

## **PLEASE NOTE**

**This image contains more than one label  
approved for this product on this date.**

70467-3

10/02/2007

1/6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**October 2, 2007**

David Swain  
Scientific & Regulatory Consultants  
**C/o Micrylium Laboratories**  
P. O. Box 1014  
Columbia City, IN 46725

Subject: Notification Application per PR Notice 98-10  
**BIOSURF**  
EPA Registration No. 70467-3  
Application Date: 26-Sept-2007  
Receipt Date: 26-Sep-2007

Dear Mr. Swain:

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

***Proposed Notification***

- Add approved organisms to label:

***General Comment***

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) 308-6422, or by email at [heyward.adam@epa.gov](mailto:heyward.adam@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward", written over a horizontal line.

Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

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**SRC**  
**Scientific & Regulatory**  
Consultants, Inc.

September 26, 2007

Mr. Adam Heyward, PM 34  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, 4th Floor  
One Potomac Yard  
2777 S Crystal Drive  
Arlington, VA 22202

SUBJECT: BIOSURF  
EPA Reg. No.: 70467-3

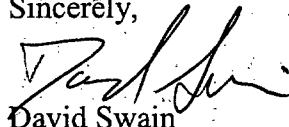
Dear Adam,

On behalf of our client Micrylium Laboratories, enclosed is a **minor label amendment** to add organisms to the subject label. They are organisms for which studies have already been accepted by EPA. A supplemental product of the basic registration is attempting to obtain registration in New York. In a communication with the state reviewer, you indicated that "registrant must list all approved organisms and the kill time for each category on the label". Therefore, we need to update the stamped label to include these organisms. Also, New York required a clarification to avoid any confusion regarding the name of the supplemental product. Therefore, we are adding the verbiage "For use on hard, non-porous imaging equipment surfaces" to the front label. This use site is consistent with other indoor use sites already accepted on the stamped label.

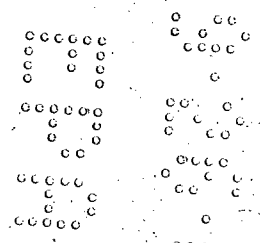
A notification dated September 13, 2007 has already been submitted to federal EPA for this product. The submitted label (3 copies) includes those changes requested by the notification. The changes from the notification are highlighted in blue. The label changes covered by this amendment are highlighted in red. Also included is a label (3 copies) without highlighting for your files.

Please contact me at (260) 244-6270 or at [dswain@srconsultants.com](mailto:dswain@srconsultants.com) if you have any questions about this notification.

Sincerely,



David Swain  
Agent for Micrylium Laboratories  
cc: D. Swift





United States  
**Environmental Protection Agency**  
 Washington, DC 20460

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

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 70467-3	2. EPA Product Manager A. Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BIOSURF	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Micrylium Laboratories 4590 Dufferin Street Toronto, Canada M3H 5T5 <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 checked="" 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 type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
 Attached is a minor label amendment to add organisms to the label. The studies for the organisms being added have already been accepted by EPA. No PRIA fees are required.  
 Please contact David Swain at dswain@srconsultants.com or at 260-244-6273 (fax) with any questions.

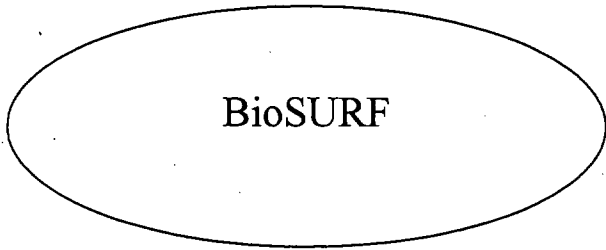
**Section - III**

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
<b>* Certification must be submitted</b>	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Other (Specify) _____
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"/> On label	
6. Manner in Which Label is Affixed to Product <input 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 David Swain	Title Agent for Micrylium Laboratories	Telephone No. (Include Area Code) (260) 244-6270
<b>Certification</b> 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, both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Micrylium Laboratories	
4. Typed Name David Swain	5. Date 9/26/07	

