

87276-28

11/19/2013

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Michael Kellogg
Envincio LLC
c/o Pyxis Regulatory Consulting
4110 136th Street, NW
Gig Harbor, WA 98332

NOV 19 2013

Subject: Label Notification(s) for Pesticide Registration Notice 98-10

Dear Mr. Kellogg:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated October 29, 2013 for the following product(s):

Cattle Armor Ultra EPA Reg. No. 87276-28

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 87276-28	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Envincio LLC / Cattle Armor Ultra	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Envincio LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ NOV 19 2013 Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of a revision to the container disposal instructions per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 2.5, 30, 55 gallons		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Michael Kellogg	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Michael Kellogg	5. Date 10/29/13	

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PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

October 29, 2013

COURIER DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (**NOTIF**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Envincio LLC – Cattle Armor Ultra (EPA Reg. No. 87276-28)
Revision to the Container Disposal Instructions per PRN 2007-4

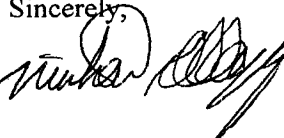
Dear Mr. Gebken,

On behalf of Envincio LLC please find the enclosed notification of a revision to the container disposal instructions to add instructions for plastic containers larger than 5 gallons to the Cattle Armor Ultra labeling.

In support of this label notification please find the enclosed documents:

1. Completed Application for Registration (EPA Form 8570-1)
2. One (1) copy of the proposed label with changes tracked
3. One (1) copy of the proposed label with changes incorporated
4. Certification With Respect to Label Integrity
5. One (1) copy of proposed label on CD
6. Letter of Authorization

Please feel free to call me if you have any questions or need any additional information.

Sincerely,

Michael Kellogg

Enclosures

Note to reviewer: Brackets [] denote optional language. The final label may include some or all of the optional text.

Cattle Armor Ultra

[Controls lice and flies on beef cattle, lactating and non-lactating dairy cattle and calves when applied as a pour-on, mist, spray or back rubber.]

[Controls keds on sheep and lambs when applied as a pour-on.]

[Controls flies on horses when applied as a wipe-on, pour-on or ready to use spray.]

[Controls] [Flies] [Keds] [Lice] [Gnats] [Ticks]

[For use on beef cattle, lactating and non-lactating dairy cattle, calves, horses, foals, sheep and lambs.]

[Premise spray in and around animal housing.]

[Ready-to-Use]

[Pour-On] [Back Rubber] [Wipe-On] [& Ready-to-Use Spray Applications] **NOTIFICATION**

[Oil-based]

[Treats 63 cattle [10 cwt cattle] [for quart size packaging]

NOV 19 2013

[Treats 126 cattle [10 cwt cattle] [for 1/2 gallon size packaging]

[Treats 252 cattle [10 cwt cattle] [for gallon size packaging]

[Treats 630 cattle [10 cwt cattle] [for 2.5 gallon size packaging]

[Controls lice and flies on beef cattle, lactating and non-lactating dairy cattle and calves when applied as a pour-on, mist spray or back rubber.]

[Controls keds on sheep and lambs when applied as a pour-on. Controls flies on horses when applied as a wipe-on, pour-on or ready to use spray.]

ACTIVE INGREDIENTS:

Permethrin* 7.4%

Piperonyl Butoxide** 7.4%

OTHER INGREDIENTS***: 85.2%

TOTAL 100.0%

*(3-Phenoxyphenyl) methyl (+ or -) cis-trans-3-(2,2-dichloroethenyl) 2,2-dimethylcyclopropanecarboxylate). Cis-trans isomers ratio: Min. 45% (+ or -) cis and Max. 55% (+ or -) trans

** (butylcarbityl)(6-propylpiperonyl) ether and related compounds

***Contains petroleum distillates

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

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 doctor for treatment advice.

IF SWALLOWED:

- Immediately call a poison control center or doctor.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give any liquid to the person.
- Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-866-257-4118 for emergency medical treatment information.

NOTE TO PHYSICIAN: May pose an aspiration pneumonia hazard. Contains petroleum distillate.

