61483-47 07/27/2005 1/9

United States Environmental Protection Agency

Dr. Hubert R. O'Neal
Chemical and Regulatory Consultant
11202 Pecan Creek Drive
Houston, Texas 770434613

JUL 27 2005

Subject: Submission of a label amendment for Rabon 97.3 Oral Larvicide
EPA Reg. No. 61483-47
Product Name: Rabon 97.3 Oral Larvicide
Dates of submission: March 11, 2005, and April 21, 2005.

Dear Mr. O'Neal;

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below.

1. On the label, revise the statement "For Use in Cattle Feeds" to the following: "**Only** For Use in Cattle Feeds"

2. Contained within the Supplemental Mixing and Use Instructions, remove the following section and associated statements:

"

REGULATORY ISSUES

In March 1987, the Environmental Protection Agency (EPA) assumed regulatory authority of feed-through pesticides such as ROL in animal feed products. This permitted the use of ROL in medicated feeds regardless of the drug component(s). Furthermore, the presence of ROL in the feed does not alter the regulatory status of the drug.

Formula feeds with only ROL and no drug(s), which are inventoried and offered for sale through retail channels, require EPA registration. However, feed with ROL added as a custom mix do not require EPA registration provided they meet the definitions of a custom mix feed (see 40 CFR, Part 167.3)

"

Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

Sincerely,

George LaRocca
Product Manager 03
Insecticide Branch
Registration Division (7505C)

Enclosure

061483-00047 S775781, S742329.wpd

ACCEPTED
with COMMENTS
In EPA Letter Dated
JUL 27 2005
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 61483-47

KMG

Net Weight: 100 Pounds
45.4 Kilograms

Rabon® 97.3 Oral Larvicide

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION
Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequent contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling.

Personal Protective Equipment (PPE)
Handlers must wear:
Long sleeved shirt and pants
Shoes and socks
Chemical resistant gloves

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
Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
Remove clothing 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.

First Aid
IF SWALLOWED - Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting or if available by administering syrup of ipecac. 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 persists.
IF IN EYES - Flush eyes with plenty of water. Call a physician if irritation persists.

Note to Physicians and Veterinarians
Poisoning Symptoms: Symptoms include weakness, headache, tightness in chest, blurred vision, non-reactive pinpoint pupils, salivation, sweating, nausea, vomiting, diarrhea, and abdominal cramps.
Treatment: Tetrachlorvinphos is an organophosphate insecticide. If symptoms of cholinesterase inhibition are present, atropine sulfate by injection is antidotal. 2-PAM is also antidotal and may be administered, but only in conjunction with atropine. Atropine is antidotal only if symptoms of cholinesterase inhibition are present.

Do not use this product on animals simultaneously or within a few days before or after treatment with cholinesterase inhibiting drugs, pesticides, or chemicals.

Environmental Hazards
This pesticide is highly toxic to fish. Do not contaminate water when disposing of equipment wash waters.

Warranty and Limitation of Damages
Seller 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. Seller makes no other express or implied warranty, including any other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.

Directions for Use
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is a specially prepared granulated material designed for use in cattle feeds. RABON 97.3 Oral Larvicide prevents the development of fly larvae in the manure of treated cattle. When used as directed, it will aid in the control of horn flies, face flies, house flies and stable flies which develop in cattle manure.
This product can be used in complete feeds, concentrates, protein supplements, mineral supplements or liquid feed supplements provided recommended guidelines are followed. RABON larvicidal rations may be fed to breeding cattle, lactating dairy cattle or growing finishing cattle, either in dry lot or on pasture.
See "RABON 97.3 Oral Larvicide Supplemental Mixing & Use Instructions" for complete directions prior to use.

Application Restrictions: 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. Feeds prepared using this product should not be pelleted unless tests are conducted to assure adequate RABON levels after pelleting. Do not mix this product with feeds containing predominantly pellets due to particle size differences and potential segregation.

