

675-19

12-14-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

DEC 14 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

David Swain  
SRC Scientific & Regulatory Consultants, Inc.  
P.O. Box 1014  
Columbia City, IN 46725

Subject: **Bulk AMPHYL**  
EPA Registration No.: 675-19  
Application Date: November 23, 2009  
Receipt Date: November 24, 2009

Dear Ms. Swain:

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

**Proposed Notification:**

- Add Influenza A and Pandemic 2009 H1N1 Claim

**General Comment:**

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

A copy of the notification is accepted and 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) 308-6427 or by e-mail at [carlisle.shaRon@epa.gov](mailto:carlisle.shaRon@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,

ShaRon Carlisle  
(Acting) Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

**CONCURRENCES**

SYMBOL								
SURNAME								
DATE								

34

2/11

Please read instructions on reverse before completing form.

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



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 675-19	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bulk Amphyl Brand Disinfectant	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Reckitt Benckiser Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), 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 (optional text additions in regards to Influenza A virus and Pandemic 2009 H1N1) per PR Notice 95-2. 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 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.

### 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	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 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 Sally Hayes	Title Agent for Reckitt Benckiser, Inc.	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 or both under applicable law.		6. Date Application Received (Stamp)
Signature 	3. Title Agent for Reckitt Benckiser, Inc.	
4. Typed Name Sally Hayes	5. Date 1/23/09	



**Scientific & Regulatory**  
Consultants, Inc.

November 23, 2009

Ms. ShaRon Carlisle (PM34)  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U. S. Environmental Protection Agency  
Room S-4900, 4<sup>th</sup> Floor  
One Potomac Yard  
2777 S Crystal Drive  
Arlington, VA 22202

SUBJECT: Notification (Influenza A and Pandemic 2009 H1N1) per PR Notice 95-2  
Bulk AMPHYL® Brand Disinfectant  
EPA Reg. No.: 675-19

Dear Ms. Carlisle:

On behalf of our client Reckitt Benckiser, Inc., enclosed is a notification in compliance with the recent Agency "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)." This is a Notification per PR Notice 95-2; therefore, no PRIA fee is required.

The new statements, as specified in the guidance, have been added to the current accepted label as optional text. No additional changes to the existing label have been made. This application contains claims consistent with the statements in Section III of the EPA Guidance, therefore meeting the criteria for the Agency's expedited review of 20 business days.

This notification, as stipulated by the guidance, 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 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.

Please contact me at (260) 244-6270 or at shayes@srconsultants.com if you have any questions.

Sincerely,

Sally Hayes  
Agent for Reckitt Benckiser, Inc.

Cc: M. Pisculli

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# RECKITT BENCKISER

November 19, 2009

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504-P)  
U.S. Environmental Protection Agency  
Room S-4900, 4<sup>th</sup> Floor  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Attention: ShaRon Carlisle, PM-34

Reference: Agent Letter of Authorization

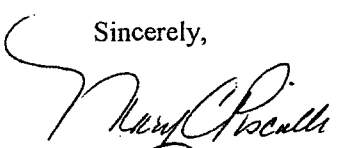
Dear Ms. Carlisle:

Reckitt Benckiser Inc. is designating Scientific & Regulatory Consultants Inc. as our agent in the submittal of the following master text label notification:

EPA Name of Record:	Bulk Amphyl Brand Disinfectant
EPA Registration No.:	675-19
Registration Action:	Notification to add Pandemic H1N1 Claims

Scientific & Regulatory Consultants Inc. is to act as our agent for this registration action only. Scientific & Regulatory Consultants Inc. has full authority to act as our agent regarding this submittal – including signatory authorities.