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NOTIFICATION  
Date Reviewed: 10-2-07  
Reviewed By: [Signature]

16.9 fl oz  
500 ml

EPA Registration Number 70467-3  
EPA Establishment 070467-CAN-001

Micrylium  
ISO 13485 : 2003

**Hospital Hard Surface Disinfectant**

BioSURF is a ready to use hard surface disinfectant for nonporous surfaces • One Step  
[For use on hard, non-porous imaging equipment surfaces]

Active Ingredients

Ethanol	70.5%
Chlorhexidine Gluconate	0.2%
<u>Other Ingredients</u>	29.3%
Total	100.0%

Tuberculocidal – Canine Parvovirucidal  
Pseudomonacidal

**CAUTION**

**READ PRECAUTIONS ON BACK PANEL • KEEP OUT OF THE REACH OF CHILDREN**

{Administrative note: any language which appears between { } and is italicized will **NOT** appear on final printed labels. Any language that appears between [ ] is considered interchangeable language which may appear on final printed labeling}

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BioSURF

[Sprays On Blue Turns Clear!]

Aldehyde • NPE • Phenol Free

BioSURF is a ready to use environmental hard surface disinfectant for nonporous surfaces.

[Restrooms • Schools • The Office • The Gym • At Home]

[BioSURF will not stain: Cotton • Nylon • Rayon • Silk • Polyester]

Directions for use

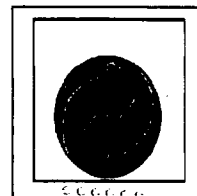
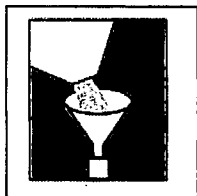
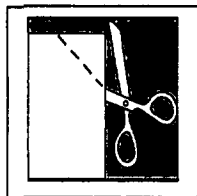
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. BioSURF kills Tuberculosis (*Mycobacterium bovis* BCG) and is Virucidal (Canine parvovirus CPV-265) in [one minute] [60 seconds] in the presence of 5% bioburden. [BioSURF kills *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* (formally *choleraesuis*) in 20 seconds in the presence of 10% bioburden.] [BioSURF kills *Trichophyton mentagrophytes* in 10 seconds in the presence of 10% bioburden.] To effectively kill bacteria, fungi and inactivate canine parvovirus use BioSURF.

{Text for refill package}

Remove trigger from 24 fl oz spray bottle. Cut this 16.9 fl oz refill pouch along the dotted line with scissors. Use a clean funnel to fill or refill bottle. Replace the trigger and rinse funnel.

BioSURF [This product][is to][can] be used on countertops [and] metal surfaces [and toilet exteriors]. [May be used on wheelchairs, metal bed frames and exteriors of toilets.] [BioSURF may be used on nonporous hard surfaces (imaging equipment, metal, glass, acrylic, and porcelain)]. Spray all areas with a light mist. Maintain wetness for [one minute] [60 seconds] [to kill *Mycobacterium bovis* BCG and Canine parvovirus CPV-265] [.] [Maintain wetness for 20 seconds to kill bacteria and 10 seconds to kill fungi.] [Blue color disappears,] [then] wipe [away germs] with [disposable paper towel[s]][included towelette][or tissue][or "Le Cloth"™ towelettes].

This product is not be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels. Any language that appears between [ ] is considered interchangeable language which may appear on final printed labeling}

6/6

Micrylium Laboratories  
Professional Disinfection  
[www.micrylium.com](http://www.micrylium.com)  
4590 Dufferin Street  
Toronto, Canada  
1-800-489-8868

**Precautionary Statements**  
**Hazards to Humans and Domestic Animals**

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**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

**PHYSICAL OR CHEMICAL HAZARDS:** Flammable. Keep away from heat or open flame. Keep out of the reach of children. **DO NOT** use on alcohol sensitive materials such as hot plastic casings, acrylic paint, styrene or disposable plastic items. Do not apply this product in or on electrical equipment due to the possibility of shock hazard.

**FIRST AID: 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. Call a Poison Control Center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-489-8868 for emergency medical treatment information.

