

## **PLEASE NOTE**

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

12/29/2009

1/4

46851-10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

DEC 29 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Lewis Ward, RA/QA Manager  
Certol International, LLC  
6120 E. 58<sup>th</sup> Avenue  
Commerce City, CO 80022

Subject: Notification per PR Notice 95-2  
Certol ProSpray wipes  
EPA Registration Number: 46851-10  
Application Date: November 19, 2009  
Receipt Date: November 30, 2009

Dear Mr. Ward:

This acknowledges receipt of your notification, submitted under the provisions of FIFRA section 3(c) 9 and PR Notice 95-2.

**Proposed Notification:**

Notification of H1N1 label claims per PR Notice 95-2.

**General Comments:**

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

Should you have further questions concerning this letter, please contact me by telephone at 703-308-6416 or by email at [mcfarlane.jacqueline@epa.gov](mailto:mcfarlane.jacqueline@epa.gov) or Killian Swift by telephone at 703-308-6346 or by email at [swift.killian@epa.gov](mailto:swift.killian@epa.gov). When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph" followed by a stylized name, likely Jacqueline McFarlane.

Jacqueline McFarlane  
(Acting) Product Manager 34  
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 Certol/46851-10	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Certol/ProSpray wipes	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Certol International, LLC 6120 58th Avenue Commerce City, CO 80022 <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 additional Influenza A virus per PR Notice 95-2. See attached Explanation page.

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
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<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 <input type="checkbox"/> On Labeling accompanying product	
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 Lewis Ward	Title RA/QA Manager	Telephone No. (Include Area Code) 303 799 9405
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 RA/QA Manager	
4. Typed Name Lewis Ward	5. Date Nov 19, 2009	

**Explanation continued:**

This notification is consistent with the provisions of PR Notice 95-2 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 95-2 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.

The product label will be amended to include the EPA recommended statement "Kills Pandemic 2009 H1N1 Influenza A Virus". This product already has EPA approval for Influenza A virus.

Kills Pandemic 2009 H1N1 Influenza A Virus

# ProSpray™ wipes

with  
Lemon Scent

Disinfectant  
Towelettes

Tuberculocidal, Virucidal\*,  
Bactericidal, Fungicidal

240 Pre-moistened Towelettes  
6 x 6.75 in. (15.24 x 17.14 cm)  
Reorder No: PSWC

Active Ingredients  
o-phenylphenol . . . . . 0.28%  
o-benzyl-p-chlorophenol . . . . . 0.03%  
Inert Ingredients . . . . . 99.69%  
Total . . . . . 100.00%

E.P.A. Reg. No. 46151-10  
E.P.A. Est. No. 75546-NJ-001

▽ CAUTION: Keep Out of Reach of Children

KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an exposed likelihood of soiling inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus type 1 (HIV-1) (associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear disposable latex gloves, gowns, masks, and eye coverings.

**CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be collected and disposed of according to local regulations for infectious waste disposal.

**CONTACT TIME:** Leave surface wet for 7 minutes. Use a 10 minute contact time for disinfection against all other virus, bacteria, and fungi listed.

**HAZARD TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed. Wash thoroughly with soap and water before eating, drinking, chewing gum or using tobacco. Harmful if inhaled. Avoid breathing vapors.

**FIRST AID:** If swallowed: Call a 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 a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or ambulance. Then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further treatment advice.

**If in eyes:** Hold eyes open and irrigate slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue irrigating. Call a Poison Control Center or doctor for treatment advice.

**HOTLINE NUMBER:** In case of emergency call toll free 1-800-525-5253. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store at room temperature.

**PESTICIDE DISPOSAL:** Do not reuse toweling. Dispose of used toweling in and empty container in regular trash.

**CONTAINER DISPOSAL:** Rinse and discard empty container. Do not reuse empty container.

**CAUTION:** Keep Out of Reach of Children

**CERTOL**  
INTERNATIONAL, LLC  
6120 E. 58th Ave.  
Commerce City, CO 80022 USA  
(1-800-843-3343)  
www.certol.com

PSW1240L02 07/07

**A BISYNTHETIC PHENOL SOLUTION IMPREGNATED IN A UNIFORM RELEASE TOWELETTE**

ProSpray wipes disinfectant towelettes are intended for use in hospitals, medical, dental and veterinary offices, laboratories, industrial clean rooms, nursing homes, ambulances, and on vehicles, hotels, schools, homes, health spas, grocery stores, shopping centers, boat, auto, and boat docks, fire and maritime facilities, and regular oil, gas, or diesel dies, kitchen glass tables, carts, bookshelves, counters, cabinets, TV phones, grocery cart handles, grocery cart child seats, shopping cart handles, shopping cart child seats, and other high-traffic surfaces.