See inside label booklet for additional PRECAUTIONARY STATEMENTS.

For Chemical Spill, Leak, Fire, or Exposure, Call: CHEMTREC 1-800-424-9300

For Medical Emergencies Only, Call: 866-257-4118

Manufactured for:
 Envincio LLC
 2155 West Croft Circle
 Spartanburg, SC 29302

Net Contents:

**PRECAUTIONARY STATEMENTS
 HAZARDS TO HUMANS AND DOMESTIC ANIMALS
 CAUTION**

Contains Petroleum Distillate. Causes moderate eye irritation. Avoid contact with eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Mixers, loaders, applicators (except for hand-held foggers or fog/mist generator use in indoor spaces) and other handlers must wear the following:

- Long-sleeve shirt,
- Long pants,
- Shoes and socks,
- Chemical-resistant gloves for all handlers except for applicators made of barrier laminate, nitrile rubber, neoprene rubber or viton,
- Chemical-resistant apron for mixers/loaders, persons cleaning equipment and persons exposed to the concentrate and for handlers performing animal dip applications.

In addition to the above PPE, applicators using hand-held foggers or fog/mist generators in indoor spaces must wear:

- Coveralls over long-sleeve shirt and long pants,
- Chemical-resistant gloves,
- Chemical-resistant footwear plus socks,
- Chemical-resistant headgear, if overhead exposure; and,
- A half-face, full-face or hood-style NIOSH-approved respirator with a dust/mist filtering cartridge (MSHA/NIOSH approval number prefix TC-21C),
- A canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or,
- A cartridge or canister with any N, R, P, or HE filter.

USER SAFETY REQUIREMENTS

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. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

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

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift and run-off from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash-waters.

Under some conditions, it may also have a potential for transport into surface water in runoff (primarily adsorbed to suspended soil particles), for several months or more after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently, flooded areas, and areas overlying extremely shallow groundwater, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-lying tile drainage system that drain to surface waters. To protect the environment, do not allow pesticide to enter or run-off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

DIRECTIONS FOR USE

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

USE RESTRICTIONS:

- Apply this product only as specified on this label.
- Do not contaminate food or feedstuffs.
- Do not use in aircraft cabins.
- This product is not for use in residential misting systems (indoor or outdoor).
- This product is not for use in metered release misting systems.
- Do not make applications with a sponge.
- Do not water treated area to the point of run-off.
- Do not use this product directly on domestic (companion) animals (dogs, cats, puppies, or kittens).
- Except when applying to livestock, do not apply this product in a way that will contact workers or other persons, either directly or through drift.
- Except when applying to livestock, do not enter or allow others to enter treated area until sprays have dried.
- Except when applying to livestock, only protected handlers may be in the area during application.
- Do not use in food/feed areas of food handling establishment, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where food is served, such as dining rooms, but excluding areas where foods may be prepared or held.
- Remove or cover exposed food and drinking water before application. Remove or cover dishes, utensils, food processing equipment, and food preparation surfaces or wash them before use.
- When used in dairy barns or facilities; close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.
- All outdoor applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses: (1) Treatment of soil or vegetation around structures; (2) Applications to lawns, turf, and other vegetation; and (3) Applications to building foundations, up to a maximum height of 3 feet. Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches, and structural surfaces (such as window, doors, and eaves) are limited to spot and crack-and-crevice applications only.
- Application of this product is prohibited directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow this product to enter any drain during or after application.
- Remove pets, birds, and cover fish aquariums and ornamental fish ponds before spraying, and turn aquarium systems off prior to use.

IMPORTANT: This is a highly concentrated formulation. Use only with an accurate measuring container or applicator.

READY TO USE – No dilution necessary except for back rubber devices.

