

08/20/2009

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

AUG 20 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mark Jernigan Federal Registration Manager Bio-Lab, Inc. PO Box 300002 Lawrenceville, GA 30049-1002

FILE COPY

Subject:

Nirvana

EPA Registration No. 5185-491 Application Date: July 22, 2009 Receipt Date: July 24, 2009

Dear Mr. Jernigan:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification:

- Revision of Storage and Disposal Statement per PR notice 2007-4
- Deletion of marketing statements
- Addition of asterisks referencing previously accepted efficacy claims

General Comments:

Based on a review of the material submitted, the following comment applies:

The notification is acceptable and a copy has been inserted in your file for future reference.

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

Sincerely,

Wanda Y. Hensdo√

Product Reviewer (32)

Regulatory Management Branch II Antimicrobials Division (7510P)

Please read instructions on reverse before cor	ting form.	· · · · · · · · · · · · · · · · · · ·	Form Appro	<u>-</u> ,		Approval expires 2-28-9
Environmental Protection Agency Amer				Registration Amendme Other	""	OPP Identifier Number
	Application	for Pestic	de - Sectio	on I		
1. Company/Product Number 5185-491		2. EPA Product Manager E. Mitchell		er	3. Proposed Classification None Restricted	
4. Company/Product (Name) Bio-Lab, Inc. / Nirvana		PM# 32				Restricted
5. Name and Address of Applicant (Include ZIP Bio-Lab, Inc. PO Box 300002 Lawrenceville, GA 30049 Check if this is a new address	Code)	6. Expedited Reveiw. 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 -				
Amendment - Explain below. Resubmission in response to Agency let Notification - Explain below. Explanation: Use additional page(s) if neces Fee Determination: Fee Category - Not Applicabl Notification to change the Pesticide Container Dis Additionally, as permitted by PR Notice 98-10, thi statements. See attached page for certification.	sary. (For section I a e (Notification) mark.je sposal language per Pl	ernigan@chemtu R Notice 2007-4	Agency letter "Me Too" App Other - Explain ura.com	olication.		ks to footnote select
	(Section - I	11			
1. Material This Product Will Be Packaged In:						
Child-Resistant Packaging Yes No * Certification must be submitted Unit Packaging Yes No If "Yes" Unit Packaging w	No. per II	Water Soluble Packaging Yes No If "Yes" Package wgt No. per Package wgt No. per		M PI	2. Type of Container Metal Plastic Glass Paper Other (Specify)	
3. Location of Net Contents Information 4. Size(s) Re		r · · · · ·		Location of Label D	n of Label Directions On container	
6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stenciled						
		Section - I	V			
1. Contact Point (Complete items directly below	v for identification of	individual to b	e contacted, if r	necessary, to proces	s this ap	plication.)
Name Mark Jernigan		Title Regulatory Affairs Manager		, in , ,	Telephone No. (include Area Code)	
I certify that the statements I have made I acknowledge that any knowlinglly false both under applicable law.	Certification on this form and all a or misleading statem	attachments the	ereto are true, a nishable by fine	or imprisonment or	te.	Eate Application Received (Stamped)
Signature Prak Jeungan		3. Title Regulatory Affairs Manager				
4. Typed Name Mark Jernigan	5. D	ate 7	/22/09	7		,

EPA Registration Number: 5185-491

Registration Name: Nirvana

Application for Pesticide dated: July 22, 2009

Section - II
Explanation (Continued)

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, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

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And

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

græk Jernigan 7/12/09



July 22, 2009

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

Re: Nirvana

EPA Registration No.: 5185-491

Dear Sir/Madam:

Please process the enclosed notification for the above referenced product.

The purpose of this notification is to:

- 1. Add language required by the Pesticide Container Rule under Storage and Disposal per PR Notice 2007-4.
- 2. Delete statements that contain the word "germs" and add asterisks to footnote select statements.

Enclosed are:

- 1. Application for Pesticide (EPA Form 8570-1);
- 2. Notification Certification Statement; and
- 3. Proposed label with changes marked.

If you have any questions, please call me at 678-502-4149 or mark.jernigan@chemtura.com.

Thank you for your attention to this matter.

Sincerely,

Mark Jernigan

Regulatory Affairs Manager

Enclosures

Bio-Lab, Inc. P.O. Box 300002 Lawrenceville, GA 30049-1002



{All text in brackets [xxx] is optional and may or may not be included on a final label.} {All text in braces {xxx} is administrative and will not appear on a final label.}

Nirvana [Bleach] Automatic Toilet Bowl Cleaner



KEEP OUT OF REACH OF CHILDREN DANGER

See [back] [side] panel for First Aid and additional precautionary statements.

Bio-Lab, Inc. PO Box 300002 Lawrenceville, GA 30049 EPA REG. NO. 5185-491 EPA EST. NO. 5185-GA-1

Net Weight: 3.5 oz (100g)

Registered Claims:

[Anti-Bacterial Toilet Bowl Cleaner]

[Sanitizes and Deodorizes with power of chlorine]

[Kills 99.9% of Bacteria in toilet bowl water after each flush.*]

[Kills and prevents the growth of bacteria for 11 (eleven) weeks in toilet*]

[Sanitizing Formula: Kills 99.9% of bacteria for 11 (eleven) weeks. *]

{One or more of the following statements will be used for the asterisked item. Or they may stand alone.}

[[*]Kills 99.9% of Escherichia Coli for 11 (eleven) weeks.]