**To Open Package:** Open the top and pull up firmly on tabs to remove the entire cap from the container. Remove protective seal. Locate top of the center of the roll and insert corner of wipe through opening in lid. Rip lid to lid. Pull sheet up and slightly to the side. The next wipe pops up automatically. Always snap lid securely shut between users to prevent moisture loss.

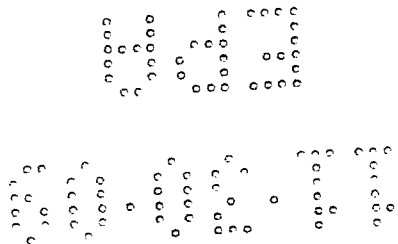
IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. READ ENTIRE LABEL BEFORE USING THIS PRODUCT.

**DIRECTIONS FOR USE:** DO NOT USE AS A BABY WIPE. Must not be used in hospital nurseries, neonatal or ProSpray wipes Disinfectant Towelette. Use 1-2 wipes daily to remove moisture applied directly to skin surface. Use a second wipe to thoroughly wet surface. Wipe surfaces on one end for 10 minutes to destroy or inactivate bacteria including: *Escherichia Coli* 0157, *Staphylococcus aureus*, *Sah aureus*, *Myxobolus*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis* var. *hominis*, *Legionella pneumophila*, and the following viruses: Herpes simplex virus types 1 & 2, Vaccinia virus, Influenza virus type A (New Jersey), Influenza B (Maryland), and HIV-1 (AIDS virus). Use on non-lod contact surfaces only. When using in grocery stores or shopping centers and similar locations, wipe thoroughly in order to clean non-lod contact surfaces on carts, aisles, grocery cart handles, and grocery cart child seats.

This product is not to be used for a formal disinfectant high-level disinfection on any surface or instrument that (1) is structurally directly into the human body, either into or on contact with the blood stream or normally sterile areas of the body, (2) contact, enter mucous membranes, but which does not substantially penetrate the oral barrier or otherwise normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



NOT A BABY WIPE



DEC 29 2009  
NOTIFICATION  
Date Reviewed: 12/29/09  
Reviewed By: K. Smith

Proposed Label

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**NEXT**

**LABEL**

46851-10

12/29/2009

1/4



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

DEC 29 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Lewis Ward  
Certol International, LLC  
6120 E. 58<sup>th</sup> Avenue  
Commerce City, CO 80022

Subject: **Certol/Birex Disinfectant Wipes**  
EPA Registration No.: 46851-10  
Notification Date: December 4, 2009  
EPA Receipt Date: December 4, 2009

Dear Mr. Ward:

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

**Proposed Notification:**

Add Pandemic 2009 H1N1Influenza A Virus Claim

**General Comment:**

Based on a review of the material submitted, your notification to add Pandemic 2009 H1N1Influenza A Virus claim is acceptable. A copy of the notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at [campbell-mcfarlane.jacqueline@epa.gov](mailto:campbell-mcfarlane.jacqueline@epa.gov) or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at [grigsby.stacey@epa.gov](mailto:grigsby.stacey@epa.gov) during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline McFarlane  
(Acting) Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

**CONCURRENCES**

SYMBOL	SURNAME	DATE					

2/4

Please read instructions on reverse before completing form.

Form Approved

EPA Form No. 2070-0060

Print Form



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

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number Certol/46851-10-51003		2. EPA Product Manager ShaRon Carlisle		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Certol/Birex Disinfectant Wipes		PM# 34			
5. Name and Address of Applicant (Include ZIP Code) Certol International, LLC 6120 E. 58th Avenue Commerce City, CO 80022 <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: <input checked="" type="checkbox"/> 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 additional influenza A virus per PR Notice 95-2. See attached Explanation page.

**Section - III**

1. Material This Product Will Be Packaged In:

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	2. Type of Container <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 <input type="checkbox"/> On Labeling accompanying product
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 Lewis Ward	Title RA/QA Manager	Telephone No. (Include Area Code) 303-799-9401
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<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 or both under applicable law.		6. Date Application Received (Stamped) _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
2. Signature 	3. Title RA/QA Manager	
4. Typed Name Lewis Ward	5. Date Dec 4, 2009	



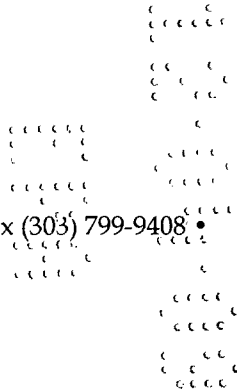


December 4, 2009

**Explanation Continued:**

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statements 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 95-2 and 409 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.