Apply To:	Target Insects	Application Instructions
Lactating and Non-Lactating Dairy Cattle, Beef Cattle and Calves	Lice, Horn Flies, Face Flies	DOSAGE: Apply 2 mL per 100 lbs. body weight of animal, up to a

Apply To:	Target Insects	Application Instructions
	<p>Aids in control of Horse Flies, Stable Flies, House Flies, Mosquitoes, Black Flies and Ticks.</p> <p>Controls Horn Flies up to 6 weeks after application.</p>	<p>maximum of 20 mL for any one animal spray.</p> <p>POUR ON: Pour correct dose along back and down the face.</p> <p>READY TO USE SPRAY: Use undiluted in a mist sprayer to apply correct dose. Apply directly to neck, face, back, legs and ears.</p> <p>BACK RUBBER USE: Mix 64 mL (2.1 fl. oz.) per gallon of mineral oil. Keep rubbing device charged. Results improved by daily forced use.</p>
<p>Sheep and Lambs</p>	<p>Sheep Keds, Lice</p>	<p>POUR ON: Pour along back. Apply one mL per 50 lbs. of body weight of animal, up to a maximum of 12 mL for any one animal. For optimum control, all animals in the flock should be treated after shearing.</p>
<p>Horses and Foals</p>	<p>Stable Flies, Horn Flies, Face Flies, House Flies, Eye Gnats and Ticks.</p> <p>Aids in control of Horse Flies, Mosquitoes and Black Flies.</p>	<p>WIPE ON: Apply 8 mL to 16 mL as a wipe on. Dampen applicator mitt, cloth or toweling (Turkish) with product. Rub over hair with special attention to the legs, shoulders, neck and facial areas where flies tend to congregate. Be especially careful not to get in horses eyes. Repeat treatment as needed.</p> <p>READY-TO-USE SPRAY: Use product after riding or exercise. Use undiluted in a mist sprayer, applying 8 mL to 16 mL per animal. Apply directly onto attached ticks. Repeat as needed.</p>
<p>Horses</p>	<p>Stable Flies, Horn Flies, Face Flies, House Flies, Eye Gnats and Ticks.</p> <p>Aids in control of Horse Flies, Mosquitoes and Black Flies.</p>	<p>POUR ON: After riding or exercise, pour 8 mL to 16 mL of this product along the back and down the face of MATURE horses, being careful to avoid the eyes. Do not use this method of application on foals. Repeat treatment as needed.</p>
<p>Premises – in and around Horse, Beef, Dairy, Swine, Sheep and Poultry premises. Animal Hospital Pens and Kennels and "outside" Meat Processing Premises.</p>	<p>House Flies, Stable Flies, Face Flies, Gnats, Mosquitoes, Black Flies, Fleas, Little House Flies (<i>Fannia</i> spp.).</p> <p>Aids in control of cockroaches, ants, spiders, and crickets.</p>	<p>READY-TO-USE SPOT OR PREMISE SPRAY: Use undiluted in a mist sprayer. Apply directly to surface to leave a residual insecticidal coating, paying particular attention to areas where insects crawl or alight. 500 mL will treat approximately 7,200 square feet.</p>

For cattle and sheep repeat treatment as needed, but no more than once every two weeks. For optimum lice control, two treatments at a 14-day interval are recommended.

This product is not effective in controlling cattle grubs.

This product is an oil-based, ready-to-use product that may leave an oily appearance on the hair coat of some animals

This product should be used in an integrated pest management system which may involve repeat treatments and the use of other pest control practices

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry (preferably locked) place in an area that is inaccessible to children and animals. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

PESTICIDE DISPOSAL: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER DISPOSAL:

[Nonrefillable Container (5 gallons or less)] Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

[Nonrefillable Container (greater than 5 gallons)] Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

CONDITION OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Direction for Use of this Product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Envincio LLC or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Envincio LLC and Seller harmless for any claims relating to such factors.

Envincio LLC warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Envincio LLC., and Buyer and User assume the risk of any such use. To the extent consistent with applicable law, ENVINCIO LLC MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, neither Envincio LLC nor Seller shall be liable for any incidental, consequential or special damages resulting from the use or handling of this product. To the extent consistent with applicable law, **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF ENVINCIO LLC AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING**

CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF ENVINCIO LLC OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Envincio LLC and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Envincio LLC.

EPA 20131029