

1117-48

3/8/2013

1/4



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 8 2013

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. John Baker
Pfizer, Inc.
7000 Portage Road, KZO 300-430SW
Kalamazoo, MI 49001

Subject: Fort Dodge Nolvasan S
EPA Registration Number 1117-48
Your Notification Dated January 30th, 2013
EPA Received Date February 6th, 2013

The notification referred to above, submitted in connection with the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to update and revise the Storage and Disposal section as per PR Notice 2007-4, is acceptable.

The notification has been part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7510P)

214

Please read instructions on reverse before completing form.

Form Approved

OMB No. 2070-0080

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1117-48	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Nolvasan S	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Pfizer Inc 7000 Portage Road, KZO 300-403SW Kalamazoo, MI 49001 <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: EPA Reg. No. _____ 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. (see full statement on attached page)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container pint and gallon		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product self-adhesive label		<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 John B Baker		Title Associate Director		Telephone No. (Include Area Code) (269) 833-3904	
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 (Stamped)
2. Signature <i>John B Baker</i>		3. Title Associate Director			
4. Typed Name John B Baker		5. Date January 30, 2013			

EPA Reg. No. 1117-48
Notification to EPA 30JAN2013
Page 2

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, 154.144, 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, 154.144, 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.

A collection of 15 small, stylized line drawings of various insects, including beetles, flies, and bees, arranged in a grid-like fashion.

4/4

Veterinary or Farm Premises

1. Remove all animals and feed from premises, vehicles and other equipment.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing litter and manure.
7. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Nolvasan S final use dilutions may be applied by wiping, mopping, or spraying on the inanimate surface.

When applying by wiping, mopping, or spraying: Applicators or other handlers must wear long-sleeve shirt and long pants, socks plus shoes, and rubber gloves. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Entry Restrictions: Thoroughly ventilate buildings, vehicles, and closed spaces following application. Do not enter, allow other persons to enter, house livestock, or use equipment in the treated area until ventilation is complete and the liquid chlorhexidine diacetate has been absorbed, set or dried.

User Safety: Follow manufacturer's instructions for cleaning/maintaining personal protective equipment. If there are no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets on or inside it, then wash both skin and clothing thoroughly and put on clean clothes. Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash skin and clothing thoroughly and change into clean clothes.

For further information contact Pfizer Animal Health at 1-800-366-5288.

2049000
13933800

Nolvasan® S

Chlorhexidine diacetate

Scented Disinfectant

Bactericide Virucide†

For Animal Premises Use Only

Active Ingredient:

1,1'-Hexamethylenebis [5-(p-chlorophenyl) biguanide] diacetate

Other Ingredients

2%

98%

100%

The product contains the active ingredient at 0.021 pounds per pint.

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

1 Pint (473 mL)



For cleaning, disinfection, deodorizing

Recommended Concentration For Use

†For disinfection of inanimate objects to aid in control of canine distemper virus, equine influenza virus, transmissible gastroenteritis virus, hog cholera virus, parainfluenza-3 virus, bovine rhinotracheitis virus, bovine viral diarrhea virus, infectious bronchitis virus, Newcastle virus, Venezuelan equine encephalitis virus, equine rhinopneumonitis virus, feline rhinotracheitis virus, pseudorabies virus, equine arteritis virus and canine coronavirus — 3 ounces (6 tablespoonfuls) per gallon of clean water. Nolvasan S has been shown to be virucidal *in vitro* against rabies virus (CVS strain) in laboratory tests when used as directed above.

For disinfection of veterinary or farm premises — 1 ounce (2 tablespoonfuls) per gallon of clean water. Not effective against *Pseudomonas aeruginosa* or gram-positive cocci on inanimate surface.*

*According to A.O.A.C. Use Dilution Test Method.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)
Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.
Remove contaminated clothing and wash before reuse.

DANGER

Corrosive: Causes irreversible eye damage. Wear protective eyewear (goggles, face shield or safety glasses.) Harmful if swallowed or absorbed through skin or inhaled. May be fatal if inhaled. Avoid breathing spray mist. Avoid contact with skin or clothing and do not swallow. Wear rubber gloves when handling or applying.

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.

IF SWALLOWED: 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 by a poison control center or doctor.

IF ON SKIN: 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 INHALED:** 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. Call a poison control center or doctor for further treatment.

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. Do not contaminate water by cleaning of equipment or disposal of waste.

STORAGE AND DISPOSAL

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

Pesticide Storage: store in a cool, dry place inaccessible to children.

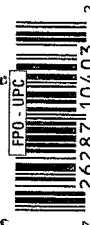
Container Disposal: Do not reuse or refill this container. Offer for recycling if available. Triple rinse container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Follow. Pesticide Disposal instructions for onsite disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture, not up off, and incinerate in a landfill.

Pesticide Disposal: pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

EPA Est. No. 1117-IA-2
EPA Reg. No. 1117-48

Distributed by: Farn Dodge Animal Health
a wholly owned subsidiary of Pfizer Inc.
New York, NY 10027

Lot:
Exp. Date:



Time/Date: 13933800.indd 1 1/30/13 8:52 AM

	Project No.		Artwork Number		Description		Country		
	11530		13933800		Nolvasan S		US		
	Dimensions		Drawing No.		SKU No.		Item		
rev. 08JUN11		5.75" x 7.25"		131		2049000		Label	
Additional Info:		Colors:						<input type="checkbox"/> EDITOR'S COPY	
BIVI # 0405U		PMS 287 PMS 107 Wyeth Red Dieline No Varnish						GS: DATE:	
Resource # L0405									
Mgr	C. Andrews	Rev	GA	PR	CHANGES	GS / ART REV (LCA)	CHANGES	GS / ART REV (FA)	CHANGES
GS	A. French	1			OK		OK		OK
GA	L. Nelson								