Storage and Disposal
Do not contaminate water, food or feed by storage or disposal.
Storage: Store in a dry place in original container.
Container Disposal: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into mixing equipment. Then offer for recycling or reconditioning, or puncture and dispose of with liner in a sanitary landfill or by incineration, if allowed by State and local authorities. If burned, stay out of smoke.
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

3/9

RABON® 97.3 Oral Larvicide

for Use in Cattle Feeds

Supplemental Mixing and Use Instructions

ACCEPTED
with COMMENTS
In EPA Letter Dated
JUL 27 2005
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.
61483-47

KMG-Bernuth, Inc.
Houston, Texas 77036 U.S.A.
(713) 988-9252

abcd

RABON 97.3

Oral Larvicide for Use in Cattle Feeds

Rabon Oral Larvicide prevents the development of Horn Flies, Face Flies, House Flies and Stable Flies in the manure of treated cattle. The following information is supplemental to the product label. Prior to use of this product, also read and observe the precautions on the label affixed to the product container.

DESCRIPTION
RABON is the registered trade name for Tetrachlorvinphos: 2-chloro-1 (2, 4, 5-trichlorophenyl) vinyl dimethyl phosphate. RABON Oral Larvicide is a specially prepared granulated material designed to provide optimum larvicidal activity in the manure. RABON 97.3 Oral Larvicide is available to the feed manufacturer for formulating larvicidal feeds.

ACTION
When fed to cattle, RABON Oral Larvicide passes through the digestive system into the animal's manure where it kills fly larvae on contact shortly after fly eggs hatch. By preventing larval development, RABON Oral Larvicide helps to control adult fly populations.

Manure from treated cattle will remain larvicidal up to six weeks; manure older than six weeks will not support fly development unless it becomes wet or contaminated with fresh manure.

TOXICOLOGY
The toxicology of RABON Oral Larvicide has been investigated in extensive field and laboratory studies in both domestic animals and wildlife. Cattle of both sexes, various ages and breeds, and maintained under a variety of management conditions, have been treated with many times the recommended dose. Milk production, reproduction, growth, and feed efficiency were not adversely affected. RABON Oral Larvicide can be used in conjunction with other organophosphate insecticides or pyrethroid compounds.

Test animals refused to eat excessive amounts of RABON Oral Larvicide. Care must be taken when feeding RABON Oral Larvicide to newborn calves. Adverse reactions in calves are not seen when RABON Oral Larvicide is fed in the grain portion of the diet, but intoxication can occur if excessive amounts are fed through the milk.

Overdosing with this compound will result in only slight inhibition of the enzyme cholinesterase within the nervous system and the neuromuscular junction. Intoxication can be reversed by the administration of atropine.

PALATABILITY
RABON Oral Larvicide is palatable to cattle when used as directed.

EFFECT ON THE ENVIRONMENT
RABON Oral Larvicide does not affect beneficial insects such as dung beetles or other insect predators that normally inhabit the manure. The manure from treated cattle may be used immediately as fertilizer.

To prevent pollution of the environment, good sanitation practices should always be followed when disposing of animal wastes.

AREA-WIDE CONTROL
RABON Oral Larvicide prevents the development of horn flies, face flies, house flies, and stable flies in the manure of treated cattle but does not affect existing adult flies. Since flies tend to migrate from farm to farm, the use of a feed additive larvicide should be considered as only a part of the total fly control program. Periodic spraying of buildings or animals with other insecticides may be necessary in order to control invading adult flies.

FEEDING AND MANAGEMENT
Start feeding RABON Oral Larvicide early in the spring before flies begin to appear and continue feeding through-out the summer and into fall until cold weather restricts fly activity. The proper feeding period will vary with climate and should be determined by the emergence date of flies in previous years for your area.
Rations containing RABON Oral Larvicide may be fed up to slaughter and to lactating dairy cows without withholding the milk from market during or after treatment.

