

70299-21

10-11-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

BioSafe Systems
22 Meadow Street
East Hartford, CT
06108

OCT 11 2011

Attention: Donna Bishel

Subject: SaniDate Sanitizing Wipes
EPA Registration No: 70299-21
Notification Dated August 31, 2011

This will acknowledge receipt of your Notification to update the container handling statement per PR Notice 2007-4 and make other minor changes to the product label, submitted under the provision of FIFRA Section 3(c)(9).

Proposed Notification:

Revise label per PR Notice 2007-4 and additional minor changes

General Comments:

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

The Notification dated August 31, 2011 is acceptable, to revise the following of the Master label, "**Add Batch Code**", on page 2 and 4 of the Master label, under the Storage and Disposal add the following phrases, "**Non-refillable container**", "**Do not reuse or refill this container**", and delete the following, "**Do not reuse the empty container**". This information has been added to your file.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080

Sincerely

A handwritten signature in black ink that reads "Marshall Swindell".

Marshall Swindell
Product Manger (33)
Regulatory Management Branch I
Antimicrobial's Division (7501P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70299-21	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SaniDate Sanitizing Wipes	PM# 33/Antimicrobial Division	
5. Name and Address of Applicant (Include ZIP Code) BioSafe Systems 22 Meadow Street East Hartford, CT 06108 <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, 156.144, 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.

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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt No. per container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 574 grams		5. Location of Label Directions <input checked="" type="checkbox"/> on container label	
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 Donna Bishel / dbishel@biosafesystems.com	Title Technical Director	Telephone No. (Include Area Code) (410) 878-7700
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 Technical Director for BioSafe Systems	
4. Typed Name Donna Bishel / dbishel@biosafesystems.com	5. Date August 31, 2011	

August 31, 2011

Marshall Swindell
Antimicrobial Division (7510P)
Regulatory Management Branch I
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**RE: SaniDate Sanitizing Wipes
Notification to update storage and disposal under PR Notice 2007-4 in response to
Agency letter dated August 8, 2011**

Dear Mr. Swindell:

BioSafe Systems hereby submit a notification to update storage and disposal per PR Notice 2007-4 in response to Agency letter dated August 8, 2011.

Enclosed with this letter you will find the following in support of a notification for the above referenced product:

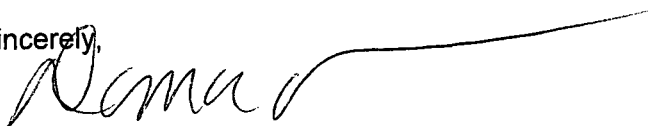
- 1) Notification form;
- 2) Copy of Agency letter dated August 8, 2011;
- 3) One (1) copy of the revised label with all changes highlighted in redline;
- 4) Three (3) clean copies of the label.

Changes included in this notification are as follows:

- Page 1 of the Master Label – Add ' Batch Code ____ '.
- Page 2 and 4 of the Master Label – Storage and Disposal : Addition of the following phrases : 'Non-refillable container. Do not reuse or refill this container'. Delete the following: 'Do not reuse empty container'.

Please contact me directly if you have any questions or comments.

Sincerely,



Donna Bishel
Technical Director for BioSafe Systems
(410) 878-7700; email dbishel@biosafesystems.com

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SANIDATE®

Sanitizing Wipes

Sublabel A: Commercial Directions for Use
Sublabel B: Residential Directions for Use

Active Ingredient:

Hydrogen Peroxide 0.108%
Other Ingredients: 99.892%
Total: 100.00%

KEEP OUT OF REACH OF CHILDREN

See (back) (side) (inside) panel for additional precautionary statements and directions for use.

EPA Registration No. 70299-21

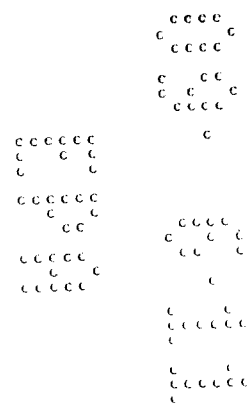
EPA Establishment No. 70299-CT-001, 75399-NJ-001 **Batch Code** _____

Sold by:

BioSafe Systems, LLC
22 Meadow Street
East Hartford, CT 06108

Net Contents:

OF (Premeasured) (Premoistened) cloths
SIZE [of each cloth]



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Sublabel A: Commercial Directions for Use

SaniDate® Sanitizing Wipes are 99.9% effective against *Staphylococcus aureus* (Staph) and *Klebsiella pneumoniae* on hard, non-porous surfaces.

