

United States Environmental Protection Agency

Mr. Mark Robbins, Research Manager  
Ridley Block Operations  
Corner of Laurel & South  
P.O. Box 431  
Whitewood, SD 57793

SEP 15 2005

Subject: Submission of an application to amend the label for Rolyx-Pro under the Federal Insecticide Fungicide, and Rodenticide Act.  
Product Name: Rolyx-Pro  
EPA Reg. No.: 7698-17  
OPP Identifier No.: none

Dear Mr. Robbins,

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. *Revise the newly inserted horse use section, and insert this statement into the new Use Restrictions section as outlined in #4 below.*
2. *Move the paragraph contained in the Storage and Disposal section that reads: "When fed to cattle and horses, ROLYX™-PRO 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, ROLYX™-PRO helps to control horn flies and face flies on pasture and house flies and stable flies in and around lots and buildings." to the Directions for Use area identified in #4 below:*
3. *Remove the boxed statement "WARNING: This product, which contains copper, should not be fed to sheep or other species that have a low tolerance to supplemental copper." Insert a new subsection contained within the Directions for Use as revised and identified in the use Restrictions section of #4 below:*

CONCURRENCES

SYMBOL ▶	H7505C							
SURNAME ▶								
DATE ▶	Sep 15, 2005							



4. *New revised section Directions for Use that contains changes as described in #1 thru 3 above:*

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#### **"DIRECTIONS FOR USE**

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

#### **Use Restrictions:**

1. This product is not to be used on horses destined for slaughter.
2. This product contains added copper, do not use on sheep or other species that have a low tolerance to supplemental copper.

#### **Use Precautions For Horses:**

1. This product contains tetrachlorvinphos, which is a cholinesterase inhibitor. The most frequently reported clinical signs of cholinesterase inhibition 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."

**ROLYX™-PRO** supplement is designed for self-feeding to grazing cattle, feedlot cattle and horses. When fed to cattle and horses, **ROLYX™-PRO** 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, **ROLYX™-PRO** helps to control horn flies and face flies on pasture and house flies and stable flies in and around lots and buildings.

Place containers in dry spots near loafing pens and watering locations. Feed at the rate of one container for every 20-30 head, with a minimum of two (2) containers in each lot or pasture to ensure proper accessibility. Free-choice consumption will depend on size of the animals fed, seasonal weather conditions, as well as quality, source and availability of other feeds. Provide free access to clean, fresh water at all times. **ROLYX™-PRO** supplement contains no salt, Provide salt free choice."

The remaining text on the directions for use: When free-choice feeding..... and sanitation practices." can be added directly below.

A stamped draft copy is enclosed for your records. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you have any questions please contact Richard J. Gebken, at (703) 305-6701.

Sincerely,



George LaRocca  
Product Manager 13  
Insecticide Branch  
Registration Division (7505C)

enclosure

007498-00017 STR1795 wpa



# ROLYX<sup>TM</sup> PRO

## For Beef and Dairy Cattle On Pasture, Feedlot Cattle, and Horses

(Contains Rabon<sup>®</sup> Oral Larvicide)

Contains RABON<sup>®</sup> to prevent the development of Horn Flies, Face Flies, House Flies and Stable Flies in the manure of treated cattle and horses.

### ACTIVE INGREDIENT

Tetrachlorvinphos: (Z)-2-chloro-1-(2,4,5-trichlorophenyl)	0.44%*
vinyl dimethyl phosphate	99.56%**
<b>INERT INGREDIENTS</b>	
*Each pound contains 2.0 g RABON <sup>®</sup>	100.00%

\*\*Refers only to ingredients which are not larvicidal

### GUARANTEED ANALYSIS

Crude Protein, minimum	20.0%
Crude Fat, minimum	4.0%
Crude Fiber, maximum	2.0%
Calcium (Ca), minimum	1.0%
Calcium (Ca), maximum	1.5%
Phosphorus (P), minimum	1.0%
Salt (NaCl)	none added
Potassium (K), minimum	2.0%
Magnesium (Mg), minimum	0.5%
Sulfur (S), minimum	0.5%
Cobalt (Co), minimum	3.3 ppm
Copper (Cu), minimum	330 ppm
Iodine (I), minimum	17 ppm
Manganese (Mn), minimum	1,330 ppm
Selenium (Se), minimum	6.6 ppm
Zinc (Zn), minimum	1,000 ppm
Vitamin A, minimum	80,000 IU/Lb
Vitamin D <sub>3</sub> , minimum	8,000 IU/Lb
Vitamin E, minimum	100 IU/Lb

### INGREDIENT STATEMENT

Molasses products, hydrolyzed feather meal, plant protein products, hydrolyzed vegetable oil, processed grain by-products, monocalcium phosphate, dicalcium phosphate, calcium carbonate, magnesium oxide, manganese sulfate, zinc sulfate, copper sulfate, copper chloride, ethylenediamine dihydriodide, calcium iodate, cobalt carbonate, sodium selenite, vitamin A acetate, vitamin D<sub>3</sub> supplement, vitamin E supplement.