RABON Oral Larvicide should be used in conjunction with other good management and sanitation practices. All potential fly breeding material such as manure, old hay, and silage which contains overwintering fly pupae should be removed from the premises. Manure should not be allowed to accumulate around barns, fences, or under feed bunks during the fly breeding season.

When starting a feeding program during the fly season, it is desirable to use other control measures to reduce the population of existing adult flies.

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

RECOMMENDED FEEDING LEVEL
For effective fly control, it is important to insure that all cattle on the premises receive adequate levels of RABON Oral Larvicide on a daily basis. The recommended feeding level of RABON Oral Larvicide to cattle is 70 mg per 100 pounds of body weight daily. The amount of RABON Oral Larvicide

consumed by individual animals on a daily basis may vary, but fly larvae control will not be affected. A practical feeding regimen can be planned whereby a single feed can be fed to all animals within a like group. Examples are illustrated below.

Growing-Finishing Beef Cattle
A single complete feed containing 26.4 mg of RABON per pound of feed can be fed to all steers and/or heifers, weighing from 400 to 1400 pounds, within a group. As long as the daily feed consumption of the larvicidal feed approximates that shown in the chart (See Figure 1), the cattle will be receiving the larvicide at an acceptable level.

Lactating Dairy Cows
A single concentrate feed containing 66 mg RABON per pound of feed fed along with roughage can be fed to all lactating cows within the herd. As long as the daily feed consumption of the larvicidal feed approximates that shown in the chart (See Figure 2), the cows will be receiving RABON at an acceptable level.

Hand-Fed Beef or Dairy Cattle
A common practice in many cattle operations is to hand-feed a supplement at a given level per head daily. A single supplement which contains 792 mg RABON per pound of supplement and which is fed at the rate of 1 pound per head daily can be fed to cattle weighing between 400 to 1200 pounds. Cattle weighing between 1200-1700 pounds should be fed this supplement at the rate of 1 ½ pounds per head daily.

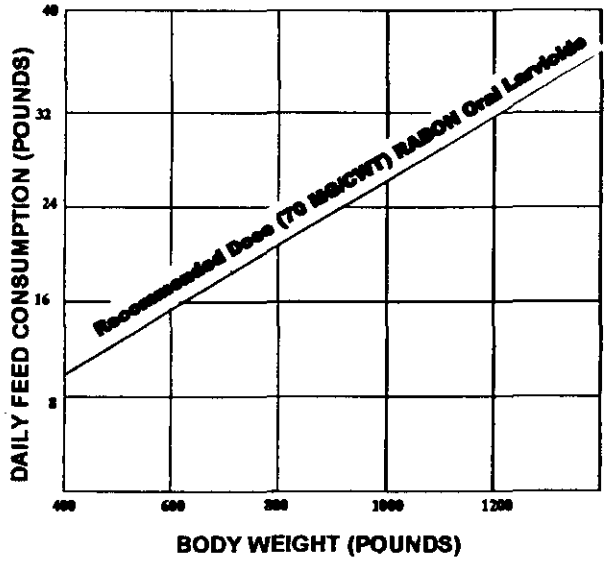

Figure 1.
Daily Consumption of Complete Ration (Containing 26.4 mg Rabon per pound of feed) Required for Fly Larvae Control