Sincerely,

  
Mary C. Pisculli  
Regulatory & Registration  
Compliance Specialist

11/07

**BULK  
AMPHYL®  
BRAND DISINFECTANT**

**NOTIFICATION**  
Date Reviewed: 11/14/09  
Reviewed By: [Signature]

[GERMICIDAL\*] [Staphylocidal] [Pseudomonacidal\*\*] [Tuberculocidal], [Salmonellacidal]  
[FUNGICIDAL\*] [Against pathogenic fungi]  
[VIRUCIDAL\*] [Against] [Influenza Virus Type A (Japan)] [Herpes Simplex Type 1] [Vaccinia]  
[Adenovirus Type 2] [and] [Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)]

\*On Hard, Nonporous Environmental Surfaces

\*\*At 2% Solution

[Prevents Mold and Mildew] {For 64 oz. container}  
[Sanitizes Laundry] [At 1% dilution, makes 48 gallons]  
[For Hospital Use] [VALUE PACK]  
[For use [only] in Institutional and Industrial Facilities]

[DILUTE AT [1:100], [2:100],[ 3:100]]

[[FOR USE] [CAN BE USED] [AS] [IN] [USEFUL AS] PART OF [AN] [A FACILITY'S] [ESTABLISHED] INFECTION CONTROL PROGRAM.]]

[[HELPS COMPLETE] [ADDS TO] [ROUNDS OUT] A FACILITY'S [ESTABLISHED] INFECTION CONTROL PROGRAM.]]

[[WORKS] [IS COMPATIBLE] [WITH OTHER RECKITT BENCKISER PROFESSIONAL PRODUCTS] [IN COMBATING CROSS CONTAMINATION] [ON ENVIRONMENTAL SURFACES] [IN THE HEALTH CARE ENVIRONMENT.]]

[[FOR] [USE BY ENVIRONMENTAL SERVICES] [IN COMBATING CROSS CONTAMINATION] [IN A HEALTH CARE FACILITY.]]

**ACTIVE INGREDIENTS:**

o-Phenylphenol.....2.80%  
o-Benzyl-p-chlorophenol.....2.70%  
**OTHER INGREDIENTS:**.....94.50%  
**TOTAL:**.....100.00%

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

Harmful if swallowed. Causes eye and skin irritation.  
See Back (Side) Panel for Additional Precautionary Statements

EPA REG. NO. 675-19

EPA EST. NO. {Insert establishment number here} [See bottom [side] panel]

NET CONTENTS: {Insert container size}

Note: Bracketed[ ] information is optional text. Text separated by a comma(,)denotes-and/or-options.  
{Bracketed Text}is for administrative purposes only and will not appear on the printed label.

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[Bulk AMPHYL® Brand Disinfectant] [This product] is recommended for use on hard, nonporous environmental surfaces in:

- [hospitals]
- [nursing homes]
- [dental offices]
- [doctors' offices]

[Bulk AMPHYL® Brand Disinfectant] [This product] may be used on:

- [floors]
- [walls]
- [bathroom fixtures]
- [surgical instruments]
- [dental instruments]
- [trays]
- [wheelchairs]
- [patient bed frames]
- [bedside tables]
- [medical lamps]
- [stands]
- [furniture]
- [counters]

**[BULK AMPHYL® BRAND DISINFECTANT] [THIS PRODUCT] IS IN CONCENTRATED FORM. DILUTE ACCORDING TO DIRECTIONS.**

**DIRECTIONS FOR USE:**

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

**DILUTION CHART**

To prepare proper dilutions in required quantities, add [this product] full strength [Bulk AMPHYL® Brand Disinfectant] to water as below.		
CORRECT SOLUTION STRENGTH	BULK AMPHYL® BRAND DISINFECTANT	WATER
1% (1:100)	10 cc. 40 cc. 4 fl. oz.	1 quart 1 gallon 3 gallons
2%† (2:100)	80 cc. 8 fl. oz.	1 gallon 3 gallons
3% (3:100)	30 cc. 4 fl. oz. 12 fl. oz. 20 fl. oz.	1 quart 1 gallon 3 gallons 5 gallons
LAUNDRY SANITIZING (1:272)	1 cup	17 gallons

† [This] [A 2%] dilution is to be used whenever bactericidal activity against *Pseudomonas aeruginosa* is desired.

ONE TABLESPOON IS EQUIVALENT TO 1/2 FLUID OUNCE OR 15 CC.

