

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 4, 2023

J. Todd Frank Senior Regulatory Affairs Consultant Elanco US Inc. 2500 Innovation Way Greenfield, IN 46140

Subject: Notification per PRN 98-10 – Addition of Pictograms & Minor Label Changes Product Name: Rabon 7.76 Oral Larvicide Premix EPA Registration Number: 11556-160 Application Date: November 4, 2022 Decision Number: 591485

Dear J. Todd Frank:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "NOTIFICATION" and placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Notification ABN or Label Acceptable v.20220527

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If you have any questions, please contact Carmen J. Rodia, Jr. via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely,

Jamica Cair

Tamica L. Cain, Product Manager 10 Invertebrate-Vertebrate Branch 2 Registration Division (7505T)

Enclosure: Master Label Stamped "Notification", August 4, 2023

NOTE TO REVIEWER: Braces "{}" indicate notes to reviewer. Brackets "[]" indicate optional language.

RABONTM 7.76 ORAL LARVICIDE PREMIX

To prevent the development of Horn Flies, Face Flies, House Flies and Stable Flies in the manure of treated cattle, House Flies in the manure of treated swine, House Flies and Stable Flies in the manure of treated horses and House Flies in the manure of treated mink.

{[Optional marketing pictograms from page 6]}

ACTIVE INGREDIENT:	<mark>% by Weight</mark>
Tetrachlorvinphos (CAS# 22248-79-9)	7.76%*
OTHER INGREDIENTS:	<u>92.24%**</u>
Total	100.00%
*RABON Insecticide - Contains 35 grams of RABON per pound. **Refers only to ingredients which are not larvicidal.	NC

EPA Reg. No. 11556-160 EPA Est. No. TBD

NOTIFICATION

11556-160

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

08/04/2023

KEEP OUT OF REACH OF CHILDREN CAUTION

[See back panel for Precautionary Statements [and First Aid]]

	FIRST AID
lf 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 give anything by mouth to an unconscious person. Do not induce vomiting unless told to by a poison control center or doctor.
If on Skin or Clothing:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
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 further treatment advice.
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 advice.
Have the produ	HOT LINE NUMBER ganophosphate that inhibits cholinesterase. ct container or label with you when calling a poison control center or doctor or going for r additional information on this pesticide product (including health concerns, medical

emergencies or pesticide incidents), you may call <mark>1-800-428-4441</mark>] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441] [or CHEMTREC at 1-800-424-9300, 24 hours per day, 7 days per week.]

NOTE TO PHYSICIAN

This product is a cholinesterase inhibitor. If symptoms of cholinesterase inhibition are present, atropine sulfate by injection is antidotal. 2-PAM is antidotal and may be administered, but only in conjunction with atropine. Product may cause aspiration pneumonia. Probable mucosal damage may contraindicate the use of gastric lavage.

[FOR CHEMICAL EMERGENCY, Spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.]

[Net Weight: 50 lbs. (22.68 kg)]

Manufactured For: Elanco US Inc 2500 Innovation Way Greenfield, IN 46140 [U.S.A.]

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction to some individuals. Wash thoroughly with soap and water after handling.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are butyl rubber, neoprene, and polyvinyl chloride (PVC). If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

Loaders, mixers, and handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves
- Protective eyewear

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds, and other wildlife. Drift and runoff may be hazardous to aquatic organisms in adjacent areas. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or when disposing of equipment wash waters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label prior to use.

USE RESTRICTIONS

Do not apply this product in a way that will contact workers or other persons, either directly or indirectly or through drift. Only protected handlers may be in the area during application. Feeds prepared with this product should not be pelleted nor be mixed with feeds containing predominantly pellets. Further, this product should not be mixed in liquid feed supplements.

For Horses: This product contains Tetrachlorvinphos, which is a cholinesterase inhibitor. The most frequently reported clinical signs of cholinesterase in the horse are abdominal pain, lethargy, sweating, tearing and excessive salivation. If these signs are seen in horses, consult your veterinarian immediately. Do not use this product simultaneously or within a week before or after treatment with cholinesterase inhibiting drugs, pesticides, or chemicals. Consult a veterinarian before using this product on debilitated, aged, pregnant, or nursing animals. This product has not been tested in breeding horses. Do not use this product on horses destined for slaughter.