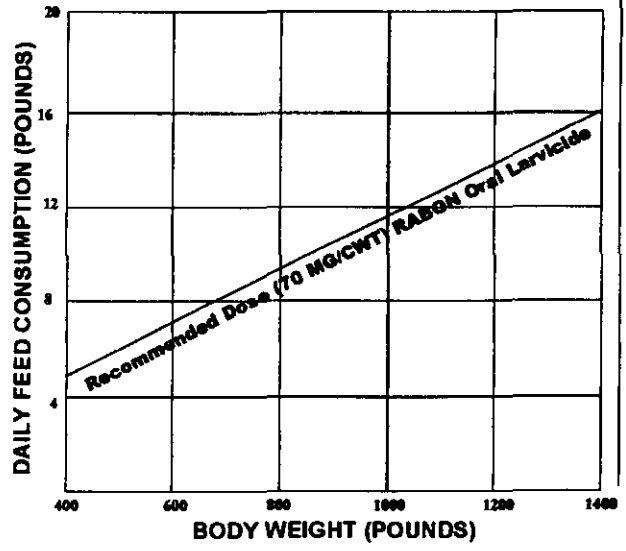

Figure 2.
Daily Consumption of Dairy Feed (Containing 66 mg Rabon per pound of feed) Required for Fly Larvae Control

DIRECTIONS FOR MIXING LARVICIDAL FEEDS
RABON Oral Larvicide will mix uniformly in cattle feeds when good blending procedures are followed. Blending studies performed in typical feed mills indicated that mixer coefficients of variation of 2 to 8 percent can be achieved. Directions for mixing various cattle feeds with RABON Oral Larvicide are given in Table 1.

Feeds prepared using this product should not be pelleted unless tests are conducted to assure adequate RABON levels after pelleting. Do not mix this product with feeds containing predominantly pellets due to particle size differences and potential segregation. This product can be used in liquid feed supplements (LFS) provided recommended guidelines are followed.

STABILITY
Under normal warehouse conditions, RABON 97.3 Oral Larvicide is stable for a minimum of 2 years.

RABON Oral Larvicide when mixed with several typical cattle rations in stability tests, was found to be stable (<10% decomposition) for up to 3 months in complete feeds, for up to 6 months in protein supplements, and for up to 1 year in mineral mixtures when stored under normal conditions. Storage of feedstuffs containing RABON Oral Larvicide at elevated temperatures (ca 100 °F) for an extended period does have a detrimental effect on the stability of RABON; therefore, complete feeds, protein supplements, and liquid feeds stored under such conditions should be fed within 4-8 weeks of manufacture.

ANALYTICAL METHODS
Sampling procedures, analytical procedures, and standards used for determining RABON Oral Larvicide in various feed products are available upon request from KMG-Bernuth, Inc.

TABLE 1. Mixing Directions in Dry Feed

Feed Product	Daily Feeding Rate	RABON in Supplement		Ratio Supplement to Feedstuffs	Use Level of RABON in Feed		Pounds RABON 97.3% Oral Larvicide/ Ton Product
		MG/LB	%		MG/LB	%	
Complete Feed	2.6 lbs./cwt.	N/A	N/A	N/A	26.4	0.0059	0.12
Supplement or Premix for Preparing Complete Feeds	N/A	132	0.029	1:4	26.4	0.0059	0.6
	N/A	264	0.059	1:9	26.4	0.0059	1.2
	N/A	528	0.12	1:19	26.4	0.0059	2.4
	N/A	1056	0.24	1:39	26.4	0.0059	4.8
	N/A	2112	0.47	1:79	26.4	0.0059	9.6
Concentrate Fed with Roughage	1.0 lbs./cwt.	N/A	N/A	N/A	66	0.015	0.3
Supplement or Premix for Preparing Concentrate Feeds	N/A	330	0.072	1:4	66	0.015	1.5
	N/A	660	0.15	1:9	66	0.015	3.0
	N/A	1320	0.29	1:19	66	0.015	6.0
	N/A	2640	0.59	1:39	66	0.015	12.0
	N/A	5280	1.17	1:79	66	0.015	24.0
Supplement for Hand Feeding	2.0 lbs./head	396	0.087	N/A	N/A	N/A	1.8
	1.5 lbs./head	528	0.12	N/A	N/A	N/A	2.4
	1.0 lbs./head	792	0.18	N/A	N/A	N/A	3.6
	0.5 lbs./head	1584	0.35	N/A	N/A	N/A	7.2
Mineral Mix	4.0 oz./head	3168	0.71	N/A	N/A	N/A	14.4
	3.0 oz./head	4224	0.93	N/A	N/A	N/A	19.2
	2.0 oz./head	6336	1.40	N/A	N/A	N/A	28.8
	1.0 oz./250 lbs.	2700	0.60	N/A	N/A	N/A	12.3
	1.0 oz./500 lbs.	5400	1.19	N/A	N/A	N/A	24.6
	1.0 oz./750 lbs.	8100	1.79	N/A	N/A	N/A	36.9

