

70585-1

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,

A handwritten signature in cursive script, appearing to read "Richard J. Gebken".

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 1% PREMIX
EPA REG. NO. 70585-1
NOTIFICATION OF LABEL CHANGE PER PR NOTICE 2007-4**

Novartis Animal Health US, Inc. is submitting this Notification for Larvadex 1% Premix, EPA Reg. No. 70585-1. 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.

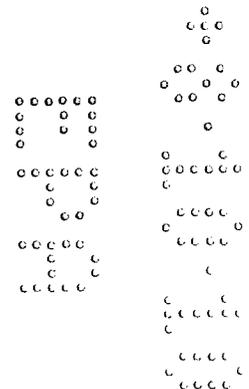
Sincerely,



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

Enclosures

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



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NOTIFICATION

SEP 2 2010

Larvadex[®] 1% Premix

25 Pounds

For fly control in and around (1) Caged or slatted flooring layer chicken operations. (2) Breeder Chicken Operations.

Larvacide

Active Ingredient: Cyromazine: N-cyclopropyl-1,3,5-triazine-2,4,6-triamine.....1.0%
Inert Ingredients: 99.0%
Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary statements on back of bag. See directions for use on back of bag

EPA Reg No. 70585-1 / EPA Est. 38092-NB-001

Larvadex[®] 1% Premix

Larvadex[®] 1% Premix

Product ID. 55160

25 Pounds

Net Weight

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 1% Premix is a premix which, when blended into a poultry ration according to the **Directions for Use** given below, will control certain fly species which develop in poultry manure. Larvadex 1% Premix is intended for use only in poultry (chickens) layer and breeder operations.

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 AND PRECAUTIONS ON THIS LABEL MAY RESULT IN INJURY, POOR FLY CONTROL, AND/OR ILLEGAL RESIDUES.

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.

Determining the threshold of fly tolerance

Fly pressure can vary depending on farm location, season of the year, and emphasis on sanitation. Newer, controlled environment poultry houses are known to be less susceptible to fly populations re-establishing, once brought under control. Frequency of manure removal and proximity of the farm to neighbors or residential areas will greatly influence the expected degree of fly control. Each farm must determine the level of fly control required and follow an appropriate control program.

Blending and Feeding Larvadex 1% Premix

Housefly, soldier fly, lesser housefly: Mix 1 lb of Larvadex 1% Premix per ton of feed. Feed the treated feed as a daily ration. Begin feeding when adult flies become active and continue treatment as prescribed through the fly season.

Important note to feed mill operators

Larvadex 1% Premix feed formulators (those mixing as a service to customers) must inform the feed user that treated feed must be removed from layers and breeders at least 3 days before slaughter. The following label statement is suggested for use on treated feed containers: "This poultry feed is formulated with 5.0 ppm (0.01 lb./ton) cyromazine. Treated feed must not be fed to layers and breeders for a minimum of 3 days (72 hrs.) before slaughter for food."

Larvadex 1% Premix will provide a high degree of fly control and will give best results when integrated with a well managed fly control program which includes minimization of fly breeding sites, a determination of the degree of fly control desired, a monitoring of adult fly populations in and around the operation; and frequent examinations of manure for maggot activity.

When and how to use Larvadex 1% Premix

First, monitor adult flies in and near the poultry house. When the population reaches a level to cause concern, use a registered adulticide spray or fog to reduce the breeding potential. Then, examine manure in the pits for maggot activity. If maggots are active, start Larvadex 1% Premix in the ration.

Feed Larvadex 1% Premix continuously as directed for 4 to 6 weeks. Usually, this is enough time for Larvadex 1% Premix to thoroughly cover the droppings and break the fly population cycle in the poultry house.

After a minimum of 4 to 6 weeks of Larvadex 1% Premix feeding, carefully examine the manure pits. If little or no activity is observed in the manure, discontinue Larvadex 1% Premix and continue the sanitary and management program. Continue monitoring the manure pits. If maggots become active again, repeat the procedure.

Use bait, sprays, or fogs as needed during and between Larvadex 1% Premix feeding periods to control any adult flies.

During winter months or during periods of low fly pressure, discontinue Larvadex 1% Premix use for at least 4 consecutive months per year.

Consult with local extension service poultry entomologists or your State Agricultural Experiment station for additional localized fly control suggestions.

Note: Do not feed Larvadex 1% Premix treated feed to broiler poultry. Larvadex 1% Premix use in poultry is limited to use as a feed-through in chicken layer and breeder operations only and may not be fed to any other poultry species.

To avoid illegal residues, Larvadex 1% Premix treated feed must be removed at least 3 days (72 hrs.) before slaughter.

Manure from chickens fed Larvadex 1% Premix may be used as a soil fertilizer supplement. Do not apply more than 3 tons of manure per acre per year. Do not apply to small grain crops that will be harvested or grazed or illegal residues may result. Do not feed manure from chickens fed Larvadex 1% Premix to animals.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal practices. Store in a dry place.

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

Container: Non-refillable container. Do not use or refill this container. Completely empty bag into mixer. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

In case of fire, accident, major spillage, or other emergency, contact Novartis at 1-800-424-9300, day or night.

Precautionary Statements	
Hazards to Humans and Domestic Animals	
CAUTION	
Harmful if inhaled or absorbed through the skin. Avoid breathing dust. Avoid contact with skin or clothing. May cause skin sensitization reactions in certain individuals. Wash thoroughly with soap and water after handling.	
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	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15- 20 minutes.
If in eyes -	<ul style="list-style-type: none">• 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 -	<ul style="list-style-type: none">• 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: Keep out of lakes, ponds, or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.	

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/LDX1/25/BGL/4 04/10

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FREIGHT SHIPPING BAG
MEETING REQUIREMENTS OF
APPLICABLE FREIGHT CLASSIFICATION
GUARANTEED BY
BANCROFT BAG, INC.
WEST MONROE, LOUISIANA

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