

9402-10

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JAN 06 2010

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC SUBSTANCES

Christina M. Swick, Lewis and Harrison
Agent for Kimberly-Clark Global Sales, LLC
122 C Street, NW Suite 740
Washington, DC 20001

Subject: **Kleenex Brand Anti-Viral Tissue**
EPA Registration Number: 9402-10
Notification Date: December 16, 2009
EPA Receipt Date: December 16, 2009

Dear Ms. Swick:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 95-2.

Proposed Notification:

- Addition of Influenza A virus (H1N1) label claim

General Comment:

Based on a review of the submitted materials, your notification for the addition of the influenza A virus (H1N1) label claim is acceptable and a part of the records on file.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at garvie.heather@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Jacqueline McFarlane".

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



EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other: Notification

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 9402-10	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Kleenex Brand Anti-Viral Tissue	PM# Team 34	
5. Name and Address of Applicant (Include ZIP Code) Kimberly-Clark Global Sales, LLC 2100 Winchester Road Neenah, WI 54956 <u>PLEASE DIRECT ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <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 to add Influenza A virus (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 the confidential statement of formula of this product. I understand that it is a violation of 18U.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.

Signature: Christina M. Swick Date: 12/16/09

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
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: Christina M. Swick, Lewis and Harrison 122 C St., NW Suite 740, Washington, DC 20001	Title: Agent for Kimberly-Clark Global Sales, LLC	Telephone No. (Include Area Code): (202) 393-3903 x16
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 <u>Christina M. Swick</u>	3. Title: Agent for Kimberly-Clark Global Sales, LLC	
4. Typed Name Christina M. Swick, Lewis & Harrison LLC	5. Date December 16, 2009	

{OVERWRAP:}

Kleenex® Brand Anti-Viral* Tissue

{Kleenex Anti-Viral Tissue Logo}

Net Contents: [75] [112] 3-Ply Tissues 8.2 x 8.2 in / 20.8 x 20.8 cm

ACTIVE INGREDIENTS:

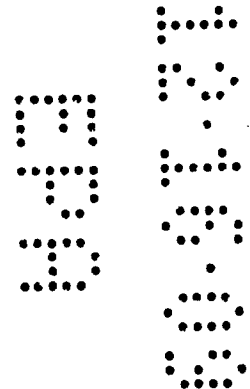
Citric Acid.....	7.51%
Sodium Lauryl Sulfate.....	2.02%
INERT INGREDIENTS.....	90.47%
Total.....	100.0%

[Kills 99.9% of Cold & Flu Viruses*]

[Kills Pandemic 2009 H1N1 influenza A virus (formally called swine flu)]

[See bottom for use directions]

NOTIFICATION
Date Reviewed: 1/16/10
Reviewed By: H. Harvie



Note to reviewer: All text in brackets [xxx] is optional and may or may not be included on a final label.
All text in brackets [xxx] is administrative and will not appear on a final label.

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{BOTTOM PANEL:}

[KLEENEX® Anti-Viral* tissue kills 99.9% of Cold and Flu Viruses*]

[Kills Pandemic 2009 H1N1 influenza A virus (formally called swine flu)]

Because cold and flu viruses are often spread by hand contact, KLEENEX® Brand has developed a tissue for your whole family. KLEENEX® Anti-Viral* tissue has three soft layers, including a moisture-activated middle layer that kills 99.9% of cold and flu viruses* in the tissue within 15 minutes. This product has not been tested against bacteria, fungi or other viruses. See below for anti-viral* details.

Directions for Use: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Use only as a facial tissue.

*Virucidal Against: Rhinoviruses Type 1A and 2 (Rhinoviruses are the leading cause of the common cold), Influenza A and Influenza B (causes of the flu); H1N1 (formally called the swine flu); Respiratory Syncytial Virus (RSV – the leading cause of lower respiratory tract infection in children).

Storage and Disposal: Store in a dry area. Dispose of used tissues promptly. Do not reuse empty container.

ACTIVE INGREDIENTS:

Citric Acid.....7.51%
Sodium Lauryl Sulfate.....2.02%
INERT INGREDIENTS.....90.47%
Total.....100.0%

EPA Reg. No.: 9402-10

EPA Est. No.:009402-SC-002, 009402-CT-001

Net Contents: [75] [112] 3-Ply Tissues 8.2 x 8.2 in / 20.8 x 20.8 cm

1-800-553-3639 Weekdays 8 a.m. to 4 p.m. CT

Manufactured for: Kimberly-Clark Global Sales, LLC, Dept. KAVBS-112, PO Box 2020, Neenah, WI 54957-2020

Made in the USA from domestic and imported material.

www.kleenex.com

® Registered Trademark of Kimberly-Clark Worldwide, Inc. The BLUE DOT PATTERN is a Trademark of KCWW

© 1986, 2007, 2009 KCWW

May be made under one or more of the following US patents: 7,132,379; 6,709,550; 6,221,211; D518,647.

{Graphic} Box Tops for Education is a registered trademark of General Mills used with permission. See www.kleenex.com for details.

{Graphic} This box is made from 100% recycled paper

{UPC Symbol}

