

1117-61

PM-03

06-09-97 10f2

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060. Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
 Other

OPP Identifier Number
253506

Application for Pesticide - Section I

1. Company/Product Number Fort Dodge Animal Health/1117-61		2. EPA Product Manager George T. LaRocca		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Fort Dodge Animal Health/Nolvamite		PM# 13			
5. Name and Address of Applicant (Include ZIP Code) Fort Dodge Animal Health 800 5th Street N.W. Fort Dodge, Iowa 50501 <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 type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request for exemption per 40 CFR 157.24

NOTIFICATION
JUN 9 1997

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	If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.75 ounce		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 <input checked="" 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 Debra Webb	Title Manager, Pharmaceutical Regulatory Affairs	Telephone No. (Include Area Code) 515-955-4600	
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)
Signature 		3. Title Manager, Pharmaceutical Regulatory Affairs	
4. Typed Name Debra Webb		5. Date 3/7/97	

282

Fort Dodge Animal Health
Label Control

r.2 / op.06 / Mf. 0299E
06/12/97 Size: 4 1/4" x 3 1/4" x 3 1/2"
code:FDL Fort Dodge Nolvamite 3/4 fl oz 12 unit
carton
file location: HD\pascal\label\0299E\0299E

PMS 185
PMS 287

Nolvamite®

With Nolvasan®*

For Control of Ear Mites in Dogs and Cats

NOTIFICATION
JUN 9 1997

For Control of Ear Mites
in Dogs and Cats

Nolvamite®

With Nolvasan®*

PRECAUTIONARY STATEMENTS (AND DOMESTIC ANIMALS)
Hazardous to Humans (And Domestic Animals)
Irritant if swallowed. Avoid contact with skin and eyes. Do not contaminate food or feed with this solution.
Do not use for prolonged period of time if condition persists or, if irritation develops, discontinue use and consult a veterinarian. Do not apply if there is suspected damage to the ear drum.
Irritation may occur after using any pesticide product for pets. If signs of irritation occur, wash the pet's face with large amounts of water. If signs continue, contact your veterinarian immediately.

Environmental Hazards
This product is toxic to fish, bees and other wildlife. Do not contaminate any body of water with this solution, or by cleaning of equipment.
Physical and Chemical Hazards
Do not store of use near heat or open flame.



EPH Reg. No. 110241 Fort Dodge Animal Health Fort Dodge, IA 50501 USA EPH Est. No. 117-04-1

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Shake well before use.

For External Use Only

To Control Ear Mites in Dogs and Cats
Apply sufficient Nolvamite solution into each ear to coat surface of the ear canal. Gently massage the base of ear. Leave solution in ear for a few minutes and carefully wipe the excess liquid and debris from the ear with cotton. Do not massage for 7 days. Do not use on dogs less than 6 weeks of age. Do not use on debilitated, aged, pregnant or nursing animals. This solution applied twice monthly will reduce the possibility of ear mite infestation.
For further information contact Fort Dodge Animal Health at 1-800-477-1985.

6648
9107
0299E
6645
0299E

READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS OR CATS.

FIRST AID

IF SWALLOWED: Call Physician
Flush with plenty of water. Get medical attention if irritation persists.
IF IN EYES: Wash with soap and warm water.
IF ON SKIN: Remove victim to fresh air and call a physician if effects occur.
IF INHALED: Remove victim to fresh air and call a physician if effects occur.

STORAGE AND DISPOSAL

Store in a cool area away from heat or open flame.
Do not reuse empty container. Wrap container and put in trash collection.

Active Ingredients:
Pyrethrin
Piperonyl butoxide, Technical
Inert Ingredients
100.000%
1.05%
98.952%
100.007%

*See package insert
*Subject to U.S. Federal registration requirements and U.S. state laws.

CAUTION

KEEP OUT OF REACH OF CHILDREN
SEE BACK AND SIDE PANELS FOR ADDITIONAL
PRECAUTIONARY STATEMENTS.

Contents: 12 Units - 3/4 Fl Oz (22mL) each