[[*]Kills 99.9% of Staphylococcus aureus for 11 (eleven) weeks.]

[[*]Kills 99.9% of Pseudomonas aeruginosa for 11 (eleven) weeks.]

[[*]Kills 99.9% of Enterococcus faecium for 11 (eleven) weeks.]

[[*]Kills 99.9% of E. Coli for 11 (eleven) weeks.]

[[*]Kills 99.9% of S. aureus for 11 (eleven) weeks.]

[[*]Kills 99.9% of P. aeruginosa for 11 (eleven) weeks.]

[[*]Kills 99.9% of E. faecium for 11 (eleven) weeks.]

[[*]Kills 99.9% of E. Coli, S. aureus, P. aeruginosa, and E. faecium for 11 (eleven) weeks.]

[[*]Kills 99.9% of Escherichia Coli, Staphylococcus aureus, Pseudomonas aeruginosa, and

Enterococcus faecium for 11 (eleven) weeks.]

Deleted state ments that contained the word "germs"

Marketing Claims:

[Now with "Power Blue" End of Life Indicator]

[Now with "True Blue" End of Life Indicator]

[Revolutionary "True Blue" inner tablet tells you when to add a new tablet to your toilet tank]

[End of Life Indicator - Tells you when to add a new tablet!]

[The only toilet tab that tells you when its time for a replacement!]

[Includes Tablet Life Monitor]

[Revolutionary "True Blue" Replacement Signal]

[Includes "True Blue" Reapplication Signal Technology]

[Contains "True Blue" Tablet Addition Signal Technology]

[Keeps bowl fresh]

[Helps keep bowl clean and fresh]

[Easy to use – just drop in tank]

[Not harmful to plumbing or septic systems]

[Keeps water crystal clear]

[Reduces the need for difficult brushing]

[Makes toilet cleaning easier]

[Cleans and Deodorizes with power of chlorine]

[Cleans and deodorizes with every flush]

[Safe for colored toilets]

[Will not harm colored toilets]

{Back panel}

[Nirvana is a revolutionary new in-tank toilet bowl cleaner containing patented [Power Blue] [True Blue] [inner tablet] technology. [The [Power Blue][True Blue] Tablet tells you when to add a new tablet to your toilet tank.] Nirvana sanitizes your toilet bowl using the power of chlorine. Nirvana's concentrated formula maintains a [clean] {or} [sanitized] toilet bowl for up to 11 weeks, reducing the need for difficult brushing. Nirvana is easy to use – just drop the tablet into your toilet tank.]

{or}

[Nirvana reduces the need for difficult brushing with a concentrated chlorine formula that keeps your bowl clean for up to eleven weeks. Better still, it won't harm plumbing or septic systems and can be used in colored toilets. Drop it in your tank and let Nirvana go to work for you.]

DIRECTION FOR USE: It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and use strictly in accordance with precautionary statements and directions for use.

To Sanitize, Clean and Deodorize:

- 1. Clean toilet bowl thoroughly including the rim and under the rim.
- 2. Remove toilet tank top. Holding the tablet pouch away from face cut open with a pair of scissors. DO NOT TOUCH THE TABLET.
- 3. Flush toilet. Before tank refills, hold pouch over tank and drop only the Nirvana Tab into the right rear corner of the tank. Discard pouch and wash hands thoroughly.
- 4. No removal necessary. Each tablet sanitizes for about 11 weeks. When the tablet is spent, [a blue color will be emitted to the bowl for 24-48 hours (approximately 10 flushes),] replace with a new Nirvana Tab. Product should only be used in a toilet that is flushed regularly.
- 5. When using Nirvana do not add any other product to the toilet tank.

FIRST AID: IF 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 IN EYES: 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 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 poison control center or doctor for treatment advice. IF SWALLOWED: Call 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 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. IN CASE OF MEDICAL EMERGENCY, CALL [1-877-800-5553] [telephone number supplied by customer].

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL: Store in original container in areas inaccessible to small children in a cool, dry, ventilated area. Do not store at elevated temperatures. CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available.

*Changed. per PR Notice 2007-4

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

DANGER: Corrosive: Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Irritating to nose and throat. Avoid breathing dust. Wear rubber gloves when handling and wash thoroughly with soap and water after handling.

PHYSICAL OR CHEMICAL HAZARDS: CONTAINS A STRONG OXIDIZING AGENT. Keep away from heat and flame. Mix only with water. Do not add this product to any toilet tank containing remnants of any other product including acids and ammonia.

NOTE: Buyer assumes all responsibility for safety and use not in accordance with directions.

{The section below will appear on the tablet pouches, which are enclosed in a box.} Cut Here To Open Contains 1 Tablet

Nirvana [Bleach] Automatic Toilet Bowl Cleaner

KEEP OUT OF REACH OF CHILDREN DANGER

[See additional precautions on outer [container] [box].] {or}

[Use only in accordance with directions and precautions on outer [container] [box].]

NET WT. 3.5 oz (100g)

Bio-Lab, Inc. PO Box 300002 Lawrenceville, GA 30049 EPA REG. NO. 5185-491 EPA EST. NO. 5185-GA-1

{Directions for use and first aid will be included on pouch if there is sufficient room to print text.} **DIRECTIONS FOR USE:** It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and use strictly in accordance with precautionary statements and directions for use.

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