

9804-5

06/17/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUN 17 2010

James P. Ringo
Director of Regulatory Affairs
Bio-Cide International, Inc.
2650 Venture Drive
Norman, OK 73069

FILE COPY

Subject: Purogene Deodorizer and Sanitizer
EPA Reg. No. 9804-5
Application Dated: May 19, 2010
Receipt Date: May 21, 2010

Dear Mr. Ringo:

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 comments.

Proposed Notification:

- Revised Container Disposal Section per PR Notice 2007-4

Comments:

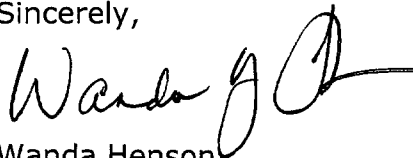
Based on a review of the material submitted, the following comments apply:

1. Change the statement "Triple rinse container promptly after emptying." to read "Triple rinse container (or equivalent) promptly after emptying."
2. Change the statement "...to for later use or disposal." to read "...or store rinsate for later use or disposal."
3. Add the statement "Turn the container over onto its other end and tip it back and forth several times." preceding the statement "Empty the rinsate..."

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

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

Sincerely,

A handwritten signature in black ink, appearing to read "Wanda Henson", with a stylized flourish extending to the right.

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



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 9804/9804-5	2. EPA Product Manager Wanda Henson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Purogene	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Bio-Cide International, Inc. P.O. Box 722170 Norman, OK 73070 <input type="checkbox"/> Check if this is a new address	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 _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

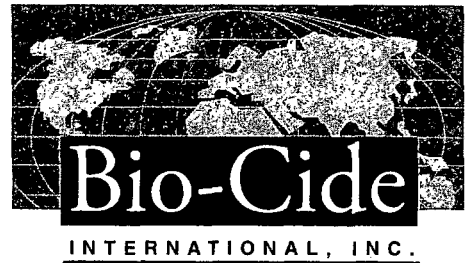
Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.146, and 156.156. - (The complete statement required by PR Notice 2007-4 is on the additional page. See attached.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 32 fl. oz; 1, 5, 30, 55 gal.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name James P. Ringo	Title Director of Reg. Affairs	Telephone No. (Include Area Code) 405-329-5556
<p align="center">Certification</p> <p>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.</p>		8. Date Application Received (Stamped)
2. Signature <i>James P. Ringo</i>	3. Title Director of Regulatory Affairs	
4. Typed Name James P. Ringo	5. Date May 19, 2010	



May 19, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Purogene®, EPA Registration No. 9804-5
Notification of label changes per PR Notice 2007-4

Dear Mrs. Henson:

The enclosed EPA Form 8570-1 is submitted for amendment by notification of the Purogene® label, EPA Reg. No. 9804-5. The purpose of this notification is to bring the Purogene® label into compliance with the requirements of Pesticide Registration Notice (PR) 2007-4: Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal; Standard for Pesticide Containers and Containment."

In accordance with PR 2007-4, please find the enclosed:

EPA Form 8570-1, with attachments, and

One (1) copy of the new label with the changes highlighted.

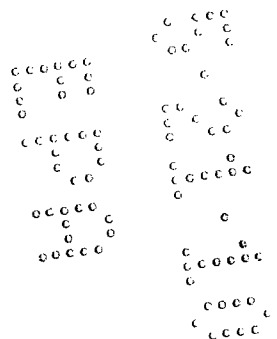
If you have any questions or need for additional information on this subject, please call me at 405-329-5556 or email me at JRingo@bio-cide.com.

Sincerely:

James P. Ringo
James P. Ringo

Director of Regulatory Affairs

- Enclosures: 1. EPA Form 8570-1, dated May 19, 2010
- 2. Highlighted copy of new label



Purogene®

premium-blend
CHLORINE DIOXIDE

NOTIFICATION
Date Reviewed: 6/17/2010
Reviewed By: [Signature]

For Commercial and Institutional Use Only

Deodorizer and Sanitizer

Inhibits the growth of bacterial colonies

Active Ingredient:

Chlorine Dioxide.....	2.00%
Other Ingredients.....	98.00%
Total.....	100.00%

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

**PRECAUTIONARY STATEMENT: HAZARD TO HUMANS AND DOMESTIC ANIMALS
HARMFUL IF SWALLOWED MAY CAUSE IRRITATION
AVOID CONTACT WITH EYES**

Corporate Address:

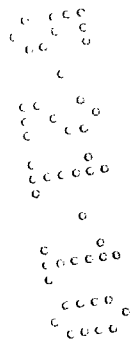
2650 Venture Drive
Norman, Oklahoma
73069
1.800.323.1398

Manufactured by:



Contents:

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



Proper Dilution of Purogene®

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

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.

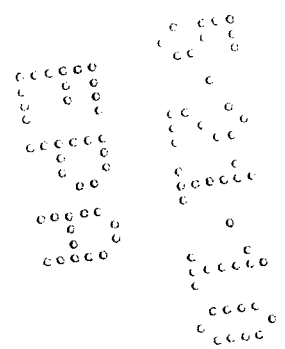
DIRECTIONS FOR SANITIZING POTABLE WATER STORAGE TANKS

- 1. Drain tank; remove sediments.
- 2. Fill tank with sanitizing solution. (See ACTIVATION AND DILUTION PROCEDURES 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.

ACTIVATION AND DILUTION PROCEDURES FOR SANITIZING POTABLE WATER STORAGE TANKS.

5-Minute Procedure: (100 ppm available ClO₂) 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 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).

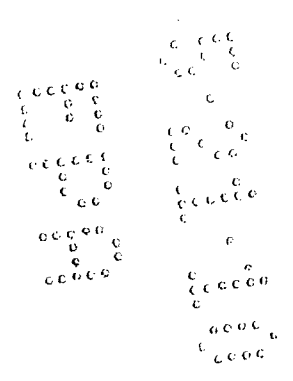
Avoid storing product under conditions in which it could evaporate to a crystalline salt.

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

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 promptly after emptying.

Triple rinse as follows: 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 ¼ full with water and recap. Pour rinsate into application equipment or a mix tank to 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 promptly after emptying.

Triple rinse as follows: 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 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.

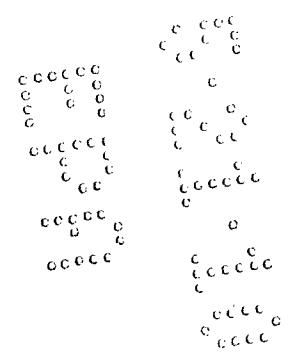
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

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	
<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.
	For 24 hour emergency information on this product, call NPIC at 1-800-858-7378 (U.S., Canada, Puerto Rico, Virgin Islands) or 1-703-527-3887 (All Other Areas)
	Have the product container or label with you when calling a poison control center or doctor or going for treatment.



{Text for non-refillable containers that are 5 gallons or smaller}

CONTAINER DISPOSAL: Non-refillable Container.

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

Triple rinse as follows: 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 ¼ full with water and recap. Pour rinsate into application equipment or a mix tank for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

{Text for non-refillable containers that are larger than 5 gallons}

CONTAINER DISPOSAL: Non-refillable Container.

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

Triple rinse as follows: Empty remaining contents into application equipment or 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this process two more times.

