12-08-2011 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

DEC - 8 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

James P. Ringo Bio-Cide International, Inc. P.O. Box 722170 Norman, OK 73072

Subject: Purogene Deodorizer and Sanitizer EPA Registration No. 9804-5 Submission Dated: September 20, 2011 Receipt Dated: September 22, 2011

Dear Mr. Ringo:

This amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

Conditions:

1. Remove the following information from the "Hazards to Humans & Domestic Animals" section of the label: Restricted Entry Intervals and Fruits and Vegetables instructions and place under the appropriate directions for use.

2. Revise the Hazards to Humans & Domestic Animals" statement as follows:

CAUTION: Harmful if swallowed. Harmful if inhaled. Avoid breathing vapor or spray mist. Causes moderate eye irritation. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or going to the restroom.

General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

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EPA Form 1320-1A (1/90)

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

Sincerely,

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

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Purogene®

ACCEPTED with COMMENTS in EPA Letter Dated:

DEC - 8 2011 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 9804-5

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premium-blend CHLORINE DIOXIDE

For Commercial and Institutional Use

Deodorizer and Sanitizer Inhibits the growth of bacterial colonies Active Ingredient:

> EPA Reg. No. 9804-5 Est. No. 9804-OK-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

STORE IN COOL DARK PLACE - KEEP FROM FREEZING

Bio-Cide International, Inc. 2650 Venture Drive Norman, Oklahoma 73070

Net Contents: ___Quart ___Gallon ___5 Gallons ___30 Gallons ___55 Gallons

Proper Dilution of Purogene[®]

Parts per Million				
5 ppm	0.032 fl. oz per gallon	or	0.25 ml per liter	2000 - C.
10 ppm	0.064 fl. oz. per gallon	or	0.5 ml per liter	
20 ppm	0.128 fl. oz. per gallon	or	1.0 ml per liter	
40 ppm	0.256 fl. oz. per gallon	or	2.0 ml per liter	
50 ppm	0.320 fl. oz. per gallon	or	2.5 ml per liter	
100 ppm	0.640 fl. oz. per gallon	or	5.0 ml per liter	
200 ppm	1.280 fl. oz. per gallon	or	10.0 ml per liter	
400 ppm	2.560 fl. oz. per gallon	or	20.0 ml per liter	

Alternative Activation

The active biocidal component of Purogene[®] system is free chlorine dioxide. Unactivated ender Purogene[®] in the neutral to mildly alkaline pH ranges is bacteriostatic. For higher level microbial control, such as disinfection and sanitation, activation of Purogene[®] is required to generate free chlorine dioxide. The use of citric acid as an activator is specified in most Purogene[®] applications. Alternatives to citric acid for activation include generally regarded as safe (GRAS) organic acids, such as acetic acid, and inorganic acids such as phosphoric, hydrochloric, and sulfuric acids. Activation equivalent to that of citric acid may be achieved by adjusting the Purogene[®] solution to pH 2-3 with an alternative acid. The activated Purogene[®] is then diluted to the required used concentration in accordance with label instructions. For food processing applications only food grade activator acids may be used. Bio-Cide International, Inc. or your Purogene[®] distributor can guide you in proper activation techniques.

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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.

FOR USE IN WATER AND ICE

- In potable water for the improvement of taste and odor and for inhibiting bacteria growth: 1.0-5.0 ppm.
- In ice, as a sanitizer, made from potable water for use in drinking glasses and cups: 20 ppm unactivated.
- 3. In individual ice flaking and cubing machines to inhibit bacterial slime buildup: 20 ppm unactivated.

For Commercial Use:

- In ice plants to inhibit bacteria and slime buildup on ice-making equipment: 40 ppm unactivated.
- 2. As a bacteriostat in ice: 40 ppm unactivated.

For Hospital & Institutional Use:

 As a sanitizer in ice, made from potable water, while in ice storage equipment: 20 ppm unactivated.

