August 5, 2003

Steven D. Goodspeed Bio-Cide International, Inc. 2845 Broce Drive Norman, OK 73072

Subject:

Purogene

EPA Registration No. 9804-5

Submissions Dated: August 7, 2002 and February 21, 2003 Receipts Dated: August 8, 2002 and February 25, 2003

Dear Mr. Goodspeed:

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

■ Revised label to add Stored Potatoes

Condition

You must place the First Aid Statement on front panel of this label.

General Comments

The use that the Agency is accepting with this amendment is storage of potatoes. Initially, the Agency considered issuing a Threshold Of Regulation (TOR), determination for the use of this product on stored potatoes, however, after careful evaluation by our scientific staff it was determined that it is unlikely there would be a residue of chlorine dioxide on the potatoes, so no food tolerance is required.

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

	CONCURRENCES	
SYMBOL 7570C		
SURNAME MITTHEN		
DATE 8-6-03		
EDA Form 1320-14 (1/00)	Printed on Demoled Bones	OFFICIAL FILE COPY

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

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

Sincerely,

Robert S. Brennis

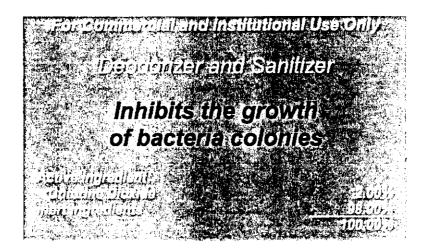
Product Manager - Team 32

Regulatory Management Branch II

Antimicrobials Division (7510C)

Purogene®

premium-blend CHLORINE DIOXIDE



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

CAUTIONKEEP OUT OF REACH OF CHILDREN

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

ACCEPTED with COMMENTS EPA Letter Dated:

"AUC - 5 2003

Corporate Address:

2845 Broce Drive Norman, Oklahoma 73072

1.800.323.1398

Manufactured by:

Contents: \square 32 Oz.

☐ 1 Gallon ☐ 5 Gallons

☐ 30 Gallons ☐ 55 Gallons

www.bio-cide.com

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

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.

ACCEPTED
with COMMENTS
FEPA Letter Dates

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Under the Federal inserticide, Fungicide, and Rodanholde Act ac amended, for the restroide, registered under EPA Reg. No. 9804-5

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 unactivated
- In ice made from potable water, for the improvement of taste and odor, 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:

 In ice made from potable water for the improvement of taste and odor, 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

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.

ACCEPTED

with COMMENTS

EPA Letter Dated

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Under die Federal Insomicide, Mandrider und Normandrie Am au zurchder Großer der Ammang 9604–5 magistores under Litter op von 9604–5

Grace :

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 by adding 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. Add 5 gallons of activated Purogene to 250 gallons of water to yield a 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 by adding 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. Add 5 gallons of Purogene to 500 gallons of water to yield a 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.

NOTE: If reducing the amount of water being added to potatoes in storage during fogging treatments, concentrations of up to 400 ppm of activated product may be applied to the air streams. Do not add more than 2.0 gatterns of repure gene concentrate per month to humidification water per 500 tons of potatoes in storage.

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

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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

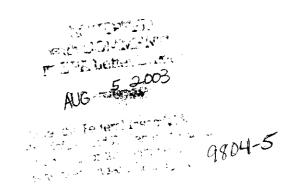
Do not allow unprotected workers in the area to be exposed above the permissible exposure limit (PEL) of 0.1 ppm for an 8 hour time weighted average (TWA), or 0.3 ppm for any 15 minute short term exposure limit (STEL).

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.



ACCIPTED
with COMMENTS
= EPA Letter Dated:

AUG - 5 2003

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

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
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.
lf on skin or clothing	 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.
If 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 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.