

1072-11

08-05-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG - 5 2010

FILE COPY

Kim Davis
Consultant/Agent for GEA Farm Technologies, Inc.
RegWest Company, LLC
8203 West 20th Street
Suite A
Greeley, CO 80634

Subject: K.O. Dyne
EPA Reg. No. 1072-11
Application Dated: July 7, 2010
Receipt Date: July 8, 2010

Dear Ms. Davis:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable with a condition.

Proposed Notification:

- Revised labeling per PR Notice 98-10 and PR Notice 2007-4

Condition:

Revise the Refillable Container Disposal section by changing the statement "Refill this container only with Sodium Hypochlorite." to read "Refill this container with pesticide only."

Comments:

Based on a review of the material submitted, the following comments apply:

This application for notification to revise the product label, as referenced above, is acceptable. A copy has been placed in our records for future reference.

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United States Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460-0001	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number <h1 style="margin:0;">Notification</h1>
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Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 1072-5-11 BP	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) K. O. Dyne®	PM # 32	
5. Name and Address of Applicant (Include ZIP Code) GEA Farm Technologies, Inc. c/o RegWest Company, LLC 8203 West 20th St., Suite A Greeley, CO 80634-4696		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. _____ Product Name _____
<input type="checkbox"/> Check if this is a new address		

Section – II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

**Submit label revision notification per PR Notices 98-10 and 2007-4:
Refer to the Reference Label for an illustration of all revisions.**

This notification is consistent with the provisions of PR Notices 98-10 and 2007-4 and EPA regulations at 40 CFR § 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notices 98-10 and 2007-4 and 40 CFR § 152.46 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:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes (gallon jugs) <input checked="" type="checkbox"/> No (all other sizes)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify): _____
*Certification must be submitted	If "Yes" Unit Packaging Wt. 1 gallon	No. Per Container 4	If "Yes" Packaging Wt. No. Per Container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 5, 15, 30 and 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 type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Other: Plastic sleeve			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name Kim Davis	Title Consultant/Agent	Telephone No. (Include Area Code) 970.353.611 kim@regwest.com
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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.

2. Signature 	3. Title Consultant/Agent
4. Typed Name Kim Davis	5. Date July 7, 2010

6. Date Application Received
(Stamped)

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July 7, 2010



Ms. Emily Mitchell, Product Manager 32
Document Processing Desk – **NOTIF**
Office of Pesticide Programs – **7504P**
U.S. Environmental Protection Agency
One Potomac Yard (South Building), Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

Dear Ms. Mitchell:

Subject: GEA Farm Technologies, Inc.
K.O. Dyne®
EPA Reg. No. 1072-11

On behalf of **GEA Farm Technologies, Inc.**, RegWest Company, LLC is submitting the attached documents as a notification label revisions pursuant to PR Notices 98-10 and 2007-4. RegWest will act as sole agent in this endeavor.

Attached are the following:

1. Application for Pesticide: Other (Notification)
2. One **Reference Label** (illustrating the revisions)
3. Two **New Labels** (incorporating the revisions)
4. Two market labels

The primary purpose of this notification is to update the label with Disposal directions per PR Notice 2007-4; we are also making other minor revisions, such as adding graphics per PR Notice 98-10. Please refer to the *Reference Label* for an illustration of the label revisions.

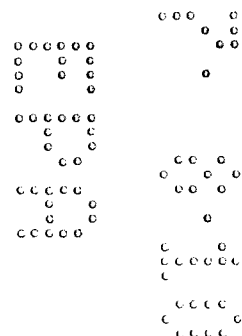
Please contact me at 970.353.0611 or kim@regwest.com if you have any questions or require additional information.

Regards,
RegWest Company, LLC

Kim Davis,
Consultant/Agent

Attachments

cc: GEA – McBride, N.



Should you have any questions or comments concerning this letter,
please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

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Sincerely,

A handwritten signature in black ink that reads "Wanda Henson". The signature is written in a cursive style with a large, stylized "H" at the end.

