

1117-48

01/17/2002

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

1117-48

Date of Issuance:

JAN 17 2002

NOTICE OF PESTICIDE:

☐ Registration
☒ Reregistration

(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Fort Dodge Nolvasan S

Name and Address of Registrant (include ZIP Code):

Fort Dodge Animal Health
100 5th Street, N.W.
Fort Dodge, IA 50501

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.

Based on your response to the Reregistration Eligibility Document for Chlorhexidine Diacetate RED, EPA has reregistered the above name product subject to the comments recorded in the succeeding paragraph. This action is taken under the authority of section 4(g)(2)(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

1. Make the following label changes:

- a. Revise the EPA Registration Number to read "EPA Reg. No. 1117-48".

Signature of Approving Official:

Marshall Swindell, PM 33
Regulatory Management Branch 1
Antimicrobial Division (7510W)

Date:

JAN 17 2002

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b. The heading "Statement of Practical Treatment" must be changed to "First Aid" and the statements must be revised as follows:

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.

d. Revise the "Precautionary Statements" that appear under the subheading "Hazards to Humans and Domestic Animals" to include the following statements:

"Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Remove contaminated clothing and wash before reuse".

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- e. In the Storage and Disposal section, remove the statement "Do not contaminate water.... and disposal" and place directly below the "Storage and Disposal" heading.
- f. Delete the subheading "Prohibitions" and add the following statement to read:

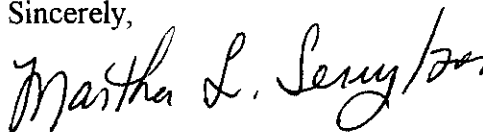
"Storage Disposal: Do not reuse empty container. Protect from freezing."
- g. The statement "Open dumping is prohibited" must be moved to the Pesticide Disposal subsection.
- h. A "Physical and Chemical Hazards" heading is required and place the following statement currently under the Storage and Disposal section "Do not use or store near heat or flame".
- i. The common name "Chlorhexidine" must be placed in front of the chemical name.
- j. A statement "The product contains the active ingredient at 0.168 pounds per gallon" must be placed directly under the ingredient statement.
- k. The entire text for the Environmental Hazards section must be included on the label.
- l. The label must bear an expiration date in a prominent position on the label in accordance with 40 CFR 156.10(g)(6) as follows: "Not for sale or use after (date)."

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure

Fort Dodge Animal Health
Label Control

r: 4 / op: drs / id#: 0406N

06/24/97

code: FDL Size: 14" x 5"

Fort Dodge Nolvasan S 1 gallon label

file location: HD/proot folder/

0406N/0406N

■ PMS 18

■ PMS 28

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.

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.

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.

Nolvasan® S

Chlorhexidine diacetate

Scented Disinfectant

Bactericide Virucide†

For Animal Premises Use Only



Active Ingredient:

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

2%

Inert Ingredients

98%

100%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

1 Gallon (3.7 L)

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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 virus 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 (5 tablespoonfuls) per gallon of clean water. Notvasan 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) DANGER

Corrosive: Causes eye damage. Do not get in eyes. Wear protective eyewear (Goggles, face shield or safety glasses.) May be fatal if inhaled: Do not breathe spray mist.

Avoid contact with skin or clothing and do not swallow. Wear rubber gloves when handling or applying.

Statement of Practical Treatment

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

If on skin: Wash with plenty of soap and water. Get medical attention if irritation observed.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Environmental Hazards

Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of waste.

STORAGE AND DISPOSAL

PROHIBITION: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container. Protect from freezing. Do not use or store near heat or open flame.

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

CONTAINER DISPOSAL: Do not reuse containers. Rinse thoroughly with water and discard in trash.

GENERAL: Consult federal, state or local disposal authorities for approved alternative procedures such as limited open burning.

Fort Dodge Animal Health

Fort Dodge, Iowa 50501 USA

EPA Est. No. 1117-IA-2

EPA Reg. No. 1117-48

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 17 2002

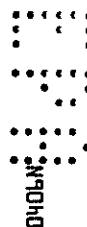
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

1117-48

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Lot
Exp. Date



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