GENERAL INFORMATION

Rations containing this product may be fed up to slaughter and to lactating dairy cows without withholding the milk from market during or after treatment.

Start feeding RABON larvicidal feeds early in the spring before flies begin to appear and continue feeding throughout the summer and into the fall until cold weather restricts fly activity.

When fed, this product passes through the digestive system into the animal's manure where it kills fly larvae on contact shortly after fly eggs hatch.

In some cases, supplemental fly control measures may be needed in and around cattle lots and barns to control adult house flies and stable flies which can breed not only in manure but in other decaying vegetable matter or silage on the premises.

In order to achieve optimum fly control, this product should be used in conjunction with other good management and sanitation practices.

This product will mix uniformly in feeds when standard mixing procedures are followed. Thus, usual problems that are common to all feed preparation and which cause stratification such as excessive free-fall or excessive handling, are to be avoided. It is recommended that appropriate pre-blending techniques be employed to assure adequate distribution throughout the feed mix. The premix should be pre-blended with ground grain, protein supplements, mineral mixes, etc. before being added to roughages such as chopped hay or silage. Mixing time should be adequate to assure uniform dispersion. Optimum performance can be assured only if this product is dispersed uniformly with the feedstuff at the recommended level. Common feed mixing equipment (i.e. vertical mixer, horizontal blender, mixer/feed truck) may be used to prepare formulated feeds.

APPLICATION INSTRUCTION

This product may be fed to cows, swine and mink up to slaughter and to lactating cows.

Cattle

In a Concentrate Feed - Roughage Fed Separately

This product can be used to prepare concentrate feeds that will provide 70 mg of RABON per 100 pounds of body weight daily. To accomplish this, prepare concentrates to provide 902 mg (0.032 oz.) of Rabon 7.76 Oral Larvicide Premix per 100 lbs. of body weight daily.

To prepare a larvicidal concentrate feed, mix this product according to the amount of concentrate to be fed per animal per day. Use the following table as a guide for determining the proper mixing rate.

MIXING GUIDE			
Pounds [Lbs.] of	RABON in the concentrate		Pounds [Lbs.] of Rabon Oral Larvicide Premix
Concentrate			
Consumed per Animal	mg/lb	%	per
per Day			Ton of Concentrate
0.5	1584	0.35	90.0
1.0	792	0.18	45.0
1.5	528	0.12	30.0
2.0	396	0.087	22.5
5.0	159	0.035	9.0
10.0	79	0.018	4.5
15.0	53	0.012	3.0
20.0	39	0.0087	2.3
25.0	32	0.0069	1.8
30.0	26	0.0059	1.5

Feed the appropriate larvicidal concentrate indicated to cattle weighing between 400 and 1200 pounds. For larger cattle weighing between 1200 and 1700 pounds, increase the amount of premix per ton of concentrate to $1\frac{1}{2}$ times that indicated.

Cattle

In a Complete Ration - No Other Roughage Fed

This product can be used to prepare rations that contain 26.4 mg of RABON per pound of complete ration.

To prepare a larvicidal ration, mix 1.5 pounds of this product per ton of complete mixed ration containing both grain and roughage.

Full feed this larvicidal complete ration to feeder cattle weighing from 400 to 1400 pounds or to dairy cattle at a rate to sustain milk production, but not less than 2.6 pounds of the ration per 100 pounds of body weight daily.

Swine

All swine should be treated.

Pigs (weaners to market weight): Mix 1.3 pounds of this product per ton of meal type feed and offer free choice. This is equivalent to 22.7 mg of RABON per pound of feed.

Sows, Boars and Breeding Gilts: Mix 2.6 pounds of this product per ton of meal type feed and offer 4 to 6

pounds of feed per animal per day. This is equivalent to 45.5 mg of RABON per pound of feed.

Horses (See special note under Use Restrictions) In a Concentrate Feed

This product can be used to prepare concentrate feeds that will provide 70 mg of RABON per 100 pounds of body weight daily. To accomplish this, prepare concentrates to provide 902 mg (0.032 oz.) of Rabon 7.76 Oral Larvicide Premix per 100 lbs. of body weight daily. All horses in the stable area should be treated.