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**FOR BROAD SPECTRUM DISINFECTION (Use at 1% Dilution – See Dilution Chart):**

To disinfect hard non-porous surfaces, first clean surface thoroughly prior to application of [Bulk AMPHYL® Brand Disinfectant] [this product]. Apply solution to surface using a sponge or mop to wet all surfaces thoroughly. Let stand 10 minutes before wiping or allow to air dry. Fresh solution should be prepared daily or more often if solution becomes diluted or soiled. For tuberculocidal activity, 1% Bulk AMPHYL® Brand Disinfectant is effective in 10 minutes at 20°C (68°F).

**FOR MOLD AND MILDEW ON HARD NON-POROUS SURFACES (Use at 1% Dilution – See Dilution Chart):**

Wash surfaces with [Bulk AMPHYL® Brand Disinfectant] solution; allow to air dry. Repeat application as necessary.

**FOR [USE IN HEALTHCARE SETTINGS] [USE AS A HOSPITAL DISINFECTANT] [HOSPITAL DISINFECTION] OR WHERE PSEUDOMONACIDAL ACTIVITY IS DESIRED (Use at 2% Dilution – See Dilution Chart):**

Clean surface thoroughly. Apply solution using a sponge or mop. Wet surfaces thoroughly. Let stand 10 minutes before wiping or let air dry.

**FOR HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [(HIV-1)] (AIDS VIRUS) ACTIVITY (Use at 2% Dilution – See Dilution Chart):**

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

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

**PERSONAL PROTECTION:** When handling items soiled with blood/body fluids, use disposable latex gloves, gowns, masks, or eye protection.

**CLEANING PROCEDURES:** Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of [Bulk AMPHYL® Brand Disinfectant] [this product].

**CONTACT TIME:** Allow surface to remain wet for 10 minutes.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood/body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**[INSTRUMENT DECONTAMINATION: (Use at 3% Dilution – See Dilution Chart):]**

[Where appropriate, follow [Universal] [Standard] Precautions]

[Bulk AMPHYL® Brand Disinfectant] [This product] is intended to help prevent protein matter from hardening on instruments and to help reduce exposure to pathogens during the decontamination process.

**This product is not to 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 devices prior to sterilization or high level disinfection.**

NOTE: Before using [Bulk AMPHYL® Brand Disinfectant] [this product], consult the instrument manufacturer's instructions for care and disinfection of their instruments. [Bulk AMPHYL® Brand Disinfectant] [This product] may cause damage to certain types of plastic trays. Refer to manufacturer's instructions for proper use.

**FOR PRECLEANING OF SURGICAL [AND] DENTAL INSTRUMENTS [AND EQUIPMENT] SURFACES PRIOR TO DISINFECTION:** Instruments must be cleaned prior to disinfection to remove all adhering blood and serous exudates, body fluids and human wastes. Apply [Bulk AMPHYL® Brand Disinfectant] [this product] directly, wetting all surfaces thoroughly. Wipe surface with a paper towel. Discard towel.

**FOR DISINFECTION OF NON-CRITICAL SURGICAL AND DENTAL INSTRUMENTS [AND EQUIPMENT]:**

Apply or immerse instruments in Bulk AMPHYL® Brand Disinfectant solution for 15 minutes to wet all surfaces thoroughly. Flush and fill the lumen of hollow instruments/equipment, avoiding entrapment of air bubbles. If instruments are to remain in the solution for substantially longer periods of time, add 1 gram of sodium bicarbonate to each quart of solution; stir to dissolve completely. Also add 2 oz. of Isopropyl alcohol per quart of solution to maintain clarity. Remove and rinse instruments. Wipe dry or allow to air dry prior to use or further processing. Change solution as needed when the solution becomes diluted or visibly soiled.

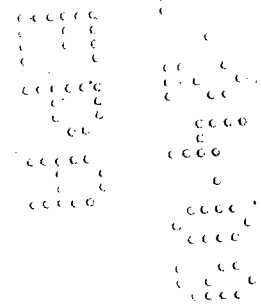
Note: Critical and semi-critical devices must be followed by appropriate sterilization or high-level disinfection process.

