

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 4, 2017

Ms. Stephanie Hacker Regulatory Affairs Manager Agent for Ridley USA, Inc. c/o Kelly Registration Systems 14481 Lochridge Boulevard Covington, GA 30014

Subject: Label Amendment – Updating Master Label for Guaranteed Analyses/Ingredients

for State Registrations; Addition of Graphics & Addition of New ABNs

Product Name: ROLYX®-PRO EPA Registration Number: 7698-17 Application Date: February 21, 2017

Decision Number: 526877

Dear Ms. Hacker:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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 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) list 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.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via email at *Rodia.Carmen@epa.gov*.

Sincerely,

Richard Gebken

Product Manager 10

Invertebrate & Vertebrate Branch 2

Registration Division (7505P)

Office of Pesticide Programs

Enclosure: Stamped "Accepted" Master Label, dated August 4, 2017

ROLYX®-PRO

{ABNs: CRYSTALYX® Brand Supplements ROLYX® Pro-Mag; FLYPatRol® 18; and ROLYX® Pro-Mag}

For Cattle [and Horses] on Pasture

Contains RABON® to prevent the development of horn, face, house and stable flies in the manure of treated cattle. [Prevents development of house and stable flies in the manure of treated horses.]

Active Ingredient:

Tetrachlorvinphos* (CAS # 22248-79-9)	0.44%
Other Ingredients**	<u>99.56%</u>
Total	

^{*}RABON® Insecticide - Contains 2 grams RABON

Guaranteed Analysis

{Will vary according to formulation and state labeling regulations.}
Crude Protein, minimum
Crude Fat, minimum 3.0%
Crude Fiber, maximum 3.0%
Acid Detergent Fiber, maximum
Neutral Detergent Fiber, maximum 5.0%
Calcium (Ca), minimum
Calcium (Ca), maximum 1.5%
Phosphorus (P), minimum
Magnesium (Mg), minimum
Cobalt (Co), minimum
Copper (Cu), minimum 500 ppm
Iodine (I), minimum
Manganese (Mn), minimum 2,000 ppm
Selenium (Se), minimum
Zinc (Zn), minimum
Vitamin A, minimum80,000 IU/Lb
Vitamin D-3, minimum
Vitamin E, minimum 100 IU/Lb

Ingredients

(Will vary according to formulation and state labeling regulations.)

Molasses products, processed grain by-products, plant protein products, magnesium oxide, monocalcium phosphate, dicalcium phosphate, hydrolyzed vegetable oil, calcium carbonate, manganese proteinate, manganous oxide, manganese sulfate, zinc proteinate, zinc oxide, zinc sulfate, copper protienate, copper sulfate, copper chloride, ethylenediamine dihydroiodide, calcium iodate, cobalt glucoheptonate, cobalt carbonate, selenium yeast, sodium selenite, Vitamin A supplement, Vitamin D-3 supplement, Vitamin E supplement and mineral oil.

ACCEPTED

08/04/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7698-17

^{**}Refers only to ingredients which are not larvicidal

Keep Out of Reach of Children CAUTION First Aid

If Swallowed:	Call a poison control center or doctor for treatment advice.
	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to do so by a poison control center or doctor.
	Do not give anything by mouth to an unconscious person.
If on Skin:	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 eye.
	Call a poison control center or physician for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call the National Pesticides Information Center at 1-800-858-7378 Monday through Friday from 8AM to 12PM Pacific Time. After 12PM Pacific Time weekdays and during the weekend, call your poison control center at 1-800-222-1222.

Note to Physicians and Veterinarians

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.

(Note: The First Aid Statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.)

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequentity repeated skin contact may cause allergic reactions in some individuals.

Personal Protective Equipment ("PPE")

All pesticide handlers must wear: Long-sleeved shirt and long pants; shoes and socks; and chemical-resistant gloves made of barrier laminate, nitrile rubber \geq 14 mils, neoprene rubber \geq 14 mils, butyl rubber \geq 14 mils and/or viton > mils.

User Safety Requirements

Follow manufacturers' 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.

User Safety Recommendations

Users should thoroughly wash hands with plenty of soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Users should immediately remove clothing if pesticide gets inside, then wash thoroughly and put on clean clothing. Users should immediately remove PPE 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 highly toxic to fish.

DIRECTIONS FOR USE

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

[Use Restriction: Not to be used on horses destined for slaughter.]

[Precautions for Horse Use: 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, immediately consult your veterinarian. 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.]

Place **ROLYX-Pro** containers near loafing and watering areas. Feed at the rate of one container for every head {for < 30 lb containers} [5-10 head {for 30-99 lb containers}] [20-30 head {for 100 lb and over containers}]. A minimum of 2 containers may be necessary. Provide free access to clean, fresh water at all times. **ROLYX-Pro** contains no salt. Provide salt free choice. Animals should not be starved for minerals prior to feeding **ROLYX-Pro**.

Cattle [and horses] should consume 1.05 lbs [pounds] of **ROLYX-Pro** per 100 lbs [pounds] of bodyweight per month. This will supply the recommended average daily intake of 70 mg RABON per 100 lbs [pounds] bodyweight. If consumption is above 1.05 lbs [pounds] per 100 lbs [pounds] of bodyweight per month, reduce the number of feeding locations or relocate containers. If consumption is below this rate, increase the number of feeding locations.

Start feeding ROLYX-Pro early in the spring before flies begin to appear and continue feeding throughout the year until cold weather restricts fly activity. ROLYX-Pro prevents development of horn, face, house and stable flies in the manure of treated cattle [and prevents development of house and stable flies in the manure of treated horses], but is not effective against existing adult flies. When starting a feeding program during fly season, use other control measures to reduce the existing adult fly population. ROLYX-Pro may be fed to cattle up until slaughter and to lactating cows. Follow feeding directions. Consumption of selenium should not exceed 3 mg per head daily.

Storage and Disposal

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

Pesticide Storage: Keep this product in its tightly closed original container. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals, and keep away from other pesticides, fertilizers, food or feed. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Handling:** *(For refillable steel drums:)* Refillable container. Refill this container with only product containing RABON. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. Dispose of empty containers in a sanitary landfill or by other procedures approved by state and local authorities. *(For non-refillable containers:)* Nonrefillable container; do not reuse or refill this container. Offer container for recycling, if available; or puncture and dispose of container in a sanitary landfill; or by other procedures approved by State and local authorities.

{For nonrefillable containers, per PR Notice 2007-4, a lot/batch number will appear on either the labeling or container.}

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

RABON® is a registered trademark of Bayer HealthCare LLC CRYSTALYX®, FLYPatROL® and ROLYX® are registered trademarks of Ridley USA Inc.

Manufactured by Ridley USA Inc. 111 West Cherry Street, Suite 500 Mankato, MN 56001

[{Batch #}] {Product Code} {Date Code}

{Graphics}







(End of Graphics)

[] Denotes language that is optional

{ } Denotes language that does not appear on the market labeling