

PM 31 1117-30

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 26 1994

Fort Dodge Laboratories
800 5th Street N.W.
Fort Dodge, Iowa 50501

Attn: Debra Webb
Regulatory Affairs Associate

Subject: Nolvasan Solution
EPA Registration No. 1117-30
Amendments dated March 3, 1994 and
March 14, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to change the statement "For disinfection of official meat, poultry, rabbit and egg establishments" to "For disinfection of federally inspected of meat, poultry, rabbit and egg establishments" on the product label, is acceptable.

The revised Confidential Statement of Formula (CSF) dated March 14, 1994 for the basic formulation is in compliance with PR Notice 91-2, agrees with the label claim, (the nominal concentration) and is acceptable.

Please note for the unregistered source of the active ingredient, you must submit all product chemistry data for the technical grade active ingredient.

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

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,



Marshall Swindell
Acting Product Manager 31
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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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.

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. Ventilate buildings, vehicles and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried.
8. 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 disinfection of 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.
7. Nolvasan Solution may 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 use directions.

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

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)**

CAUTION

May be harmful if swallowed. May be irritating to eyes or mucous membranes. In case of contact, immediately flush eyes with plenty of water. Get medical attention if irritation persists.

Environmental Hazards

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

Nolvasan[®]
Solution
 Chlorhexidine diacetate
 Disinfectant
 Bactericide Virucide†



Active Ingredient:	
1,1'-Hexamethylenebis [5-(p-chlorophenyl) biguanide] diacetate	2%
Inert Ingredients	98%
	100%

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

1 Gallon (3.7 L)

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
APR 26 1994

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act
 as amended, for the pesticide
 registered under EPA Reg. No.
 111-30

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Nolvasan Solution

Chlorhexidine diacetate

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, paramfluenza-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 (6 tablespoonfuls) 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 tablespoonfuls) per gallon of clean water.
- III. For disinfection of federally inspected meat, poultry, rabbit and egg establishments — 1 ounce (2 tablespoonfuls) 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.

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.

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 Laboratories, Inc.

Fort Dodge, Iowa 50501 USA

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

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0626K

Lot
Exp. Date



BEST AVAILABLE COPY

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code: FDL job: 5124 Fort Dodge Nolvasan Solution 1 gallon label
14" x 5" 0626K