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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 Solution
EPA Registration Number 1117-30
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 that reads "M. Swindell".

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

Please read instructions on reverse before completing form.

Form Approved MB No. 2070-0080

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11 17-30	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Nolvasan Solution	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
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 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
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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 (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. 1117-30
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.

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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. Nolvasan Solution final use dilutions may be applied by wiping, mopping, or spraying on the inanimate surface. It may also be used in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's directions.

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.

When applying by wet-mist fogging: Applicators and other handlers exposed to the fog during wet-mist fogging applications and until the fog has dissipated and the enclosed area has been thoroughly ventilated must wear: Long sleeve shirt and long pants, rubber gloves, socks plus shoes, and a full face respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14-G).

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.

For entry into fogged areas before ventilation is complete and the fog has completely dissipated, absorbed, set, or dried, all persons must wear: Long sleeve shirt and long pants, rubber gloves, socks plus shoes and a full face respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14-G).

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.

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.

For use in federally inspected meat, poultry, rabbit and egg establishments

1. All food products and packaging material must be removed from the room or carefully covered and protected.
2. Remove any loose dirt, litter, etc., that might be lying on floor or attached to the equipment.
3. Thoroughly clean all surfaces with soap or detergent and rinse with water.
4. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
5. Expose or soak all equipment and/or utensils with the recommended disinfecting solution for a period of 10 minutes.
6. After disinfection all equipment and/or utensils must be thoroughly rinsed with potable water before operations are resumed.

For dipping teats as an aid in controlling bacteria that causes mastitis

Immediately after the cow is milked dip each teat into the dipping solution. Teat dipping should start one week before the cow freshens. When drying off a cow, the teats should continue to be dipped once a day for 3 to 4 days. Udder and teats of the cow must be thoroughly washed before milking.

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Nolvasan Solution

Chlorhexidine diac

Disinfectant

Bactericide Virucide†

For Animal Premises Use O

Active Ingredient:
Chlorhexidine (1,1'-Hexamethylenebis [5-(p-chlorophenyl) biguanide]) diacetate

Other Ingredients

The product contains the active ingredient at 0.1 gallon.

KEEP OUT OF REACH OF CHILDREN
DANGER
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

1 Gallon (3.7



Time/Date: 13933900.indd 1 1/28/13 11:00 AM

 rev. 08JUN11	Project No.	Artwork Number	Description		Country
	11530	13933900	Nolvasan Solution		US
	Dimensions		Drawing No.	SKU No.	Item
5" x 14"		129	2055000	Label	
Additional Info:		Colors:			<input type="checkbox"/> EDITOR'S COPY
BIVI # 0626Q Resource # L0626		<input type="checkbox"/> PMS 287 <input type="checkbox"/> PMS 107 <input type="checkbox"/> Wyeth Red <input type="checkbox"/> Dieline <input type="checkbox"/> No Varnish			GS: DATE:
Mgr	C. Andrews	Rev	GA	PR	GS / ART REV (LCA)
GS	A. French	1		CHANGES	CHANGES
GA	L. Nelson			OK	OK

Nolvasan[®] Solution

Chlorhexidine diacetate Disinfectant

Bactericide Virucide†
For Animal Premises Use Only

Active Ingredient:
Chlorhexidine (1,1'-Hexamethylenebis
[5-(p-chlorophenyl) biguanide]) diacetate

Other Ingredients

The product contains the active ingredient at 0.168 pounds per gallon.

2%
98%
100%

KEEP OUT OF REACH OF CHILDREN
DANGER
SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

1 Gallon (3.7 L)



Recommended Concentration For Use

- I. For disinfection of inanimate objects to aid in control of canine distemper virus, hog cholera virus, parainfluenza-3 virus, bovine rhinotracheitis virus, Newcastle virus, Venezuelan equine encephalitis virus, equine rhinopneumonitis, equine arteritis virus and canine coronavirus — 3 ounces (6 tablespoons) to be virucidal *in vitro* against rabies virus (CVS strain) in laboratory tests with 1 gallon clean water.
- II. For disinfection of veterinary or farm premises — 1 ounce (2 tablespoons) per gallon clean water.
- III. For use in federally inspected meat, poultry, rabbit and egg establishments — For dipping teats as an aid in controlling bacteria that causes mastitis. Make up of Nolvasan Solution in a clean gallon container, adding 6 ounces of glycerin and 1/2 ounce of sodium hypochlorite.
- IV. Not effective against *Pseudomonas aeruginosa* or gram-positive cocci on inanimate surfaces.

