

70585-7

6/11/2007

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U.S. ENVIRONMENTAL PROTECTION
AGENCYOffice of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460EPA Reg.
Number:
70585-7Date of
Issuance:

JUN 11 2007

Term of Issuance:
ConditionalName of Pesticide Product:
Neporex 2SG

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Norvartis Animal Health
3200 Northline Avenue
Greensboro, NC 27408

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. You will submit and/or cite all data required for registration/reregistration 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. You will make the following label changes before you release the product for shipment:

a. Revise the EPA Registration Number to read "EPA Registration Number 70585-7."

b. You may delete the "If on skin or clothing", "If Swallowed" and "If inhaled" sections since the toxicity category for these routes of exposure is IV.

Signature of Approving Official:

Date:

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EPA Reg. No. 70585-7

c. Make the following revisions to the warranty statement:

1. Change "should be followed" to "must be followed" in the second paragraph.

2. Add "To the extent consistent with applicable law" to the beginning of the following sentences: "NAHUS makes no warranties xxx etc.", "The exclusive remedy of the user or buyer ... etc" and "In no event shall NAHUS or Seller... etc.".

d. Under "Notes" item (5) following the first sentence add "Do not apply more than 4 tons of manure treated with Neporex 25G per acre per year."

e. Delete "Other Fly Breeding Sites" on page 7 and front panel. These additional sites were not on the labeling with your initial application nor were they assessed by all science divisions.

3. The efficacy data provided in MRIDs 4650802, 46550803, and 46550808 are adequate to conditionally support the registration of the subject formulation. However, you must submit the numeric data for each observation interval and the raw data sheets within 3 months of the date of this registration notice. See the enclosed efficacy review.

ACUTE TOXICITY REVIEW

STUDY	MRID	CATEGORY	CLASSIFICATION
Acute Oral	46550825	IV	Acceptable
Acute Dermal	46550827	IV	Acceptable
Acute Inhalation	46550828	IV	Waived
Eye Irritation	46550831	III	Acceptable
Dermal Irritation	46550833	IV	Acceptable
Dermal Sensitization	46550835	Negative	Acceptable

A copy of the reviews are enclosed for your records.

4. Please submit two (2) copies of your final printed labeling before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

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Neporex® 2SG

For control of fly larvae in cattle, hog, and poultry operations, and certain other fly breeding sites

Active Ingredient:

Cyromazine: (CAS No. 66215-27-8) 2.0%

Other Ingredients: 98.0%

Total: 100.0%

EPA Reg. No. 70585-

EPA Est. 79789-DEU-1

Product ID. _____

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See additional precautionary statements on label.

25 pounds
Net Weight

ACCEPTED
with COMMENTS
in EPA Letter Dated
JUN 11 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
70585-7

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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	

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 should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop 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. NAHUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

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. **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.

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, Horse Barns Where Horses are not Intended for Slaughter or Food, plus Certain Other Fly Breeding Sites

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

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 on fly breeding sites with a knapsack sprayer or with automatic 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 TREATED MANURE TO SMALL GRAIN CROPS THAT WILL BE HARVESTED OR GRAZED, OR ILLEGAL RESIDUES MAY RESULT.

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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.

Other Fly Breeding Sites

NEPOREX 2SG may be used in fly breeding sites **outdoors** around the following: dog kennels, dumpsters, latrines, dumps, incinerators, recycling areas, zoos, canneries, dairy, meat, and poultry processing plants, food processing plants, horse barns, and **outside** around agricultural production facilities like broiler houses, turkey houses, caged layer houses, feedlots, dairy barns, and swine confinement buildings. Scatter or spray treatment sites where 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: 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.

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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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Novartis Animal Health US, Inc.
Greensboro, North Carolina 27408

[internal label code]