**STORAGE & DISPOSAL:** Do not reuse container. Do not store near open flame, at elevated temperature or in intense light. Rinse thoroughly and dispose of any packaging materials in domestic waste.

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*{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels. Any language that appears between [ ] is considered interchangeable language which may appear on final printed labeling}*

**NEXT**

**LABEL**



70467-3

10/02/2007

1/6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**October 2, 2007**

David Swain  
Scientific & Regulatory Consultants  
C/o Micrylium Laboratories  
P. O. Box 1014  
Columbia City, IN 46725

Subject: Notification Application per PR Notice 98-10  
**BIOSURF**  
EPA Registration No. 70467-3  
Application Date: 13-Sept-2007  
Receipt Date: 17-Sep-2007

Dear Mr. Swain:

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

**Proposed Notification:**

- Add/delete certain text.

**General Comment:**

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

The notification is not acceptable for the following reason(s):

- All of the organisms approved by the EPA for the product referred to above must be listed on the master labeling. See enclosed EPA letter dated February 3, 2004, section I, "Efficacy comments."

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or by email at [heyward.adam@epa.gov](mailto:heyward.adam@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward", written over a horizontal line.

Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

**SRC**  
**Scientific & Regulatory**  
Consultants, Inc.

September 13, 2007

Mr. Adam Heyward, PM 34  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, 4th Floor  
One Potomac Yard  
2777 S Crystal Drive  
Arlington, VA 22202

SUBJECT: BIOSURF  
EPA Reg. No.: 70467-3

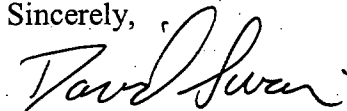
Dear Adam,

On behalf of our client Micrylium Laboratories, enclosed is a submission for BIOSURF (EPA Reg. No. 70467-3). **This is a notification per PR Notice 98-10. Therefore no PRIA fee is required.**

The purpose of this notification is to add/delete minor text that may be used by the basic registrant in future labeling and in their supplemental distributor's offerings of the primary product under their own product names. The enclosed master label includes the most recent text additions accepted in previous notifications to the agency along with the new proposed additions. All new text additions are marked by highlighting the effected text or markings in blue on the Master Label. The original reference to Zenith Dental has been deleted since they no longer have a business relationship with Micrylium Laboratories and this reference is not necessary in the labeling. A clean version of the label is also enclosed without the markings for your files. This notification is consistent with PR Notice 98-10.

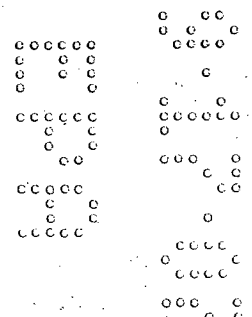
Please contact me at (260) 244-6270 or at [dswain@sriconsultants.com](mailto:dswain@sriconsultants.com) if you have any questions about this notification.

Sincerely,



David Swain  
Agent for Micrylium Laboratories

cc: D. Swift





United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 70467-3	2. EPA Product Manager A. Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BIOSURF	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Micrylium Laboratories 4590 Dufferin Street Toronto, Canada M3H 5T5 <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 text additions through PR Notice 98-10. 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 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. Please contact David Swain at dswain@srconsultants.com or at 260-244-6273 (fax) with any questions.

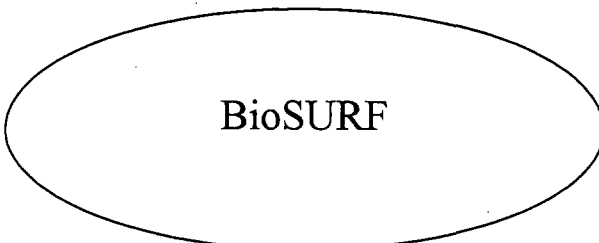
**Section - III**

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) _____
* Certification must be submitted		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"/> On label	
6. Manner in Which Label is Affixed to Product			<input 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 David Swain	Title Agent for Micrylium Laboratories	Telephone No. (Include Area Code) (260) 244-6270
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 Agent for Micrylium Laboratories	
4. Typed Name David Swain	5. Date 9/13/07	

