

1072-11

6/27/2011

1 of 5



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 27, 2011

Kim Davis
Consultant/Agent,
GEA FARM Technologies, Inc.
c/o RegWest Company LLC
8203 West 20th St., Suite A, Greeley, CO 80634-4696

FILE COPY

Subject: K.O. DYNE
EPA Registration No. 1072-11
Application Dated: April 29, 2011
Receipt Dated: May 04, 2011

Dear Ms. Davis:

This acknowledges the receipt of your Amendment application dated April 29, 2011 in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment

Amend Reference Label and also to update the Storage & Disposal statement of K.O. Dyne (EPA Reg#1072-11) as per PR Notice 2007-4.

General Comments

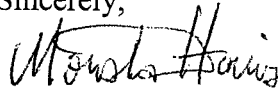
Based of the review of the submitted materials, this submitted label amendment is acceptable with conditions.

- a. Under the "**Precautionary Statement - Hazards to Humans and Domestic Animals**", add the following sentence to read "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
- b. Delete the "**Udder Washing**" direction claim from the label, because this claim is regulated by the FDA under FFDCa and is NOT regulated by the EPA under FIFRA, see 40 CFR 152.5(d) and 40 CFR 152.6(d). Also delete the "cattle udder logo" on page 3.

A stamped copy of the label with comments is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling. This amendment and a copy of this letter have been inserted in your file for future reference.

If you have any questions or comments concerning this letter, please contact David Liem by email at liem.david@epa.gov or call at (703) 305-1284.

Sincerely,



Monisha Harris
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

K.O.DYNE®

Concentrated Iodine Detergent Sanitizer Udder Wash

Active Ingredient:

Iodine*	1.75%
Other Ingredients	98.25%
Total	100.00%

*From Nonylphenoxypoly (ethyleneoxy) ethanol iodine complex.

Net Contents: ___ U.S. Gal (___ L)
{1, 5, 15, 30 and 55 gallons}
(Code) (Rev. _____)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 27 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,

EPA Reg. No. 1072-11

[UPC]

EPA Est. 1072-IL-1 registered under EPA Reg. No. 1072-11

KEEP OUT OF REACH OF CHILDREN

DANGER

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

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.}

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. *Wash thoroughly with soap and water after handling...*

Add

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.

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}

<p style="text-align: center;">Storage and Disposal</p> <p style="text-align: center;">Do not contaminate water, food or feed by storage or disposal.</p> <p>Pesticide 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.</p> <p>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 K.O. DYNE. 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. Offer for recycling, if available, or reconditioning, if appropriate; otherwise, discard in the trash [or dispose of in a sanitary landfill].</p>
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{For products in rigid, non-refillable containers 5 gallons or less}

<p style="text-align: center;">Storage and Disposal</p> <p style="text-align: center;">Do not contaminate water, food or feed by storage or disposal</p> <p>Pesticide 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</p>
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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; otherwise, discard in the trash [or dispose of in a sanitary landfill].

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

Storage and Disposal

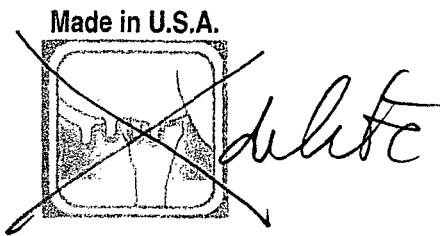
Do not contaminate water, food or feed by storage or disposal

Pesticide 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. Offer for recycling, if available, or reconditioning, if appropriate; otherwise, discard in the trash [or dispose of in a sanitary landfill].

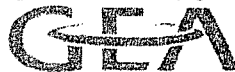
{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

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.



[Distributed by:]



GEA Farm Technologies
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[] Denotes alternate/optional language
{ } Denotes language not appearing on market label