Wanda Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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K.O.DYNE®



GEA Farm Technologies

Concentrated Iodine Detergent Sanitizer Udder Wash

[Distributed by:]
GEA Farm Technologies, Inc.
1880 Country Farm Drive
Naperville, IL 60563 U.S.A.

NOTIFICATION
Date Reviewed: 8/5/2010
Reviewed By: W. Henson

Active Ingredient:	
Iodine*	1.75%
Other Ingredients	<u>98.25%</u>
Total	100.00%

*From Nonylphenoxypoly (ethyleneoxy) ethanol iodine complex.

(Code) (Rev. ____)

Net Contents: __ U.S. GAL (____ L)

[UPC]

EPA Reg. No. 1072-11

EPA Est. 1072-IL-1

**KEEP OUT OF REACH OF CHILDREN
DANGER**

[See side panel for First Aid and additional Precautionary Statements]

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER: Corrosive. Concentrate causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food).

Environmental Hazards

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

State and Local Regulations

Consult your dealer, state or local health authorities for additional information.

First Aid

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.
If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor for treatment advice. • Immediately drink large quantities of milk if available; otherwise drink large quantities of water. • 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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-451-8346 for emergency medical treatment information.	
Note to Physician: 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.}

DIRECTIONS FOR USE

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

Sanitizing Dairy Equipment: After cleaning and before use, sanitize all milk contact surfaces with a 25 ppm solution of K.O. DYNE as required by state and local health authorities. Refer to Table of Proportions for proper dilution rate. Contact time must be at least two minutes. Thoroughly drain and air dry.

Udder Washing: Prepare a sanitizing solution in warm water (not over 110°F / 43°C). Refer to Table of Proportions for proper dilution rate. Use a clean, single service towel for each cow. Wash and massage teats and udder. Never dip used towel back into solution. Discard solution when visibly dirty. Prepare a fresh solution for each milking. Dry teats and udder with clean, single service towel prior to attachment of milking machine.

Do not use as a teat dip.

Note: Amber to brown color of use dilution is an indicator of solution strength. Prepare a fresh solution if a noticeable change occurs in the solution's initial color.

Table of Proportions

- 25 ppm – 1 oz. (30 ml) in 5 gallons (18.9L) water
- 50 ppm – 1 oz. (30 ml) in 2.5 gallons (9.45L) water

{For products in refillable containers}

Storage and Disposal

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

Storage: Store in a cool, dry area away from direct sunlight. Keep from freezing. If frozen, separation may occur. Completely thaw and mix well prior to use. In case of spill, flood area with large quantities of water. **Pesticide**

Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. **Container Disposal:** Refillable container. Refill this container with only Sodium Hypochlorite. 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. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

{For products in rigid, non-refillable containers 5 gallons or less}

Storage and Disposal

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

Storage: Store in a cool, dry area, away from direct sunlight and heat to avoid deterioration. Keep from freezing. If frozen, separation may occur. Completely thaw and mix well prior to use. In case of spill, flood area with large quantities of water. **Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency or the hazardous waste representative at the nearest EPA Regional Office for guidance. **Container Disposal:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available. Promptly clean container 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.

{For product in rigid, non-refillable containers greater than 5 gallons}

Storage and Disposal

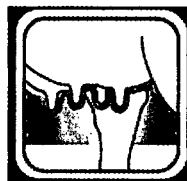
Do not contaminate water, food or feed by storage or disposal

Storage: Store in a cool, dry area, away from direct sunlight and heat to avoid deterioration. Keep from freezing. If frozen, separation may occur. Completely thaw and mix well prior to use. In case of spill, flood area with large quantities of water. **Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency or the hazardous waste representative at the nearest EPA Regional Office for guidance. **Container Disposal:** Non-refillable container; do not reuse or refill this container. Triple rinse (or equivalent) container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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.

Formula contains not more than 1.9% phosphorous or 0.12 grams per gallon (3.8L) average use concentration.

ONLY FOR FARM, COMMERCIAL & INDUSTRIAL USE
K.O. DYNE is a Registered Trademark of GEA Farm Technologies, Inc.

Made in U.S.A.



- [] Denotes alternate/optional language
- { } Denotes language not appearing on market label