To prepare a larvicide concentrate feed, mix this product according to the amount of concentrate to be fed per animal per day. Use the following table as a guide for determining the proper mixing rate.

MIXING GUIDE				
	Pounds [Lbs.] of RABON 7.76 Oral Larvicide			
Pounds [Lbs.] of	Premix Per Ton of Concentrate			
concentrate consumed per	250 LB	500 LB	1000 LB	2000 LB
horse per day	Horse	Horse	Horse	Horse
2.5	4.0	8.0	16.0	32.0
5.0	2.0	4.0	8.0	16.0
10.0	1.0	2.0	4.0	8.0
15.0	0.7	1.4	2.7	5.4

As a Topdressing

Add this product daily to the grain or concentrate portion of the horse's diet to provide 70 mg of RABON 7.76 per 100 pounds of body weight. This is equivalent to the following: ½ tablespoon for a 250 lb. animal; 1 level tablespoon for a 500 lb. animal; 2 level tablespoons (8.8 g) for a 1000 lb. animal or 4 tablespoons for a 2000 lb. animal.

All horses in the stable area should be treated.

Mink

When fed to mink, RABON passes through the digestive system into the droppings where fly larvae are killed on contact shortly after the fly eggs hatch. This product can be mixed in mink feeds to prevent the development of house flies but should not be used as the sole method of control. It is recommended that appropriate pre-blending techniques be employed when mixing to assure an adequate distribution of RABON throughout the feed mix. Pre-blend with soybean meal, alfalfa meal, mineral mix, etc. before being added to other ingredients. Common feed mixing equipment (i.e. vertical mixers, horizontal blenders) may be used to prepare formulated feeds.

Add this product to the total feed at a rate that will ensure that each animal will consume 3 mg of RABON per kg of body weight (1-2 mg/pound) per day.

Use the following table as a guide.

MIXING GUIDE FOR MINK			
Food Consumption (lbs.)	Amount of RABON 7.76 to Mix in Food		
Daily Per Animal	500 lb.	1000 lb.	2000 lb.
0.10	318 grams	1.4 lbs.	2.8 lbs.
0.25	114 grams	227 grams	1.0 lbs.
0.33	90 grams	180 grams	360 grams
0.50	59 grams	118 grams	236 grams

0.75	40 grams	80 grams	160 grams
1.00	35 grams	70 grams	140 grams

Start feeding Mink larvicidal feeds early in the spring before flies begin to appear and continue feeding throughout the summer until cold weather restricts fly activity. Supplemental adult fly control measures may be needed in and around the animal facilities and feed building to control adult flies, especially house flies that can breed in many kinds of organic matter.

In order to achieve optimum fly control, this product should be used in conjunction with other good management and sanitation practices.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store product in its original container in a cool, dry place in an area that is inaccessible to children and animals.

Pesticide Disposal: Wastes resulting from the use of this product may

be disposed of on site in accordance with the label instructions or at an approved waste disposal facility. Open dumping is prohibited.

Container Disposal: Nonrefillable container. Do not refill or reuse empty container. Completely empty bag into application equipment. Dispose of empty bag in a sanitary landfill, or incinerate, or by other procedures approved by state and local authorities.

CONDITIONS OF SALE: The directions on this label were determined through research to be appropriate for the correct use of this product. This product has been tested under different environmental conditions both indoors and outdoors similar to those that are ordinary and customary where the product is to be used. Insufficient control of pests or plant injury may result from the occurrence of extraordinary or unusual conditions, or from failure to follow label directions. In addition, failure to follow label directions may cause injury to animals, man, and damage to the environment. To the extent permitted by applicable law, Elanco offers, and the buyer accepts and uses, this product subject to the conditions that extraordinary or unusual environmental conditions, or failure to follow label directions are beyond the control of Elanco and are, therefore, the responsibility of the buyer.

WARRANTY AND LIMITATIONS OF DAMAGES

Elanco US Inc warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. Elanco makes no other express or implied warranty of Fitness or of Merchantability, and no agent of Elanco is authorized to do so except in writing and with specific reference to this warranty. To the extent permitted by applicable law in no event shall Elanco's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.

{[Optional marketing pictograms and pictures appearing on any location:]}









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