

1117-48

04/14/1966

1/6

U. S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
PESTICIDES REGULATION DIVISION

REGISTRATION NO.

1117-48

DATE OF ISSUANCE

April 14, 1966

NAME OF ECONOMIC POISON

NOLVASAN-S (CHLORHEXIDINE)

**NOTICE OF REGISTRATION UNDER THE FEDERAL
INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT**

NAME AND ADDRESS OF REGISTRANT

Fort Dodge Laboratories, Inc.
P. O. Box 515
Fort Dodge, Iowa 50502

Attention: Dr. J. R. Eppley

NOTE: Changes in labeling or formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Pesticides Regulation Division prior to use of the label in interstate commerce. In any correspondence on this product always refer to the above registration number.

On the basis of the information furnished by the registrant, the above named economic poison is hereby registered under Section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this registration is returned herewith.

Registration is in no way to be construed as an endorsement or approval of this product by this Department. In order to protect the public, the Secretary, on his own motion, may at any time cancel the registration of an economic poison in accordance with Section 4 (c) of 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 a trademark held by others.

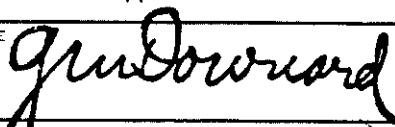
The following paragraphs are applicable only when checked:

- ☒ To expedite registration, this notice is being issued on the basis of the draft submitted with the application. Certain defects, given below, have been noted. These corrections must be incorporated when the printed labeling is prepared. Five copies of the printed labeling must be submitted to complete the file on this product.
- ☐ The registration for this product is being issued with the understanding that certain defects in the labeling which are noted below will be corrected as soon as possible. Objection is not raised to the use of the present labeling for a reasonable period of time while fully corrected labeling is being prepared. Five copies of the corrected labeling must be submitted.
- ☒ 1. We are not familiar with the name of the active ingredient given in the ingredient statement. If you have not verified that this is the name used by Chemical Abstracts, you should request Dr. Kurt L. Loening, Nomenclature Director, Chemical Abstracts Service, The Ohio State University, Columbus, Ohio, 43210, to furnish you with this name.

kst

☐ Attachment is applicable.

SIGNATURE



HEAD, REGISTRATION SECTION
PESTICIDES REGULATION DIVISION

PR FORM 9-225
OCT. 1964

EXISTING STOCK OF PR FORM 9-225, MAR. 1962, WILL BE USED UNTIL EXHAUSTED

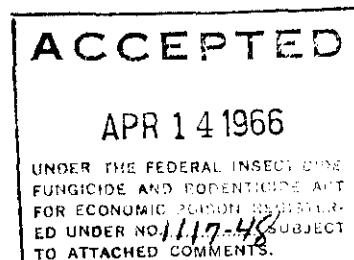
Label Copy
7-13-65

{ 1 Gallon }
{ 1 Pint }

FORT DODGE ^R

NOLVASAN^{*}-S

(CHLORHEXIDINE)



Active ingredient:

Hexamethylenebis (p-chloro-phenyl-diguanide) diacetate . 2%
Inert ingredients 98%

General Directions for Disinfection

After thorough washing, rinse the containers or utensils in a solution made by adding 1 tablespoonful of Nolvasan to each gallon of clean water.

For aiding in the control of virus diseases, such as infectious bronchitis or canine distemper-clean the walls, cages or utensils thoroughly and spray the surfaces with a diluted Nolvasan solution by adding 1 or 2 tablespoonfuls to each gallon of clean water.

CAUTION: May be irritating to eyes or mucous membranes. Avoid contamination of feed and foodstuffs.

Fort Dodge Laboratories, Inc.

Fort Dodge, Iowa

L_____

Made in U.S.A. by arrangement with Imperial Chemical Industries Limited

Sales to Veterinarians Only

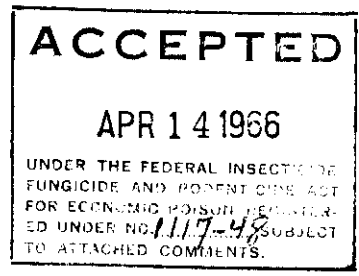
* R 619,354 of related company

Caution: Keep out of reach of children.