**FOR SANITARY DISPOSAL OF URINE , FECES:**

To urine, add equal amount of Bulk AMPHYL® Brand Disinfectant solution. For feces, place [3% Bulk AMPHYL® Brand Disinfectant] solution in pan in amount slightly larger than expected discharge. After receiving feces, mix thoroughly with solution then cover and let stand for one hour before disposal.

**FOR SANITARY LAUNDRY, LINENS, BLANKETS AND DIAPERS (See Dilution Chart):**

To each 10 pounds of blankets or linen, introduce 17 gallons of water. Add 1 cup (8 fl. oz.) of [Bulk AMPHYL® Brand Disinfectant] [this product]. Agitate for a minimum of 3 minutes to ensure saturation. Allow to soak for 10 minutes, then add soap or detergent and wash in usual manner.





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**CONDUCTIVE FLOORS:**

Certain areas of a hospital or an industrial plant require that a safe level of conductivity be maintained on the floors. The established levels of safe conductivity are between 25,000 – 1,000,000 ohms. Electric discharges must be dissipated rapidly to avoid static discharges that might affect flammable materials, such as anesthetics or sensitive electrical equipment. Using improper disinfectants or detergents can cause a residue formation which can impair conductivity. [Bulk AMPHYL® Brand Disinfectant] [This product] has no effect on the resistant properties of conductive flooring as per the requirements of the National Fire Protection Association, NFPA-99-1993, Chapter 12, Section 12-4.1.3.8. Test results are available upon request.

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals**

**WARNING:** Harmful if swallowed. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

<b>FIRST AID</b>	
<b>If swallowed</b>	<ul style="list-style-type: none"><li>• Call poison control center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person</li></ul>
<b>If in eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>CONTACT NUMBER</b>	
Questions? Comments or In case of an emergency call toll free (1-800-677-9218). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>NOTE TO PHYSICIAN:</b>	
Probable mucosal damage may contraindicate the use of gastric lavage.	

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**STORAGE AND DISPOSAL** {For sizes 1 gallon or less}

Store in original container in areas inaccessible to small children. Keep securely closed. Do not reuse empty container. Rinse thoroughly with water and detergent. [Wrap and] Discard in trash.

{For sizes over 1 gallon}

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

**PESTICIDE STORAGE:** Store in original container in areas inaccessible to small children. Keep securely closed.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{For sizes 5 gallons or more}

**ENVIRONMENTAL HAZARDS**

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 System (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.

[Please encourage your state and local authorities to establish a recycling program so that this [container] [bottle] [pail] [drum] can be recycled.]

{For 55 gallon size:}

[This label is printed on \_\_\_% recycled paper (\_\_\_% post consumer)]

NOTICE: This product contains a chemical known to the State of California to cause cancer.

Questions? Comments? Call 1-800-677-9218.

[Monday – [thru] Friday, 8:45 a.m. – [to] 4:30 p.m. [Eastern time].]

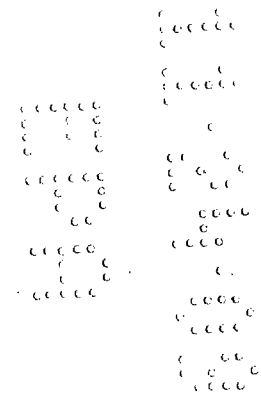
[Visit us at [www.reckittprofessional.com](http://www.reckittprofessional.com)]

[Distributed by:]

Reckitt Benckiser, Inc.  
Morris Corporate Center IV  
399 Interpace Parkway  
Parsippany, NJ 07054-XXXX

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[Made in USA]



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{Optional Text. For use on product label or collateral labeling}

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. Bulk AMPHYL® Brand Disinfectant is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Virus Type A (Japan) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Bulk AMPHYL® Brand Disinfectant has demonstrated effectiveness against Influenza Virus Type A (Japan) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.

Bulk AMPHYL® Brand Disinfectant has demonstrated effectiveness against Influenza Virus Type A (Japan) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 Influenza A virus.