Use this product in general commercial environments to clean, sanitize, and deodorize hard, nonporous surfaces:

- Garbage cans/bins, diaper pails, bathroom surfaces, toilet seats, light switches, doorknobs, telephones, computers, tools, shopping carts, gym equipment, kennels, cages.

DIRECTIONS FOR USE

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

To Open Package: Remove lid and locate center of the roll and insert corner of the wipe through the opening in lid. Replace lid. Pull sheet up and slightly to the side. Always snap lid securely closed between uses to prevent moisture loss.

To Sanitize:

Cleaning and sanitizing procedure: Preclean all surfaces prior to sanitizing. Use SaniDate Sanitizing Wipe to clean and sanitize surface. Wipe surface; use enough wipes for treated surface to remain visibly wet for 5 minutes. Let surface air dry. Do not reuse dried out wipes.

- **NOT FOR USE ON SKIN**
- **NOT FOR USE AS A DIAPER WIPE OR FOR PERSONAL CLEANSING**

STORAGE AND DISPOSAL

Dispose of wipe in trash after use. Do not flush. Tightly close lid between uses to retain moisture. Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If recycling is not available, discard container in trash.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

This product is reasonably fit for the purposes described on the label when used in strict accordance with label instructions. The manufacturer is not responsible for any use of this product that is contrary to the label instructions on the container, or under abnormal conditions that are not reasonably foreseeable by the manufacturer and or seller. The buyer assumes all risk associated with use beyond label instructions or under abnormal conditions.

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Sublabel B: Residential Directions for Use

SaniDate® Sanitizing Wipes are 99.9% effective against *Staphylococcus aureus* (Staph) and *Klebsiella pneumoniae* on hard, non-porous surfaces.

Use this product to clean, sanitize, and deodorize hard, nonporous household surfaces:

- Counter tops, tables, chairs, exteriors of appliances, sinks, garbage cans/bins, diaper pails, high chairs, bathroom surfaces, toilet seats, light switches, doorknobs, telephones, computers, tools, shopping carts, gym equipment, kennels, cages.

DIRECTIONS FOR USE

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

To Open Package: Remove lid and locate center of the roll and insert corner of the wipe through the opening in lid. Replace lid. Pull sheet up and slightly to the side. Always snap lid securely closed between uses to prevent moisture loss.

To Sanitize:

Cleaning and sanitizing procedure: Preclean all surfaces prior to sanitizing. Use SaniDate Sanitizing Wipe to clean and sanitize surface. Wipe surface; use enough wipes for treated surface to remain visibly wet for 5 minutes. Let surface air dry. Do not reuse dried out wipes.

- NOT FOR USE ON SKIN
- NOT FOR USE AS A DIAPER WIPE OR FOR PERSONAL CLEANSING

STORAGE AND DISPOSAL

Dispose of wipe in trash after use. Do not flush. Tightly close lid between uses to retain moisture. Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If recycling is not available, discard container in trash.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

This product is reasonably fit for the purposes described on the label when used in strict accordance with label instructions. The manufacturer is not responsible for any use of this product that is contrary to the label instructions on the container, or under abnormal conditions that are not reasonably foreseeable by the manufacturer and or seller. The buyer assumes all risk associated with use beyond label instructions or under abnormal conditions.

Optional Label Claims:

- Easy to use
- Quick and easy cleaning
- Sanitizes hard, non-porous surfaces
- Ready to use Activated Peroxide Sanitizer
- Contains no phosphates
- Sanitizes
- Leaves no residue
- Kills 99.9% of Bacteria! * **Staphylococcus aureus, Klebsiella pneumoniae*
- Versatile Sanitizer
- Sanitizes household surfaces
- Sanitizes bathroom surfaces
- Sanitizes commercial surfaces
- Effective sanitizer against *Staphylococcus aureus, Klebsiella pneumoniae*
- Leaves household surfaces sanitized
- Kills odor causing bacteria
- Use throughout the home
- Use for a cleaner kitchen
- Use for a fresher kitchen
- Peroxide Sanitizer
- Leaves no harmful residue
- Deodorizes
- Deodorizes kitchen surfaces
- Removes stains
- Contains no harsh chemicals
- Contains no abrasives
- For daily use
- Antibacterial
- Kills odor causing bacteria
- Breaks down into oxygen and water
- Easy
- Convenient wipe

