cyclopropyl-1,3,5-triazine-2,4,6-triamine.....2%
Inert Ingredients: 98%
Total: 100%

Contains 0.17 lb. cyromazine per gallon.
See directions for use inside booklet.

STORE AT TEMPERATURES ABOVE 32°F.

EPA Reg No. 70585-2
EPA Est. 67517-MO-1

KEEP OUT OF REACH OF CHILDREN

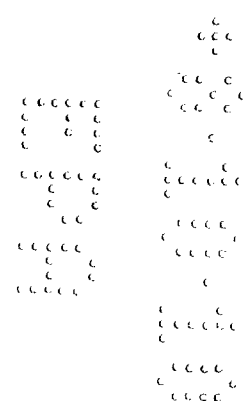
CAUTION

See additional precautionary statements at end of label booklet.

Larvadex® is a trademark of Novartis AG
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Distributed by:
Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408
NAH/LDX2SL/0.17/BL/3/2

08/1006/03



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DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

IMPORTANT: Read the entire **Directions for Use** and the **Conditions of Sale and Warranty** before using this product. If terms are not acceptable, return the unopened product container at once.

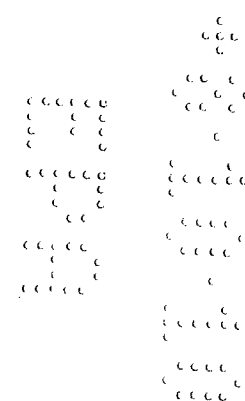
CONDITIONS OF SALE AND WARRANTY

The **Directions for Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials or the manner of use or application all of which are beyond the control of Novartis or the Seller. All such risks shall be assumed by the Buyer.

Novartis warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use** subject to the inherent risks referred to above. **Novartis makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall Novartis or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product.** Novartis and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty**, which may be varied only by agreement in writing signed by a duly authorized representative of Novartis.

GENERAL INFORMATION

Larvadex 2SL is a soluble concentrate, which, when diluted with water according to the **Directions for Use** given below, will act as a larvicide to control fly species which develop in poultry manure and refuse. Larvadex 2SL controls fly infestations by breaking the life cycle at the maggot stage.



DIRECTIONS FOR USE

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

FAILURE TO FOLLOW DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN INJURY, POOR FLY CONTROL, AND/OR ILLEGAL RESIDUES.

Do not apply this product in such a manner as to directly or through spray drift expose workers or other persons.

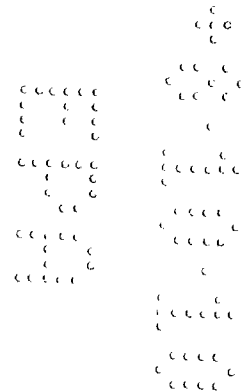
For Housefly, Lesser Housefly and Soldier Fly Control in Poultry Operations Including Layer and Breeder Chickens

Fly control in poultry operations should include appropriate sanitary and management practices to reduce the number and size of fly breeding sites. A successful sanitary and management program may allow less than constant use of insecticides. This, in turn, should prolong the effective life of such control agents.

Eliminating Fly Breeding Sites:

Certain conditions around poultry operations encourage flies and should be brought under control or eliminated as an aid to fly control. These include:

- Removing broken eggs and dead birds.
- Cleaning up of feed spills, manure spills, especially if wet.
- Reducing feed spills in the manure pits.
- Reducing moisture in manure in the pits.
- Repairing water leaks that cause wet manure.
- Cleaning out weed-choked water drainage ditches.
- Minimizing sources from other fly-infested animal operations in close proximity to the poultry house.



When and How to Use Larvadex 2SL

First, monitor adult flies in and near the poultry house. When the population reaches a level to cause concern, use registered adulticide baits, sprays or fogs to reduce fly numbers and breeding potential. Then, examine manure and other fly breeding areas for maggot activity. If maggots are active, treat breeding sites with Larvadex 2SL.

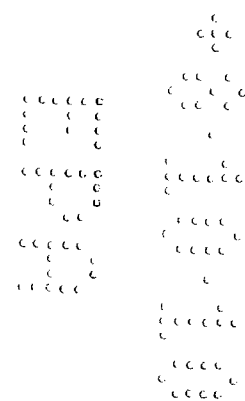
Mixing Application

Dilute Larvadex 2SL with water to make a 0.1% spray (see following Dilution Chart). Apply 1 gallon of finished spray per 100 sq. ft. of area over surface of manure, manure storage areas, spilled feed and other sites where maggots are active. Do not apply Larvadex 2SL more frequently than once every 21 days.

Registered baits, sprays or fogs should be used to reduce adult flies present at the onset of larvicide program and best management practices followed. They should also be used to help control any influx of adult flies from other areas.