The product label will be amended to include the EPA recommended statement "Kills Pandemic 2009 H1N1 Influenza A Virus". This product already has EPA approval for Influenza A virus.



## Kills Pandemic 2009 H1N1 Influenza A Virus

**A SYNTHETIC PHENOL SOLUTION IMPREGNATED IN A UNIFORM RELEASE TOWELETTE**

**Birex** Disinfectant Wipe Sample is intended for use in hospital, medical, dental and veterinary offices, laboratories, industrial clean rooms, nursing homes, ambulances, police vehicles, hotels, schools, homes, health clubs, grocery stores, shopping centers, book stores, and hotel lobbies. Use on non-porous surfaces and equipment such as stainless steel, chrome, mirrors, glass tables, carts, benches, counters, cabinets, telephones, grocery cart handles, grocery cart child seats, shopping cart handles, shopping cart child seats, and other hard non-porous surfaces.

**To Open Package:** Open cap lid and pull up firmly on lid to remove the entire cap from the canister. Remove protective seal. Locate wipe at the center of the roll and insert corner of wipe through opening in lid. Replace lid. Pull sheet up and slightly to the side. The next wipe pops up automatically. Always snap lid securely shut between uses to prevent moisture loss.

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. READ ENTIRE LABEL BEFORE USING THIS PRODUCT.

**DIRECTIONS FOR USE: DO NOT USE AS A BABY WIPÉ.** Must not be used in hospital nurseries. Remove one Prototype EPA Registered Disinfectant Wipe, unfold wipe surface to remove excess organic debris and thoroughly clean surface. Use a second towellette to thoroughly wet surface. Excess surface remains wet for 10 minutes to destroy all available bacteria including: *Escherichia Coli* 0157, *Staphylococcus aureus*, *Salmonella typhosa*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis var bovis*, lung including *Typhophyton meningitiformis*, and the following viruses: "Hepes virus types 1 & 2", "Vaccinia virus", "Influenza virus types A1 (New Jersey), "Influenza B (Maryland) and "H5N1 (AUS) virus". Use on non-blood contact surfaces only. When using in grocery stores or shopping centers and similar facilities, wipe thoroughly in order to clean non-blood contact surfaces on carts, such as grocery cart handles and grocery cart child seats.

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



NOT A BABY WIPÉ

# BIREX

## Disinfectant Wipe

**Disinfectant  
Towelettes**  
**Tuberculocidal, Virucidal,  
Bactericidal, Fungicidal**

**Contains: 240 6X6.75" wipes**  
**Net Contents: 2lbs 3oz**  
**Part No: X397**  
**Sample: Not for sale**

with  
**Lemon Scent**

**Active Ingredients**  
o-phenylphenol . . . . . 0.26%  
o-benzyl-p-chlorophenol . . . . . 0.03%  
Inert Ingredients . . . . . 99.69%  
Total . . . . . 100.00%

E.P.A. Reg. No. 46851-10-51003  
E.P.A. Est. No. 46851-CO-003

**KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACE/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling inanimate surface/objects with blood or body fluids and in which the surface/object is likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (inactivated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACE/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear disposable latex gloves, gowns, masks, and eye coverings.

**CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be collected and disposed of according to local regulations for infectious waste disposal.

**CONTACT TIME:** Leave surface wet for 2 minutes. Use a 10 minute contact time for disinfection against all other virus, bacteria, and fungi claimed.

**PRECAUTIONARY STATEMENT**

**HARMFUL TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed. Wash thoroughly with soap and water before eating, drinking, chewing gum or using tobacco. Harmful if inhaled. Avoid breathing vapors.

**FIRST AID:**

If swallowed: Call a 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 poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further 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, and then continue rinsing. Call a Poison Control Center or doctor for treatment advice.

**NOTICE NUMBER:** In case of emergency, call toll free 1-800-535-5053. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in room temperature.

**PESTICIDE DISPOSAL:** Do not reuse towellettes. Dispose of used towellette and empty container in regular trash.

**CONTAINER DISPOSAL:** Rinse and discard empty container. Do not reuse empty container.

Manufactured for:

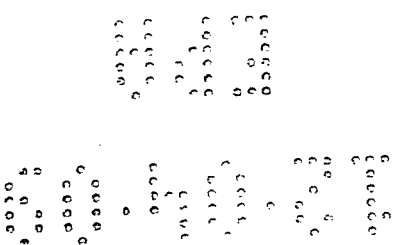
**BIOTROL**

13705 Shoreline Court East  
Earth City, MO 63045

1-800-832-8350

Keep Out of Reach of Children

CAUTION



**NOTIFICATION**  
Date Reviewed: 12/24/09  
Reviewed By: [Signature]

# Proposed Label

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