UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

December 12, 2004

MEMORANDUM:

Efficacy Review EPA Reg. No. 9402-10 *Kleenex Anti-Viral Tissue*
DP Barcode 311439

From: Nancy Whyte, Efficacy Team Leader (Acting)
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To: Adam Heyward, PM Team 34
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Thru: Michele E. Wingfield, Chief
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Applicant:: Kimberly-Clark Corporation
2100 Winchester Road
Neenah, Wisconsin 54956

Formulation Label: **% by wt.**
Active Ingredient(s)

Citric acid.....7.53%
Sodium lauryl sulfate.....2.02%
Other ingredients.....90.49%
Total.....100.0%

I. Background:

The report of efficacy data conducted by Hill Top Research, Inc., Cincinnati, OH to determine the effectiveness of the product against Rhinovirus 2, ATCC VR-482 was received by the Product Science Branch on December 10, 2004. The testing had been done in February 2003 and was reported in MRID No. 4568754-01. Testing previously done against this organism in 2002 was not acceptable to support a label claim for effectiveness of the product

against Rhinovirus 2 because the recoverable virus titer achieved in the testing was not 10^4 for any of the three product lots tested. Efficacy data submitted at that time for four other organisms, Rhinovirus 1, ATCC VR-1364, Influenzae A, ATCC,VR-1469, Influenzae virus B, CDC !D# 2001701156 and Respiratory Syncytial Virus, ATCC VR-26 had been accepted in support of label claims. The testing was done using Good Laboratory Practices, and a Quality Assurance Statement was included in the testing report to the Agency.

II. Use Directions:

The use directions printed on the package label state that the product is to be used as a facial tissue, and has not been tested against bacteria, fungi, or other viruses. The tissues are to stored in a dry area, and disposed of promptly after use.

III. Agency Standards for Proposed Claims:

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products Test (for spray disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique with multiple replicates per dilution. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

IV. Summary of Study:

There were no specific details presented about the actual testing procedure or the preparation of the virus prior to testing. A Protocol to Measure the Virucidal Efficacy of Facial Tissues prepared by Hilltop Laboratories was included in the testing report. This document outlined the experimental design for such testing, and contained a copy of Efficacy Data Requirements for Virucides proposed by the Registration Division, Office of Pesticide Programs of the Agency in 1976 which are consistent with the requirements of DIS/TSS-7 (see above). Results of the testing were reported as follows on the next page of this review.

Inoculating Facial Tissue Disks at 15 Minute Exposure Period against Rhinovirus 2, ATCC VR-482

Log_{10} $TCID_{50}$/0.1 mL*

Test Substance	Average Titer**	Reduction in Virus Titer	Percent Reduction in Virus Titer
3-7-02-4A	0.5*	4.3	>99.99
3-7-02-4B	0.5	4.3	>99.99
3-7-02-4C 60 da. stability sample	0.5	4.3	>99.99
3-7-02-4D Control	NA	NA	NA

* Triplicate runs
NA= Not Applicable

Results of Virucidal Tests Rhinovirus 2, ATCC VR-482

Sample: 3-7-02-4A
Control: 3-7-02-4D

CYTOPATHIC EFFECT						
Dilution Inoculated	Virus Control*			Sample + Virus*		
	a	b	c	a	b	c
10^{-1}	++++	++++	++++	0000	0000	0000
10^{-2}	++++	++++	++++	0000	0000	0000
10^{-3}	++++	++++	++++	0000	0000	0000
10^{-4}	++++	++++	+00+	0000	0000	0000
10^{-5}	0++0	0+0+	000+	0000	0000	0000
10^{-6}	0000	0000	0000	0000	0000	0000
Viral Titer (Log_{10}**$TCID_{50}$/0.1 mL)	5.0	5.2	4.2	0.5	0.5	0.5
Average Viral Titer (Log_{10}**$TCID_{50}$/0.1 mL)	4.8			0.5		

*Triplicate runs
Note: + = virus recovered: 0 = no virus recovered
$TCID_{50}$ Calculated by method of Reed and Muench

Results of Virucidal Test for Rhinovirus 2, ATCC VR-482

Sample: 3-7-02-4B
Control 3-7-02-4D

CYTOPATHIC EFFECT						
Dilution Inoculated	**Virus Control***			**Sample + Virus***		
	a	**b**	**c**	**a**	**b**	**c**
10^{-1}	++++	++++	++++	0000	0000	0000
10^{-2}	++++	++++	++++	0000	0000	0000
10^{-3}	++++	++++	++++	0000	0000	0000
10^{-4}	++++	++++	+00+	0000	0000	0000
10^{-5}	0++0	0+0+	000+	0000	0000	0000
10^{-6}	0000	000+	0000	0000	0000	0000
Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	5.0	5.2	4.2	0.5	0.5	0.5
Average Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	4.8			0.5		

*Triplicate runs
Note: + = virus recovered: 0 = no virus recovered
$TCID_{50}$ Calculated by method of Reed and Muench

Results of Virucidal Test for Rhinovirus 2, ATCC VR-482

Sample: 3-7-02-4C (60 day Stability Study)
Control 3-7-02-4D

CYTOPATHIC EFFECT						
Dilution Inoculated	**Virus Control***			**Sample + Virus***		
	a	**b**	**c**	**a**	**b**	**c**
10^{-1}	++++	++++	++++	0000	0000	0000
10^{-2}	++++	++++	++++	0000	0000	0000
10^{-3}	++++	++++	++++	0000	0000	0000
10^{-4}	++++	++++	+00+	0000	0000	0000
10^{-5}	0++0	0+0+	000+	0000	0000	0000
10^{-6}	0000	000+	0000	0000	0000	0000
Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	5.0	5.2	4.2	0.5	0.5	0.5
Average Viral Titer (Log_{10} **$TCID_{50}$/0.1 mL)	4.8			0.5		

*Triplicate runs
Note: + = virus recovered: 0 = no virus recovered
$TCID_{50}$ Calculated by method of Reed and Muench

VI. Recommendations and Comments

1. The original viral titer was at least 10^4 (average 4.8) and efficacy testing of the product, *Antiviral Kleenex Tissue,* achieved at least a 3 $\log_{10}$ reduction in virus titer as required by DIS/TSS-7.

2. The label claim, already appearing on the product packaging, that the product is effective against Rhinovirus 2, ATCC VR-482 following 15 minutes exposure to the product, is supported by the efficacy testing submitted to the Agency.