Leaflet Copy
7-12-65

FORT DODGE ^R

Nolvasan ^R
chlorhexidine



The unique
antiseptic
disinfectant
bactericide
fungicide
virucide

Nolvasan is unique among antibacterial agents in that it is unrelated to any drugs or antibiotics used in the prevention or treatment of bacterial infections.

It is a synthetic chemical (chlorhexidine) which is alkaline in reaction, slightly soluble in water, and which possesses high efficacy in low concentrations. Its phenol coefficient is higher than that of any disinfectant heretofore available.

The bactericidal potential of Nolvasan is so high it may be diluted 10,000 times and still be equal to 5% phenol in bactericidal activity when tested by the official A.Q.A.C. Phenol Coefficient Method.

It is nonirritant and nontoxic on intrauterine, topical and oral administration in recommended concentrations. Nolvasan is characterized by its broad-spectrum activity and its wide field of application against both gram-positive and -negative bacteria associated with most common diseases

ACCEPTED

APR 14 1966

IF THE FORMER
RECEIVED FROM THE
FOR THE USE OF THE
ED UNDER NO. 1117-1118
TO ATTACHED FORM 1117

-2-

of animals, as well as infections by certain fungi and viruses.

In the solution form, it excels conventional disinfectants in destroying, swiftly and efficiently, organisms associated with outbreaks of mastitis; and its use in mastitis control programs materially reduces the incidence of the disease.

Successful treatment of sterility of cattle caused by *Vibrio foetus* and *Corynebacterium pyogenes* has been reported.

Nolvasan is not inactivated by organic matter usually present where disinfection is indicated, and has no objectionable odor. It can be highly recommended for veterinary hospital disinfection since it is effective against the prevalent bacteria and viruses.

The Five Forms of Nolvasan

Solution (2% diacetate). Recommended for use in dilution of 1/2 to 1 ounce per gallon of clean water. The solution is not inactivated when diluted in hard water but precipitation may occur on standing. It is inactivated by soap, but not by the non-ionic and cationic detergents.

Usages -

- (a) General disinfection: Premises (veterinary hospitals, dairy buildings, poultry processing plants) and equipment (operating tables, dairy utensils, udder cloths and teat-cups).
- (b) Cleansing: Udders and infected wounds. Does not cause chapping of teats or drying out of the skin of the udder.
- (c) Irrigation: Vagina, uterus, prepuce and fistulous tracts.

In gallons.

ACCEPTED

Apr. 14 1966

UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED, FOR REVIEW OF THE PRODUCT OF THE ABOVE NAMED MANUFACTURER TO DETERMINE IF THE SAME COMES WITHIN THE SCOPE OF THE ACT AND TO ATTACH RECOMMENDATIONS.

1117-98

Nolvasan 'S'. A heavily scented solution which fulfills the need for a sanitizing agent which will also effectively prevent and mask hospital odors. In pints and gallons.

Ointment (1% diacetate). A bland, soothing, hydrophilic cream. Nonirritating and may be used under bandage if desired.

Indications -

(a) Topical application in infections and wounds of ear, prepuce, vagina, teats, udder, and skin. A valuable aid in treatment of ringworm, dermatitis and external ear infections in small animals.

(b) Application to hands and arms of operator to remove odor and prevent infection.

Packages 12/1 oz. tubes and 12/8 oz. jars.

Cap-tabs (1 Gm. dihydrochloride). Effervescent action distributes the medication over entire infected area. For treatment of bacterial infections associated with metritis, pyometra, and retained placentas accompanied with accumulation of fluids in the uterus. Insert 1 to 2 cap-tabs in each uterine horn. If uterus is dry use 2 to 3 oz. of Nolvasan Solution (2%) in 500 cc. or more water.

In bottle of 50 cap-tabs.

Suspension (1 Gm. dihydrochloride). In disposable syringe. For treatment of metritis, vaginitis, and preputial infections caused by susceptible bacteria. This preparation is specially formulated for intrauterine administration through an artificial insemination pipette when the cervix is constricted.

This suspension is satisfactory for treatment of penetrating wounds and external ear infections, but should not

6/6

-4-

be used in udder infusion or treatment of dermatitis.

28 cc. plastic syringe and pipette.

'Nolvasan' made in U.S.A. by arrangement
with Imperial Chemical Industries Ltd.

Fort Dodge Laboratories, Fort Dodge, Iowa

