

9804-5

5/24/2007

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United States
Environmental Protection
Agency

Office of Pesticide Programs

May 24, 2007

James P. Ringo
Bio-Cide International, Inc.
2845 Broce Drive
Norman, OK 73072

Subject: Purogene Deodorizer and Sanitizer
EPA Registration No. 9804-5
Submission Dated: February 12, 2007
Receipt Date: February 12, 2007

Dear Mr. Ringo:

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

The proposed label claim that this product is an effective sanitizer on hard non-porous surfaces against *Salmonella typhi* for a contact time of 5 minutes is acceptable.

Conditions

1. Remove the following terminology from the proposed label under the Blending & Time Chart for Sanitizing Water Storage Tanks heading: "For sudden or severe bacteria contamination . . ." This statement must be removed as it is not defined adequately on the proposed label.
2. The efficacy data supported the proposed 5 minute contact claim as previously stated. Bio-Cide International, Inc. must define conditions that warrant a 4-hour procedure, 2-hour procedure, and a 1 hour procedure under the Blending & Time Chart for Sanitizing Water Storage Tanks section. Until this clarification is submitted and approved by the Agency, these contact times must be removed from the proposed label.
3. The acute toxicity data submitted in December 7, 1984, classified this product as a category III for acute oral, dermal and eye irritation. Therefore, the misleading Class 4 has been removed from the First Aid statement.
4. The following statement must be added to the First Aid section: Have product container or label with you when calling a poison control center or doctor or going for treatment.

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.

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

Sincerely,

Emily H. Mitchell
Product Manager – Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

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Purogene®

premium-blend
CHLORINE DIOXIDE

For Commercial and Institutional Use Only

Deodorizer and Sanitizer

Active Ingredient:	2.00%
Chlorine Dioxide	95.00%
Inert Ingredients:	100.00%

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

CAUTION
KEEP OUT OF REACH OF CHILDREN
SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

ACCEPTED
with COMMENTS
EPA Letter Dated:
MAY 24 2007

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

Corporate Address:

Manufactured by:

Contents:

2845 Broce Drive
Norman, Oklahoma
73072

1.800.323.1398



- 32 Oz.
- 1 Gallon
- 5 Gallons
- 30 Gallons
- 55 Gallons

www.bio-cide.com

PROPER ACTIVATION OF PUROGENE®

MEASURE out the desired volume of Purogene® concentrate into a clean vessel in a well-ventilated area. **ADD** the required amount of activator, stir and **allow to react for ten minutes**. Avoid breathing any fumes that may be produced. After five minutes, **DILUTE** with clean water to your desired final concentration.

<u>Concentration</u>	<u>Ounces per 5 Gallons</u>	<u>Activator</u>
5 ppm	0.016 fl. oz./5 Gallon	0.5 g
10 ppm	0.032 fl. oz./5 Gallon	1.0 g
20 ppm	0.064 fl. oz./5 Gallon	2.0 g
40 ppm	1.28 fl. oz./5 Gallon	4.0 g
50 ppm	1.60 fl. oz./5 Gallon	5.0 g
100 ppm	3.20 fl. oz./5 Gallon	10.0 g
200 ppm	6.40 fl. oz./5 Gallon	20.0 g
500 ppm	16.00 fl. oz./5 Gallon	50.0 g

PROPER DILUTION OF PUROGENE®

<u>Parts per Million</u>	<u>0.064 fl. oz. per gallon</u>	<u>or</u>	<u>0.5 ml per liter</u>
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
30 ppm	0.192 fl. oz. per gallon	or	1.5 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

Alternative Activation

The active biocidal component of Purogene® system is free chlorine dioxide. Unactivated 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® application. Alternative to citric acid for activation include 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.

Directions for use with water and ice.

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

- 1. In potable water for the improvement of taste and odor and for inhibiting bacteria growth: 1.0-5.0 ppm
- 2. 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:

- 1. 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:

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

Directions for use in sanitizing potable water storage tank.

- 1. Drain tank; remove sediments
- 2. Fill tank with sanitizing solution. (See chart below)
- 3. 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.
- 6. Fill tank with potable water.

Blending & Time Chart for Sanitizing Potable Water Storage Tanks

4-hour Procedure: Mix in 32 fl. oz. of Purogene for each 50 gallons of tank capacity.

2-hour Procedure: Mix in 64 fl. oz. of Purogene for each 50 gallons of tank capacity.

1-hour Procedure: *For sudden or severe bacteria contamination* - 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 (2) gallons of potable water. Pour solution into tank and fill with water.

5-Minute Procedure: *For sudden or severe bacteria contamination* - 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 (2) gallons of potable water. Pour solution into tank and fill with water.

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:

DIRECTIONS FOR USE:

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

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.

3) 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 or 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.

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

Container Disposal: Triple rinse. Then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or by incineration; or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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

ENVIRONMENTAL HAZARDS

This pesticide 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. □

FIRST AID Class IV	
<i>If inhaled</i>	<ul style="list-style-type: none"> - 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.
<i>If on skin or clothing</i>	<ul style="list-style-type: none"> - 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.
<i>If eyes</i>	<ul style="list-style-type: none"> - 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.
<i>If swallowed</i>	<ul style="list-style-type: none"> - Call a poison control center or doctor immediately for treatment advice. - Have a 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.