

20585-7

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)

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

 Environmental Protection Agency United States Washington DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number Notification
	Application for Pesticide - Section I	

1. Company/Product Number <p style="text-align: center;">70585-7</p>	2. EPA Product Manager <p style="text-align: center;">Richard Gebken</p>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <p style="text-align: center;">Neporex 2 SG</p>	PM# <p style="text-align: center;">10</p>	
5. Name and Address of Applicant (Include ZIP Code) Novartis Animal Health US, Inc. 3200 Northline Avenue, Suite 300 Greensboro, NC 27408 <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: <div style="text-align: center; font-weight: bold; font-size: 1.2em;">NOTIFICATION</div> EPA Reg. No. _____ <div style="text-align: center; font-size: 1.5em; font-weight: bold;">SEP 2 - 2010</div> Product Name _____

Section - II	
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.
 Novartis is amending the Storage and Disposal section of the label by Notification according to the directions stated in PR Notice 2007-4.

Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> 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 <p style="text-align: center;">Rebecca Barnes</p>	Title <p style="text-align: center;">Regulatory Affairs Manager</p>	Telephone No. (Include Area Code) <p style="text-align: center;">(336) 387-1674</p>
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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 <div style="text-align: center; font-weight: bold; font-size: 1.2em;">(Stamped)</div>
2. Signature 	3. Title <p style="text-align: center;">Regulatory Affairs Manager</p>	
4. Typed Name <p style="text-align: center;">Rebecca Barnes</p>	5. Date <p style="text-align: center; font-size: 1.5em;">8/9/10</p>	

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

**NEPOREX 2SG
EPA REG. NO. 70585-7
NOTIFICATION OF LABEL CHANGE PER PR NOTICE 2007-4**

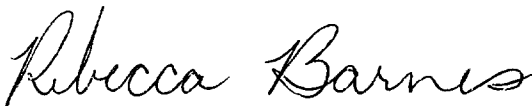
Novartis Animal Health US, Inc. is submitting this Notification for Neporex 2SG, EPA Reg. No. 70585-7. Novartis is amending the Storage and Disposal section of the label by Notification according to the directions stated in PR Notice 2007-4.

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.

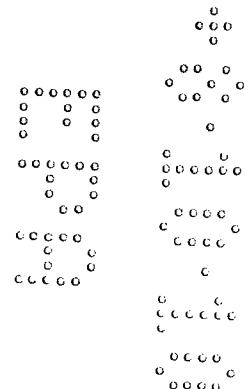
Sincerely,



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

Enclosures

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



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Neporex® 2SG

NOTIFICATION

SEP 2 2010

For control of fly larvae in cattle, hog, and poultry operations

Active Ingredient:

Cyromazine: (CAS No. 66215-27-8).....	2.0%
Other Ingredients:	98.0%
Total:	100.0%

EPA Reg. No. 70585-7

EPA Est. 79789-DEU-1

Product ID. 56101

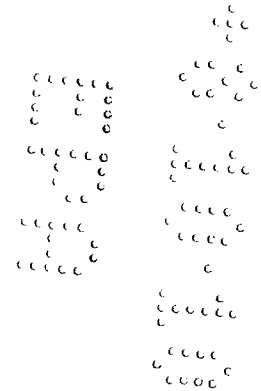
Product of Germany

KEEP OUT OF REACH OF CHILDREN.

CAUTION

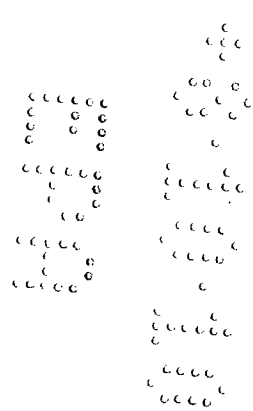
See additional precautionary statements on label.

11 pounds
Net Weight



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FIRST AID	
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.• Call a poison control center or doctor for treatment advice.
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.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• 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 by mouth to an unconscious person.
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 by mouth-to-mouth, if possible.• 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.	
USA HOT LINE NUMBERS	
For 24 Hour Medical Emergency Assistance (Human or Animal) Call 1-800-637-0281	
For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-424-9300	



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PRECAUTIONARY STATEMENTS

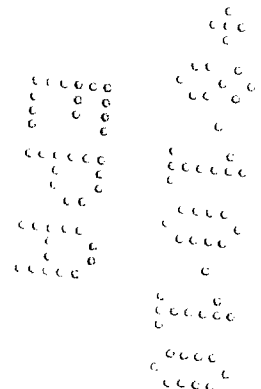
Hazards to Humans and Domestic Animals

CAUTION

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

Environmental Hazards

Do not contaminate water when disposing of equipment washwater or rinsate.



CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

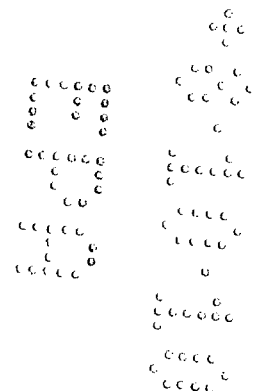
NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of NOVARTIS ANIMAL HEALTH US, Inc. (NAHUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NAHUS and Seller harmless for any claims relating to such factors.