4/6



16.9 fl oz  
500 ml

EPA Registration Number 70467-3  
EPA Establishment 070467-CAN-001

Micrylium  
ISO 13485 : 2003

### Hospital Hard Surface Disinfectant

BioSURF is a ready to use hard surface disinfectant for nonporous surfaces • One Step

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Active Ingredients

Ethanol	70.5%
Chlorhexidine Gluconate	0.2%
<u>Other Ingredients</u>	29.3%
Total	100.0%

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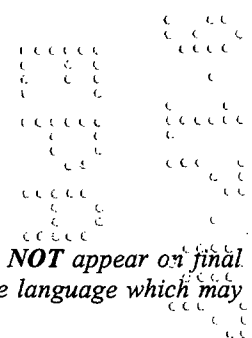
Tuberculocidal – Canine Parvovirucidal  
Pseudomonacidal

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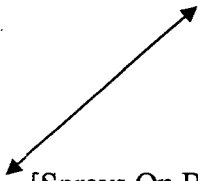
### CAUTION

READ PRECAUTIONS ON BACK PANEL • KEEP OUT OF THE REACH OF CHILDREN

{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels. Any language that appears between [ ] is considered interchangeable language which may appear on final printed labeling}



BioSURF



[Sprays On Blue Turns Clear!]

Aldehyde • NPE • Phenol Free

BioSURF is a ready to use environmental hard surface disinfectant for nonporous surfaces.  
[Restrooms • Schools • The Office • The Gym • At Home]  
[BioSURF will not stain: Cotton • Nylon • Rayon • Silk • Polyester]

Directions for use

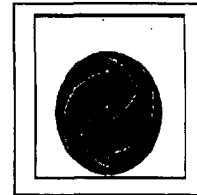
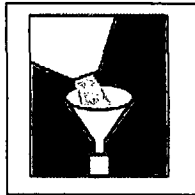
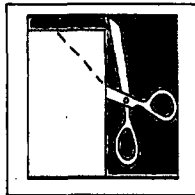
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. BioSURF kills Tuberculosis (*Mycobacterium bovis* BCG) and is Virucidal (Canine parvovirus CPV-265) in [one minute][60 seconds]in the presence of 5% bioburden. To effectively kill bacteria, fungi and inactivate canine parvovirus use BioSURF.

*{Text for refill package}*

Remove trigger from 24 fl oz spray bottle. Cut this 16.9 fl oz refill pouch along the dotted line with scissors. Use a clean funnel to fill or refill bottle. Replace the trigger and rinse funnel.

BioSURF [This product][is to][can] be used on countertops [and] metal surfaces [and toilet exteriors]. [May be used on wheelchairs, metal bed frames and exteriors of toilets.] [BioSURF may be used on nonporous hard surfaces (metal, glass, acrylic, and porcelain)]. Spray all areas with a light mist. Maintain wetness for [one minute] [60 seconds][.] [Blue color disappears,] [then] wipe [away germs] with [disposable paper towel[s]][included towelette][or tissue][or "Le Cloth™ towelettes].

This product is not be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



Micrylium Laboratories  
Professional Disinfection  
[www.micrylium.com](http://www.micrylium.com)  
4590 Dufferin Street  
Toronto, Canada  
1-800-489-8868

*{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels. Any language that appears between [ ] is considered interchangeable language which may appear on final printed labeling}*

Precautionary Statements  
Hazards to Humans and Domestic Animals

---

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

**PHYSICAL OR CHEMICAL HAZARDS:** Flammable. Keep away from heat or open flame. Keep out of the reach of children. **DO NOT** use on alcohol sensitive materials such as hot plastic casings, acrylic paint, styrene or disposable plastic items. Do not apply this product in or on electrical equipment due to the possibility of shock hazard.

**FIRST AID: 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. Call a Poison Control Center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-489-8868 for emergency medical treatment information.

**STORAGE & DISPOSAL:** Do not reuse container. Do not store near open flame, at elevated temperature or in intense light. Rinse thoroughly and dispose of any packaging materials in domestic waste.

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*{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels. Any language that appears between [ ] is considered interchangeable language which may appear on final printed labeling}*