### STORAGE AND DISPOSAL

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

**Storage:** Store product in a cool, dry warehouse in the original container.

**Disposal:** Allow animals to completely empty container. Then return containers for recycling or dispose of empty containers in a sanitary landfill. Do not burn containers. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

When fed to cattle and horses, ROLYX<sup>TM</sup>-PRO 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, ROLYX<sup>TM</sup>-PRO helps to control horn flies and face flies on pasture and house flies and stable flies in and around lots and buildings.

EPA REG. NO. 7698-17

RABON<sup>®</sup> IS A REGISTERED TRADEMARK OF BOEHRINGER INGELHEIM VETMEDICA, INC.

EPA EST. NO. 7698 - SD - 003 • 7698 - MN - 003 • 7698 - CA - 001 • 7698 - TX - 001

3927-5<sub>1</sub>

250 Lb.

3.4 kg net

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
PRECAUTIONARY STATEMENTS

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

### First Aid

If swallowed	<ul style="list-style-type: none"> <li>Call poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment.

### NOTE TO PHYSICIAN

Note to Physician/Veterinarian: 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 not in conjunction with atropine.

### PERSONAL PROTECTIVE EQUIPMENT

Handlers: Wear long-sleeved shirt and pants, chemical resistant gloves, shoes and socks for protection when handling.

### USER SAFETY REQUIREMENTS

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

### USER SAFETY RECOMMENDATIONS

Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. ROLYX<sup>TM</sup>-PRO supplement is designed for self-feeding to grazing cattle, feedlot cattle and horses. This product is not to be used on horses destined for slaughter. Place containers in dry spots near loafing areas and watering locations. Feed at the rate of one container for every 20-30 head, with a minimum of two (2) containers in each lot or pasture to ensure proper accessibility. Free-choice consumption will depend on size of the animals fed, seasonal weather conditions, as well as quality, source and availability of other feeds. Provide free access to clean, fresh water at all times. ROLYX<sup>TM</sup>-PRO supplement contains no salt. Provide salt free choice.

When free-choice feeding ROLYX<sup>TM</sup>-PRO, cattle and horses should consume 1.05 pounds of ROLYX<sup>TM</sup>-PRO per 100 pounds of body weight per month. This will supply the recommended average daily intake of 70 mg RABON<sup>®</sup> Oral Larvicide per 100 pounds body weight. Animals should not be starved for minerals before initiation of the RABON<sup>®</sup> program is started. Allow one container for each 20-30 head, and place near watering and loafing areas. Put out no more than a two to three week supply at a time.

If consumption of ROLYX<sup>TM</sup>-PRO is above 1.05 pounds per 100 pounds of body weight per month, reduce the number of feeding locations or relocate the containers. If consumption is below 1.05 pounds per 100 pounds of body weight per month, increase the number of feeding locations. Start feeding ROLYX<sup>TM</sup>-PRO early in the spring before the flies begin to appear, and continue feeding throughout the summer and into the fall until cold weather restricts fly activity.

ROLYX<sup>TM</sup>-PRO may be fed until slaughter and to lactating cattle.

ROLYX<sup>TM</sup>-PRO prevents the development of horn flies, face flies, house flies and stable flies in the manure of treated animals, but, is not effective against existing adult flies. 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 lots and buildings 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, ROLYX<sup>TM</sup>-PRO should be used in conjunction with other good management and sanitation practices.

**CAUTION:** This product contains tetrachlorvinphos, which is a cholinesterase inhibitor. The most frequently reported clinical signs of cholinesterase inhibition 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.

**WARNING:** This product, which contains added copper, should not be fed to sheep or other species that have a low tolerance to supplemental copper.



Manufactured For:  
**HUBBARD FEEDS INC**  
Markato, Minnesota 56001  
CRYSTALYX<sup>TM</sup> is a registered trademark of  
RIDLEY BLOCK OPERATIONS

U.S. Patent No. 6,244,217 - 6,390,024 - 6,561,133

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