NAHUS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or NAHUS, and Buyer and User assume the risk of any such use. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW NAHUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

To the extent consistent with applicable law in no event shall NAHUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NAHUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NAHUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

NAHUS and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitations of Warranty and of Liability, which may not be modified except by written agreement signed by a duly authorized representative of NAHUS.



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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.

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, Stable Fly and Soldier Fly Control in Cattle Operations, Hog Operations, Poultry Operations Including Layer and Breeder Chickens, and Horse Barns Where Horses are not Intended for Slaughter or Food

Fly control in cattle, hog, poultry, and horse 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 cattle, hog, poultry, and horse operations encourage flies and should be brought under control or eliminated as an aid to fly control. These include:

- For chickens, 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 or livestock pens.

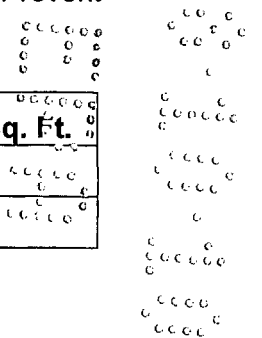
How to Use NEPOREX 2SG

NEPOREX 2SG is a larvicide with specific and unique properties developed for the control of fly larvae in manure and other breeding sites. It can be used simultaneously or alternatively with fly adulticides and is thus an important component of any integrated fly control program.

NEPOREX 2SG acts as a growth regulator and affects the molting process of fly larvae. It does not kill adult flies. The elimination of adult fly population occurs gradually and becomes visible one to two weeks after application. To achieve a faster reduction of the adult fly population, the concurrent use of an adulticide is recommended.

NEPOREX 2SG is a water-soluble granule suitable for dry scattering or spraying. The application rate is 0.02 lb cyromazine per 200 sq. ft., independent of the method of application. Apply NEPOREX 2SG only on fly breeding sites. It is not intended for application to fly resting sites (walls, ceilings, etc.), as it has no effect on adult flies. Prevent contamination of feed troughs and water troughs.

Application Method	Neporex 2SG Rate Per 200 Sq. Ft.
Dry scattering	1 lb
Spraying	1 lb per gallon of water



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Dry scattering: Apply NEPOREX 2SG directly and evenly on the fly breeding sites. Use dry scattering only in case of wet or liquid manure. Wear gloves when scattering

Spraying: Thoroughly mix the indicated quantity of NEPOREX 2SG with the corresponding volume of water. Apply as a coarse low-pressure spray on fly breeding sites with hand-pressurized or power-operated sprayers, or other suitable spray equipment.

Note

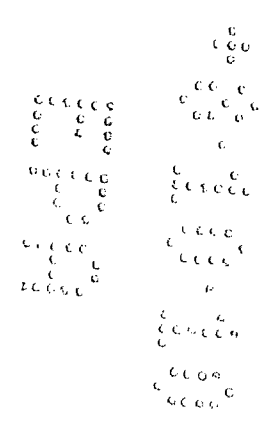
Do not administer via feed or drinking water or contaminate feed troughs or water troughs.

Treatment Interval

The recommended treatment interval depends on management and housing systems as well as on climatic conditions. It can vary from 21 days up to several months. More specific recommendations are given in the application schedules below. Do not apply NEPOREX 2SG more frequently than once every 21 days.

Notes

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



Application Schedules

Cattle Facilities

Deep litter: Treat edges and spillage areas around feed troughs and water troughs and where manure accumulates. In calf hutches placed outside, treat the whole floor surface. Apply NEPOREX 2SG by spraying approximately 3 days after manure removal and repeat treatment after each removal or when fly larvae are found.

Slatted floor: Treat areas where manure and other refuse accumulates to create a fly breeding site where fly larvae are present.

Hog Facilities

All-in, all-out system: Apply NEPOREX 2SG preferably by scattering immediately after cleaning and prior to the installation of the pigs on any fly breeding sites where fly larvae are present.

Slatted floors: Treat areas where manure or other refuse accumulates to create a fly breeding site where fly larvae are present.

Deep litter: Apply NEPOREX 2SG by spraying approximately 3 days after manure removal and repeat treatment after each removal or when fly larvae are found. Treat entire manure surface and wet spots around feed troughs and water troughs.

Poultry Facilities

Apply NEPOREX 2SG by spraying the entire manure area approximately 1 week after manure removal. Repeat treatment after each removal or when fly larvae are found.

Horse Barns (for horses not intended for slaughter or food)

Stalls, manure pile: Treat all areas where manure, spilled feed, and/or moisture accumulate. Scatter or spray treatment sites. Scatter NEPOREX 2SG underneath bedding on stall floors after cleaning. Repeat treatment after each removal or when fly larvae are found.

STORAGE AND DISPOSAL

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

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

Container: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. 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.

Storage: Store in a cool, dry place. Do not store this product under wet conditions. Avoid direct sunlight and temperatures exceeding 95° F (35° C).

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Distributed by: Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408

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