

38092-3

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 27, 2006

Reid S. Adkins, Ph.D., Vice President, General Manager
International Nutrition, Inc
PO Box 27540
Omaha, Neb. 68127

Subject: Label amendment for the removal of all references to the use of Fly-Curb 7.76% Premix in horses.

EPA Registration Number: 38092-3

Product Name: Fly-Curb 7.76% Premix

Date of Submission: January 28, 2005

Dear Dr. Adkins;

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. Note: **Three copies of the finished labeling incorporating all of the changes identified below must be submitted prior to releasing the product for shipment.**

1. The Federal Fungicide and Rodenticide Act (FIFRA) required Signal Word "CAUTION" is required to appear on the front panel of the label, directly below the Child Hazard Warning statement (Keep Out of Reach of Children) and also in the Precautionary Statements section immediately below the subheading "Hazards to Humans and Domestic Animals. Therefore modify the following section of the label as follows:

**"KEEP OUT OF REACH OF CHILDREN
CAUTION
PRECAUTIONARY STATEMENTS"**

2. Revise the entire **FIRST AID** section, replacing all text within this subsection as follows:

First Aid Organophosphate	
If swallowed	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for further treatment advice.
If in eyes	<ul style="list-style-type: none"> • 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 eye. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
<p>This product contains an organophosphate that inhibits cholinesterase. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-821-7467 for emergency medical treatment information.</p>	
NOTE TO PHYSICIAN AND VETERNARIANS	
<p>This product is a cholinesterase inhibitor, 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. Product may cause aspiration pneumonia. Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

3. Directly after the revised FIRST AID section identified in #2 above, **insert** the **HAZARDS TO HUMANS AND DOMESTIC ANIMALS** as follows:

“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 hands before eating, drinking, chewing gum, using tobacco using the toilet.”

Note: Refer to #1 above for the required “CAUTION” FIFRA signal word to be added to the HAZARDS TO HUMANS AND DOMESTIC ANIMALS language.

4. Directly below the “HAZARDS TO HUMANS AND DOMESTIC ANIMALS” section described in #3 above, **revise and insert** the following Personal Protective Equipment (PPE) header and language:

“Personal Protective Equipment (PPE)

“Some materials that are chemical-resistant to this product are”¹. “If you want more options, follow the instructions for category”²“on an EPA chemical-resistance category selection chart. Loaders, applicators and other handlers must wear:

- long-sleeved shirt and long pants,
- shoes plus socks
- chemical resistant gloves”

¹ (International Nutrition inserts correct chemical-resistant material)

² [International Nutrition inserts A,B,C,D,E,F,G,or H]

- 5. Directly below the **Personal Protective Equipment (PPE)** insert a new subsection entitled User Safety Requirements and insert the appropriate language as follows:

“Personal Protective Equipment (PPE)

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

- 6. Directly below the subsection entitled Personal Protective Equipment (PPE), **insert a subheading and associated language** for “**User Safety Recommendations**” This section, including the sub-header must be placed within a box.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.” “Users should 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.”

- 7. **Revise** the language within the “ENVIRONMENTAL HAZARDS” subsection as follows:

“ENVIRONMENTAL HAZARDS

“This product is toxic to fish and aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wastewater or rinsate.”

- 8. **Enclose** the “STORAGE AND DISPOSAL” subsection of the label within a box as shown below:

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 container into application (mixer/feeder) equipment. Then dispose of empty bag in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

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9. Within the DIRECTIONS FOR USE, and directly after the FIFRA required sentence "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Insert the following USE RESTRICTIONS subsection including sub-header:

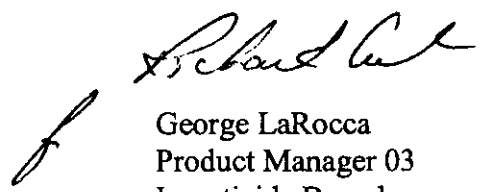
"USE RESTRICTIONS

Do not use this product on animals simultaneously or within a few days 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. 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. "

10. Within the DIRECTIONS FOR USE, "SWINE" subsection, revise the sentence "All swine should be treated." To "Treat all swine."
11. You may insert non-emergency contact information such as "For additional information on Fly-Curb 7.76% Premix call 1-800-228-2022." at the end of the label.

If you have any questions, you may contact Richard J. Gebken, at (703) 305-6701.

Sincerely,



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

Enclosure

PRECAUTIONARY STATEMENTS

FIRST AID

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, 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 ON EYES: Flush 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. For additional first aid information on RABON Oral Larvicide call 1-800-821-7467 and ask for Boehringer Ingelheim Vetmedica, Inc. technical service department. For additional information on FLY-CURB 7.76% PREMIX call 1-800-228-2022.

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

HAZARD TO HUMANS

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. Wear Personal Protective Equipment (PPE) such as long sleeved shirt, long pants, shoes and socks and chemical resistant gloves when handling. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. 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.

Users should 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.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

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 container into application (mixer/feeder) equipment. Then dispose of empty bag in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

DIRECTIONS FOR USE

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

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. It prevents the development of fly larvae in the manure of treated animals, but is not effective against existing adult flies.

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 preblending techniques be employed to assure adequate distribution throughout the feed mix. The premix should be preblended 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 mixers, horizontal blenders, mixer/feeder truck) may be used to prepare formulated feeds.

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.

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 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.

Pounds of Concentrate Consumed per Animal per Day	MIXING DIRECTIONS		Pounds of Fly-Curb 7.76% Premix per ton of Concentrate
	RABON* in the Concentrate mg/lb.	%	
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 1.5 times that indicated.

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 45.4 mg. of RABON* per pound of feed.

EPA Est. No.: **38092-NB-001**

EPA Reg. No.: **38092-3**

International Nutrition, Omaha, NE 68127

Code No: 911

NET WEIGHT: 45 LB (20.4 KG)

ACCEPTED
with COMMENTS
In EPA Letter Dated
JUN 27 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
38092-3