FOR SANITIZING POTABLE WATER STORAGE TANKS

- 1. Drain tank; remove sediments.
- 2. Fill tank with sanitizing solution. (See ACTIVATION AND DILUTION PROCEDURES below)
- Drain small amount of sanitizer solution from all outlets, then add makeup solution to tank.
- 4. Allow sanitizing solution to stand for specified amount of time. (See below)
- 5. Drain and flush system with potable water.
- Fill tank with potable water or water treated at 1 to 5 ppm.

ACTIVATION AND DILUTION PROCEDURES FOR SANITIZING POTABLE WATER STORAGE TANKS.

5-Minute Procedure: (100 ppm available CIO_2) For each 50 gallons of tank capacity, mix 32 fl. oz. of Purogene with 1/2 cup (4 oz.) citric acid or equivalent in a plastic container. Let mixture stand five (5) minutes. Dilute activated concentrate with two (2) gallons of potable water. Pour solution into tank and fill with water. Allow active sanitizing solution to stand in tank for at least five minutes.

1-Hour Procedure: (50 ppm available ClO₂) For each 50 gallons of tank capacity, mix 16 fl. oz. of Purogene with 1/4 cup (2 oz.) citric acid or equivalent in a plastic container. Let mixture stand five (5) minutes. Dilute activated concentrate with two (2) gallons of potable water. Pour solution into tank and fill with water. Allow active sanitizing solution to stand in tank for one hour.

TO CONTROL BUILD-UP OF SLIME AND ODOR CAUSING BACTERIA AND ENHANCE THE TASTE OF STORED POTABLE WATER.

i) Prior to treatment of potable water, thoroughly clean and disinfect the water storage system to ensure a sanitary condition. Thoroughly rinse with clean, potable water.

ii) Potable water should be treated at a rate of one (1) fl. oz. Purogene[®] per 30 gallons potable water (5 ppm available CIO_2) and may be injected or batch treated.

iii) Water storage tank should be sufficiently sealed to prevent outside contamination and direct sunlight.

iv) Using a Bio-Cide test kit, confirm the chemical level to be 5 ppm and check to see this level does not fall below 1 ppm

TO CONTROL THE SPREAD OF LATE BLIGHT, SOFT ROT, DRY ROT, SILVER SCURF, RING ROT, PINK ROT, BLACK SCURF AND OTHER TUBER DISEASE CAUSING ORGANISMS IN POTATO STORAGE SHEDS:

Activation of Purogene

Prior to dilution, the product concentrate must be activated by addition of a food grade acid in order to generate free chlorine dioxide. See below for directions on activation.

FOR THE TREATMENT OF WATER USED TO SPRAY OR RINSE POTATOES PRIOR TO STORAGE.

1) Activation:

For piling applications, activate 5 gallons of Purogene with 25 oz. (1.6 lbs.) of citric acid (99% fine granular), or 7.5 fl. oz. of 75% phosphoric acid. Wait 30 minutes.

2) Dilution:

Dilute activated concentrate to 400 ppm. 5 gallons of Purogene + 250 gallons of water = 400 ppm solution.

 Apply 400 ppm solution directly on tubers going into storage using any appropriate means such as spraying or misting. For small volume applications, refer to the Technical Data Sheet.

FOR THE TREATMENT OF HUMIDIFICATION WATER TO CONTROL TUBER DISEASE CAUSING ORGANISMS ON STORED POTATOES.

1) Activation:

For humidification applications, activate 5 gallons of Purogene with 7.5 oz. (0.47 lbs.) of citric acid (99% fine granular), or 2.5 fl. oz. of 75% phosphoric acid. Wait 30 minutes.

2) Dilution:

Dilute activated concentrate to 200 ppm. 5 gallons of Purogene + 500 gallons of water = 200 ppm solution.

3) For continual treatment of high risk storage, an initial treatment up to 200 ppm

may be added to the humidification as either a mist into the air stream, or as a fog directly into the plenums.

4) For the periodic treatment of storage with unknown risk, a treatment up to 200 ppm may be applied as either a mist into the air stream, or as a fog directly into the plenums.