NOTES

- (1) DO NOT APPLY LARVADEX 2SL DIRECTLY TO POULTRY OR POULTRY FEED AS ILLEGAL RESIDUES MAY RESULT.
- (2) DO NOT FEED MANURE TREATED WITH LARVADEX 2SL TO ANIMALS.
- (3) TO AVOID ILLEGAL RESIDUES, ALLOW 1 DAY (24 HOURS) BETWEEN LAST APPLICATION AND SLAUGHTER.
- (4) DO NOT USE LARVADEX 2SL IN CONJUNCTION WITH LARVADEX 1% PREMIX. IF CHICKENS HAVE BEEN FED LARVADEX-TREATED FEED, DO NOT APPLY LARVADEX 2SL TO MANURE.
- (5) MANURE TREATED WITH LARVADEX 2SL MAY BE USED AS A SOIL FERTILIZER SUPPLEMENT. DO NOT APPLY MORE THAN 4 TONS OF MANURE TREATED WITH LARVADEX 2SL PER ACRE PER YEAR.
- (6) DO NOT APPLY TREATED MANURE TO SMALL GRAIN CROPS THAT WILL BE HARVESTED OR GRAZED, OR ILLEGAL RESIDUES MAY RESULT.



Larvadex 2SL Dilution Chart

Gallons of Finished Spray Needed	Amount of Larvadex 2SL to Use for 0.1% Finished Spray
1	6.5 fl. oz. (13 tablespoons)
5	32.00 fl. oz. (4 cups or 2 pints)
25	160.00 fl. oz. (20 cups or 10 pints)

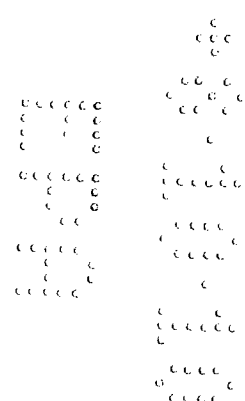
Storage and disposal

Do not contaminate water, food, or feed by storage or disposal, or cleaning of equipment. Store at temperatures above 32°F. Crystals may form at lower temperatures. If this occurs, place the product in a warm room (72°F or above) and shake the container at frequent intervals until all crystals are dissolved. Since this formulation contains water, it can also freeze solid at temperatures below 32°F. However, when reconstituted and crystals redissolve, product performance is not affected.

Pesticide Disposal: Improper disposal of unused pesticide, spray mixture, or rinsate is a violation of federal law. Pesticide, spray mixture, or rinsate that cannot be used according to label instruction, must be disposed of according to federal, state or local procedures. For guidance in proper disposal methods, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office.

Container Handling: ~~Do not reuse empty container. Triple rinse (or equivalent) and offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration, or by open burning if allowed by state and local authorities. If burned, keep out of smoke.~~ Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinses as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if available. Puncture and dispose of in sanitary landfill, by incineration, or by open burning if allowed by state and local authorities. If burned, keep out of smoke.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire or other emergency, call 1-800-424-9300 day or night.



Precautionary statements

Hazards to humans and domestic animals

CAUTION

Causes moderate eye irritation. Harmful if swallowed, absorbed through the skin or inhaled. Avoid contact with eyes, skin or clothing. Do not breathe vapors or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID

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

If on skin or clothing

-Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

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 eye.

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.

HOT LINE NUMBER

1-800-637-0281

Environmental hazards

Do not contaminate water by cleaning of equipment or disposal of wastes.

Physical or chemical hazards

Corrosive to tin.

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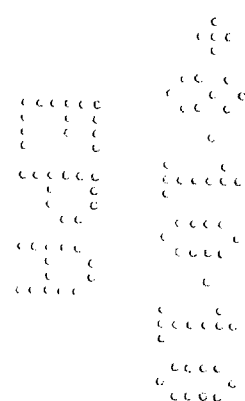
Novartis Animal Health U.S, Inc.

3200 Northline Avenue, Suite 300

Greensboro, NC 27408

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(Pages 7 and 8 constitute the label that is affixed to the container)

Larvadex®

2SL

LIQUID LARVICIDE

For fly control in and around chicken layer and breeder operations only

Active Ingredient: Cyromazine: N-cyclopropyl-1,3,5-triazine-2,4,6-triamine.....2%
Inert Ingredients: 98%
Total: 100%

Contains 0.17 lb. cyromazine per gallon.

EPA Reg No. 70585-2
EPA Est. 67517-MO-1

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DIRECTIONS FOR USE

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One Gallon

U.S. Standard Measure

KEEP OUT OF REACH OF CHILDREN

CAUTION

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