Note: Calculations presented in this table serve as guidelines in preparing feeds which contain RABON Oral Larvicide. Some calculation inconsistencies occur in the table due to rounding. A head weight of 1165 lbs. was used for these calculations. N/A = Not Applicable

CHARACTERISTICS OF LIQUID FEED SUPPLEMENTS (LFS)

A great diversity of suspension formulations exist in the liquid feed industry. The degree of variability in formulation content is dependent upon which market the finished feed product is going to be used (i.e., pasture beef, dairy cattle or the feedlot market). Variation in moisture, sugar, mineral and protein content as well as the intended consumption rate, all affect the composition of the finished product. Therefore, no two LFS possess the same physical and chemical characteristics. One of the most important physical characteristics with respect to ROL in LFS is viscosity, which can vary dramatically. Viscosity of a given medium plays an important role in keeping insoluble particulate matter such as ROL in suspension.

CRITERIA FOR ROL USE IN LFS

In order to successfully use ROL in LFS, two criteria must be met. First, the ROL must remain positionally stable in the LFS with no settling during the feedout period (6-8 weeks). Second, the ROL must be chemically stable in the LFS.

SUSPENDABILITY OF ROL IN LFS

Kelflo™ is a high quality xanthan gum polysaccharide product that has been specially formulated as a suspending and stabilizing agent in LFS. Solutions of Kelflo xanthan gum exhibit pseudoplastic (or shear-thinning) flow behavior. That is, stored LFS have excellent suspension stability. When shear is applied (mixing, pumping, spraying, transport, lick wheel movement), the viscosity decreases, resulting in a free-flowing liquid. When shear is removed, the original at-rest viscosity is restored so that suspension stability is maintained. Xanthan gum is routinely used at 3 lb/ton LFS by some manufacturers to suspend drug products.

Laboratory studies at BIVI have shown that hydrated xanthan gum at various concentration levels will suspend ROL in LFS. As a general rule, LFS with viscosities of 400-600 centipoise (cP, Brookfield viscometer at 20 rpm, spindle No. 3 for 2.5 minutes at 68-72°F) require 3 lb xanthan gum for LFS to provide positional stability of ROL.

This amount of xanthan gum increases the viscosity of the final product above 1900 cP. Xanthan gum must be fully hydrated prior to the addition of ROL. In the laboratory, xanthan gum requires 24 hours to become hydrated. For this reason, we recommend that xanthan gum be added to the LFS at manufacture, not at the distributor or consumer level.

For LFS with low viscosities (i.e., 30-55 cP), 9-12 lb xanthan gum/ton LFS would likely be required to suspend ROL. However, the cost/ton of LFS would most likely be prohibitive.

~~REGULATORY ISSUES~~

~~In March 1987, the Environmental Protection Agency (EPA) assumed regulatory authority of feed through pesticides such as ROI in animal feed products. This permitted the use of ROI in medicated feeds regardless of the drug component(s). Furthermore, the presence of ROI in the feed does not alter the regulatory status of the drug.~~

~~Formula feeds with only ROI and no drug(s), which are inventoried and offered for sale through retail channels, require EPA registration. However, feed with ROI added as a custom mix do not require EPA registration provided they meet the definitions of a custom mix feed (see 40 CFR, Part 187.3)~~

GUIDELINES

The following steps are recommended for the successful use of ROL in LFS:

1. The LFS manufacturer should determine the viscosity of the liquid product being considered for ROL inclusion. The viscosity should be performed using a Brookfield viscometer at 20 rpm, spindle No. 3 for 2.5 minutes at 68-72°F. The viscosity reading will establish the feasibility of adding ROL to the LFS.
2. For LFS with viscosity readings of 400-600 cP at 20 rpm, the addition of 3 lb xanthan gum/ton LFS appears to adequately suspend ROL.
3. For LFS with very low viscosities, 9-12 lb xanthan gum/ton LFS will likely suspend ROL. Manufacturers interested in suspending ROL in such low viscosity LFS should contact BIVI for technical assistance or conduct suspendability studies themselves.
4. Addition of xanthan gum to the LFS must be conducted during manufacture in order to ensure full hydration of the gum prior to the addition of ROL.
5. ROL and xanthan gum should not be added to the LFS at the same time. The ROL will settle out.
6. ROL and xanthan gum should not be added to the LFS at manufacture. However, ROL could be added to LFS (previously charged and hydrated with the proper level of xanthan gum) at the distributor level provided adequate mixing of the ROL is accomplished.
7. ROL remains stable chemically when mixed and stored in products with low pH values (6 or less).
8. Field trials to determine the positional and chemical stability of ROL in LFS should be conducted. Dating of the product (normally 6-8 weeks) will be based on the results of the field trial.
9. LFS containing ROL should be fed out in 6-8 weeks.
10. Lick tanks should be emptied prior to refilling to ensure the maximum dating of the product. Chemical stability and efficacy of the product in the field will be severely compromised if fresh product is mixed with outdated material.
11. LFS with ROL must be accompanied with end-use labeling directions.
12. ROL can be added to LFS containing drug products.

DIRECTIONS FOR MIXING IN LIQUID FEED SUPPLEMENTS

This product is a specially prepared granulated material designed for use in cattle Liquid Feed Supplements (LFS). The proper positional and chemical stability of ROL in liquid feeds is dependent upon acceptable physical characteristics and proper blending technique. Depending on the viscosity of the liquid feed, it may be necessary to add xanthan gum.

The Liquid Feed Supplement (LFS) plus xanthan gum must be fully hydrated prior to the addition of the RABON Oral Larvicide.
RABON Oral Larvicide should be fed in Liquid Feed Supplements (LFS) for cattle (including lactating dairy cattle) to supply the recommended feeding level of 70 mg of this product per 100 pounds of body weight daily.

All cattle in the area should be treated. To prepare a larvicidal liquid feed, mix this product according to the amount of LFS to be fed per animal per day. Use Table 2 below as a guide, depending on the most convenient method for measurement, for determining the proper mixing rate.

TABLE 2. Mixing Directions In Liquid Feed Supplements

Pounds LFS Consumed/Day	Cattle Weight	600 lb.	800 lb.	1000 lb.	1200 lb.	1350 lb.
1.0	Grams of Rabon 97.3 Oral Larvicide/TON of LFS[a]	850 g.	1134 g.	1418 g.	1701 g.	1928 g.
1.5		624 g.	850 g.	1048 g.	1247 g.	1418 g.
2.0		425 g.	567 g.	709 g.	850 g.	964 g.

Pounds LFS Consumed/Day	Cattle Weight	600 lb.	800 lb.	1000 lb.	1200 lb.	1350 lb.
1.0	Fluid Ounce Equivalents[b] of Rabon 97.3 Oral Larvicide/TON of LFS[a]	34 oz.	45 oz.	56 oz.	67 oz.	76 oz.
1.5		25 oz.	34 oz.	42 oz.	50 oz.	56 oz.
2.0		17 oz.	23 oz.	28 oz.	34 oz.	38 oz.

[a]Mix proportionately for other cattle weights or consumption levels.
[b]Use volumetric measuring cup.