5) To reduce the amount of water added to the storage during fogging treatments, concentrations of up to 400 ppm of activated product may be applied to the air streams.

Owners/operators of potato storage facilities must ensure adequate protection of workers and handlers, according to the following guidance.

PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment (PPE) that must be worn during mixer/loader task associated with pre-storage applications of Purogene includes: chemical-resistant gloves, goggles/face shield, and NIOSH approved canister/cartridge respirator rated for chlorine/acid gas vapors of specified for chlorine dioxide.

Chemical resistant gloves must be worn for all other handler activities in which the worker is placed in direct contact with either the wet treated potatoes (e.g., during inspection/disease monitoring in the storage shed) or the humidification water system/process water tank (during equipment cleaning/maintenance.)

RESTRICTIONS

Do not allow unprotected workers in the area to be exposed above the permissible exposure limit (PEL) of 0.1 ppm for an 8 hour time weighted average (TWA), or 0.3 ppm for any 15 minute short term exposure limit (STEL).

Avoid storing product under conditions in which it could evaporate to a crystalline salt.

All potatoes treated must have a potable rinse applied before further processing. Avoid accidental contact with acids, chlorine compounds, hypochlorite (bleach), sulfur and sulfite compounds, phosphorus, organic solvents, and combustible/flammable materials. Exposure to acids or chlorine compounds can produce uncontrolled generation of chlorine dioxide.

Do not allow chlorine dioxide to accumulate in confined spaces.

Waste water containing residual chlorine dioxide and its breakdown products like chlorite, chlorate, or chloride ions will not be transferred to public water ways but kept in an open pond or reservoir to go through aeration (which helps in the dissociation of chlorine dioxide) in the confines of the treatment facility and only discarded after the levels of these pesticides are equal to or lower than the ones recommended by EPA's Office of Water.

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STORAGE AND DISPOSAL

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

Product Storage: Store in a cool, dry, well-ventilated location away from acids, chlorine and chlorine compounds, hypochlorites (bleach), organic solvents, sulfur and sulfite compounds, phosphorus, combustible/ flammable materials, and direct sunlight. Keep containers tightly closed when not in use and open carefully to prevent spillage. Storage on wooden floors and pallets is not recommended. Keep from freezing.

CONTAINER DISPOSAL: Nonrefillable Container.

{Text for nonrefillable containers that are 5 gallons or smaller}

Do not reuse or refill this container. Offer for recycling if available. Offer for reconditioning if appropriate. Triple rinse container or equivalent, promptly after emptying.

<u>Triple rinse as follows</u>: Empty the remaining contents into applications equipment or a mix tank and drain for ten seconds after the flow begins to drip. Fill the container ¹/₄ full with water and recap. 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.

CONTAINER DISPOSAL: Nonrefillable Container.

{Text for nonrefillable containers that are larger than 5 gallons}

Do not reuse or refill this container. Offer for recycling if available. Offer for reconditioning if appropriate. Triple rinse container, or equivalent, promptly after emptying.

<u>Triple rinse as follows</u>: Empty remaining contents into application equipment or mix tank; Fill the container ¼ full with water. Replace and tighten closures. Tip the 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 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 process two more times.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: CAUTION: Harmful if swallowed. Harmful if inhaled. Avoid breathing vapor or spray mist. Remove contaminated clothing and wash clothing before reuse. Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling. Handlers applying chlorine dioxide in an occupational setting must wear gloves. People must vacate the premises during fogging treatment; a one-hour restricted entry interval (REI) is required. Fruits and vegetables treated with chlorine dioxide must be blanched, cooked, or canned before consumption or distribution in commerce.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public 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 sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

	FIRST AID			
If inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice 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. 			
lf on skin				
lf eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. 			
If swallowed	 Call a poison control center or doctor immediately 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. 			
	 Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on this product, call National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT) seven days a week. During other times, call the poison control center 1-800-222-1222 			