

1448-93

4/02/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 02 2003

Buckman Laboratories, Inc.
1256 North McLean Blvd
Memphis, TN 38108

Attention: Crystal W. Brown
Regulatory Affairs Specialist


Subject: BUSAN 1016
EPA Registration No. 1448-93
Notification Dated February 26, 2003

This will acknowledge receipt of your notification to include additional label layout comments, submitted under the provisions of FIFRA Section 3(c)9. Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobial Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

<p>United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number _____
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Application for Pesticide - Section I

1. Company/Product Number Buckman Laboratories, Inc./1448-93	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Buckman Laboratories, Inc./BUSAN 1016	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Buckman Laboratories, Inc. 1256 North McLean Blvd. Memphis, TN 38108 <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.)

New label format

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
<i>Certification must be submitted</i>		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued 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 Crystal W. Brown	Title Regulatory Affairs Specialist, III	Telephone No. (Include Area Code) 901-272-8253
Certification 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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Specialist, III	
4. Typed Name Crystal W. Brown	5. Date 26 February 2003	

BUCKMAN LABORATORIES INTERNATIONAL, INC.

1256 NORTH McLEAN BLVD.
MEMPHIS, TN 38108-1241 U.S.A.
TELEPHONE (901) 278-0330
FAX (901) 276-5343
www.buckman.com
e-mail: knetix@buckman.com

26 February 2003

Mr. Marshall Swindell
Product Manager 33
Management Regulatory Branch I
Antimicrobial Division (7510C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202 - 4501

Re: BUSAN 1016, EPA Reg. No. 1448-93
Letter Correspondence dated: 23 January 2003

Dear Mr. Swindell:

The BUSAN 1016 (EPA Reg. # 1448-93) product label layout has been revised to include additional label layout comments from the EPA product managers. The label format has been revised to more closely reflect the requirements of 40 CFR 156.10. Since our current software package does not efficiently handle multiple layouts, we are revising all pesticide product label layouts.

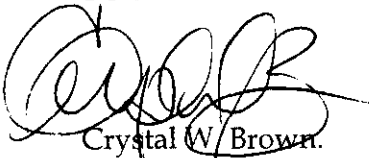
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of these products. I understand that it is a violation of 18 USC. § 1001 to willfully make any false 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.

Enclosed please find the following information to support this request:

- Completed EPA Form 8570-1
- Five (5) copies of the draft labels for each product.

If you have any questions or require any additional information, please contact me at (901) 272-8258.

Sincerely,
BUCKMAN LABORATORIES INTERNATIONAL, INC.



Crystal W. Brown
Regulatory Affairs Specialist



Directions for Use

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

Busan 1016 is a broad-spectrum microbicide that is effective in the control of the bacteria and fungi that cause sucrose losses, slime, and odors during the manufacture of raw cane and beet sugar. Busan 1016 is composed of materials which meet the requirements of 21 CFR 173.320.

CANE SUGAR MILLS: Busan 1016 should be added to the cane juice at points where the microbicide will circulate to all parts of the grinding equipment, troughs, screens, and pipes with which the juice comes in contact. Approximately 35% of the dosage should be added to the juice from the crusher and the remainder to the juice from the next-to-last mill. Busan 1016 should never be added to the maceration water. Busan 1016 should be fed continuously at a total feed rate of 20.0 ppm based on the weight of the ground cane. This is equivalent to 11.3 mL of Busan 1016 per minute for each 1000 tonnes of cane ground per 24-hour day (or 0.35 fl oz of Busan 1016 per minute for each 1000 tons of cane ground per 24-hour day). Do not exceed a total feed rate of 16.3 L (20.0 kg) of Busan 1016 per 1000 tonnes of cane ground per 24 hours (or 3.9 gallons (19.13 lb) of Busan 1016 per 1000 tons of cane ground per 24 hours). THIS PRODUCT IS NOT APPROVED FOR CANE SUGAR APPLICATIONS IN CALIFORNIA.

BEET SUGAR MILLS: Busan 1016 can be used in beet sugar mills to treat the wash water, the diffuser system, and the raw juice. It is added to the wash water continuously as it enters the washer at dosages of 4.0-8.0 ppm. This is equivalent to 2.3-4.6 mL of Busan 1016 per minute for each 1000 tonnes of beets sliced per 24-hour day (or 0.07-0.14 fl oz of Busan 1016 per minute for each 1000 tons of beets sliced per 24-hour day). In diffuser systems, Busan 1016 should be added to the diffuser water supply at a dosage rate of 20.0 ppm. This is equivalent to 11.3 mL of Busan 1016 per minute for each 1000 tonnes of beets sliced per 24-hour day (or 0.35 fl. oz Busan 1016 per minute for each 1000 tons of beets sliced per 24 hour day). If the diffuser system is not treated with Busan 1016 and the raw juice from the diffuser has to be stored for 1 to 3 days during a shutdown, the raw juice should be treated with 20.0 ppm of Busan 1016. Do not exceed a total feed rate of 16.3 L (20.0 kg) of Busan 1016 per 1000 tonnes of beets sliced per 24 hours (or 3.9 gallons (39.5 lb) of Busan 1016 per 1000 tons of beets sliced per 24 hours).

ACTIVE INGREDIENT(S)

Disodium cyanodithioimidocarbonate.....	14.5%
Sodium N-methyldithiocarbamate.....	18.0%
INERT INGREDIENTS.....	100.0%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID

If in Eyes	<ul style="list-style-type: none"> - Hold eyes 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 further treatment advice.
If on Skin, Clothes	<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 for treatment advice.
If ingested	<ul style="list-style-type: none"> - 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.
If Inhaled	<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 by mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-278-0330 or 1-800-BUCKMAN for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.	

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, rubber gloves and protective clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Do not take internally.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish. 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 Systems (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.

Do not contaminate water.
PESTICIDE STORAGE: Store in a well-ventilated area. Do not store more than four drums high. Damaged drums should not be used. Do not store in areas where absorbed in sawdust or other combustible materials when not in use.
PESTICIDE DISPOSAL: Do not mix with other pesticides. Excess pesticide, spray, or container cannot be disposed of in household waste. Pesticide or Environmentally Sensitive Area. Contact the nearest EPA Regional Office for disposal information.
CONTAINER DISPOSAL: Recycle if possible. Do not reuse. Do not burn. Do not puncture. Do not reuse for any other purpose. Do not use for anything other than approved by state and local authorities.

Manufactured by

1256 North Mc

EPA Est. No.

EPA Reg. No.

Product Weight

HM

Health 3 Fla