

70585-6

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)

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
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Application for Pesticide - Section I

1. Company/Product Number <p style="text-align: center;">70585-6</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;">Novartis Cyromazine Technical Spec Ground</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: <p style="text-align: center; font-size: 24px; font-weight: bold;">NOTIFICATION</p> EPA Reg. No. _____ <p style="text-align: center; font-size: 24px; font-weight: bold;">SEP 2 - 2010</p> Product Name _____

Section - II

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

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 both under applicable law.		6. Date Application Received <p style="font-size: 24px; font-weight: bold;">(Stamped)</p>
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: 24px;">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

**NOVARTIS CYROMAZINE TECHNICAL SPEC GROUND
EPA REG. NO. 70585-6
NOTIFICATION OF LABEL CHANGE PER PR NOTICE 2007-4**

Novartis Animal Health US, Inc. is submitting this Notification for Novartis Cyromazine Technical Spec Ground, EPA Reg. No. 70585-6. 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.

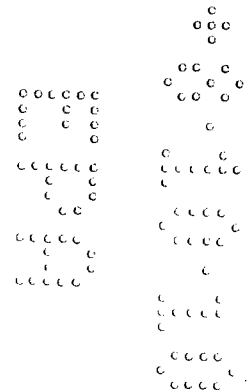
Sincerely,



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

Enclosures

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



(Import Label)

NOTIFICATION

Novartis Cyromazine Technical Spec Ground

SEP 2 - 2010

For use only in the formulation of end-use products used in layer and breeder chicken operations

Active Ingredient:	
Cyromazine: (CAS No. 66215-27-8)	97.0%
Other Ingredients:	3.0%
Total:	100.0%

Product of China

EPA Reg. No. 70585-6

EPA Est. 75813-CHN-1

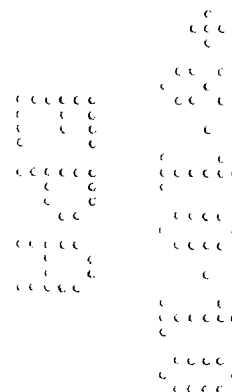
Product ID. 80000

KEEP OUT OF REACH OF CHILDREN.

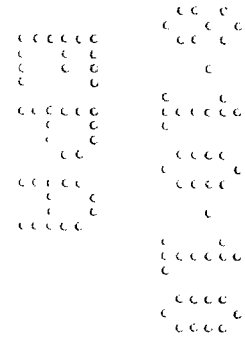
CAUTION

See additional precautionary statements on label.

77.1 pounds (35 kilograms)
Net Weight



FIRST AID	
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.
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 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.
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	
INTERNATIONAL HOT LINE NUMBER For 24 Hour Medical Emergency Assistance (Human or Animal) or for Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call +41 61 696 33 33	



PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

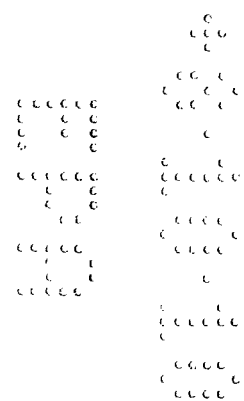
Harmful if inhaled or absorbed through the skin. Avoid breathing dust. Avoid contact with skin or clothing. May cause skin sensitization reactions in certain individuals. Wash thoroughly with soap and water after handling.

Environmental Hazards

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.

Chemical and Physical Properties

Please refer to: Technical bulletins, technical labeling for formulated products, or other appropriate information for cyromazine



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. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NOVARTIS and Seller harmless for any claims relating to such factors.

NOVARTIS 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 NOVARTIS, and Buyer and User assume the risk of any such use. NOVARTIS 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 NOVARTIS 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 NOVARTIS 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 NOVARTIS OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

NOVARTIS 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 NOVARTIS.

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INSTRUCTIONS FOR FORMULATION

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

Only for the formulation of end-use products used in layer and breeder chicken operations.

For use only by authorized formulators. Refer to appropriate technical bulletins furnished by Novartis for instructions for formulation and other information.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place. Do not store this product under wet conditions.

Pesticide Disposal

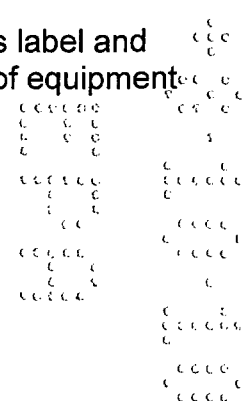
Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling

Nonrefillable container. Do not reuse or refill this container. Completely empty container including any liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused to contain additional cyromazine technical, dispose of in the same manner as the liner.

Emergency Response

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.



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The Novartis logo is a trademark of Novartis AG

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Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro, North Carolina 27408

[internal label code]