PRECAUTIONARY STATEMENTS — HAZARDS TO HUMANS (AI)
Prolonged or frequently repeated skin contact may cause allergic reaction. Remove contaminated clothing and wash before reuse.

DANGER

Corrosive: Causes irreversible eye damage. Wear protective eyewear (goggles, face shield or safety glasses).
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. 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. If person is not breathing, call 911 or an ambulance, then give artificial respiration, 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 bodies of water. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewerage authority. For further information contact your State Water Board or Regional Office of the EPA. Do not contaminate water by cleaning of equipment.

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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or in a sanitary landfill.
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mix, or empty containers may be hazardous to humans. Do not reuse or refill this container. Offer for recycling if available or in a sanitary landfill. These wastes cannot be disposed of by use according to label instructions; contact your State Pesticide or Waste representative at the nearest EPA Regional Office for guidance.

For further information contact
Pfizer Animal Health at 1-800-366-5288
EPA Est. No. 1117-IA-2 EPA Reg. No. 1117-30

inate surface. It may also be used in
sintecting procedures. Fog (wet mist)
eve shirt and long pants, socks, plus
mist fogging applications and until the
and long pants, rubber gloves, socks
number prefix TC-14-G).
gh drift. Only protected handlers may
Do not enter, allow other persons to
uid chlorhexidine diacetate has been
rbed, set, or dried, all persons must
in a canister approved for pesticides
ent. If there are no such instructions,
/ from other laundry.
ilet. Users should remove clothing,
clean clothes. Users should remove
efore removing. As soon as possible,
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imals, as well as forks, shovels and
waterers with soap or detergent, and
hments
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eriod of 10 minutes.
ore operations are resumed.
stills
it one week before the cow freshens.
feats of the cow must be thoroughly
2055000
13933900

Description		Country	
Nolvasan Solution		US	
Drawing No.	SKU No.	Item	
129	2055000	Label	
No Varnish		<input type="checkbox"/> EDITOR'S COPY	
CHANGES	GS/ART REV (LCA)	GS:	DATE:
OK	CHANGES	GS/ART REV (FA)	CHANGES
	OK		OK

Recommended Concentration For Use

- I. 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 diarrhoea 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 tablespoons) per gallon of clean water. *Nolvasan Solution has been shown to be virucidal in vitro against rabies virus (CVS strain) in laboratory tests when used as directed above.*
 - II. For disinfection of veterinary or farm premises — 1 ounce (2 tablespoons) per gallon of clean water.
 - III. For use in federally inspected meat, poultry, rabbit and egg establishments — 1 ounce (2 tablespoons) of Nolvasan Solution to each gallon clean water.
 - IV. For dipping teats as an aid in controlling bacteria that causes mastitis. Make up a final dipping solution by putting 32 ounces (one quart) of Nolvasan Solution in a clean gallon container, adding 6 ounces of glycerin and then adding clean potable water until you have a total volume of one gallon.
- 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.
- 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

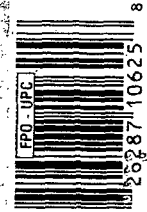
- Do not contaminate water, food or feed by storage or disposal.
- Pesticide Storage:** store in a cool, dry place inaccessible to children.
- Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal Instructions for rinsate 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 and dispose of in a sanitary 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.

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

Distributed by: Fort Dodge Animal Health
a division of Wyeth
a wholly owned subsidiary of Pfizer Inc
New York, NY 10017

EPA-Est. No. 1117-IA-2 EPA Reg. No. 1117-30

Lot:
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