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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. Date of Issuance 72642-4 03/02/07

Term of issuance

Conditional

Name of Pesticide Product

GF-1758 Oral Larvicide

NOTICE OF PESTICIDE:

X Registration

Reregistration

lunder FIERA as amendedi

Name and Address of Registrant (include ZIP Code):

Elanco Animal Health 2001 West Main St. P.O. Box 708 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. Submit estimates of projected market share for feed through use in dairy cattle. The Agency concludes that the proposed feed through use will not necessitate an increase in livestock tolerances. However, this use may necessitate a revised risk assessment. Thus, the need for projections for spinosad feed through use in cattle. See enclosed residue chemistry review.
- 3. Make the following labeling changes before you release the product for shipment:
 - a. Revise the EPA Registration Number to read: "EPA Registration No. 72642-4"

Signature of Approving Official:

George LaRocca

Product Manager (RM 13)

Insecticide Branch

Registration Division (MC 7505P)

Date:

March 02, 2007

EPA Form 8570-6

- b. Revise the first part of the sentence on the front panel to read, "For use only in the manufacture of cattle feed products to be consumed by . . . etc."
- c. Add the signal word "Caution", "Keep out of reach of children", and the referral statement "Refer to side/back panels for additional precautions".
- d. Add the following Precautionary and First Aid statements*:

Hazards to Humans and Domestic Animals:

CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

First Aid:

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.

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

*Please see enclosed copy of our acute toxicology review for more information.

- 4. 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.
- 5. Submit two (2) copies of the final printed label bearing the above stated revisions prior to releasing this product for sale.

Please note that we have only reviewed the product chemistry for the manufacturing use product. The data for the typical end use products will be reviewed when your customers submit applications for new registrations along with the appropriate PRIA fees.

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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

ACCEPTED with COMMENTS In EPA Letter Dated:

(logo) Elanco Animal Health

GF-1758

ORAL LARVICIDE
For Manufacturing Use Only

MAR 2 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

- Prevents the development of horn flies (*Haematobia irritans*) and face flies (*Musca autumnalis*) in the manure of treated cattle
- For use only in the manufacture of products to be consumed by lactating and nonlactating dairy or beef cattle maintained on pasture or range

Active Ingredien	dient	nared	Active
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 Spinosad (A mixture of spinosyn A and spinosyn D)
 20.0%*

 Other Ingredients
 80.0%**

 Total
 100.0%

Notice: Read entire label. Use only according to label directions. Before using this product, read Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies at the end of the label. If terms are unacceptable, return at once unopened.

EPA Registration No. 72642-? EPA Establishment No. xxxxx-xx-xx

NET CONTENTS:____

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

^{*}Contains 91 grams of active ingredient pound

^{**}Refers only to ingredients which are not larvicidal

PRECAUTIONARY STATEMENTS

Environmental Hazards

This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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

For Manufacturing Use Only

In a Block or Loose Mineral – GF-1758 can be used to prepare protein blocks, mineral blocks, or loose mineral mixes that will provide approximately 13.6 mg of spinosad per 100 lb. body weight. Mix GF-1758 according to the amount of block or loose mineral to be fed and consumed per animal per day. Use the table below as a guide for determining the proper mixing rate.

Feed the appropriate mixture of GF-1758 and block/loose mineral for cattle weighing between 500-800 lb., 800-1100, or 1100-1400 lb. Begin feeding treated blocks/loose mineral early in the spring before flies begin to appear and continue feeding throughout the summer and into the fall, until cold weather restricts fly development.

Directions for preparing mineral mixes with GF-1758:

Daily Feeding Rate (oz)	Cattle Weight Range	Spinosad in Mineral Mix (mg / lb)	Pounds Premix per Ton
8.0	500 - 800	176.3	3.9
4.0	500 - 800	353.6	7.8
3.0	500 - 800	471.5	10.4
8.0	800 - 1100	258.4	5.7
4.0	800 - 1100	516.8	11.4
3.0	800 - 1100	689.0	15.2
8.0	1100 - 1400	340.0	7.5
4.0	1100 - 1400	680.0	15.0
3.0	1100 - 1400	906.7	20.0

This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group or grower has complied with the U.S. EPA submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container only. In case of leak or spill, container

Store in original container only. In case of leak or spill, contain material with

absorbent materials and dispose as waste.

Pesticide 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: Paper bag – Completely empty bag into application equipment. Then 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.

Fiber drum – Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in the

manner required for its liner.

TERMS AND CONDITIONS OF USE

If terms of the 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 Limitations 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. Elanco MAKES NO OTHER EXPRESS OR IMPLIED 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 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. 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 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.