TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 03-22-83 OUT 05-02-83

Dennis G. Guse

Reviewed By Dennis G. Guse Date 05-02-83

EPA Reg. No. or File Symbol 9402-G

EPA Petition or EUP No. None

Date Division Received 03-17-83

Type Product Impregnated virucidal facial tissue

Data Accession No(s). 249743

Product Manager 32 (Castillo)

Product Name Kleenex Virucidal Tissue

Company Name Kimberly-Clark Corporation

Submission Purpose New product application with virucidal efficacy data and proposed label

Type Formulation Dry impregnated tissue for use as is

Active Ingredient(s):	%
Citric acid	10
Malic acid	5
Sodium lauryl sulfate	2

200.0 Introduction.

200.1 Use(s).

Chemically impregnated dry facial tissue intended to inactivate viruses deposited on the tissue in nasal and oral discharges, thereby reducing the spread of virus contamination. See the attached proposed label.

200.2 Background.

Refer to the previous review of a pre-registration submission for this product by TSS (Efficacy), DB, RD, dated 12-02-82.

201.0 Data Summary.

201.1 Brief Description of Tests (Accession No. 249743).

a. Effectiveness Data - IITRI. Report by Kathleen V. Ketels and James D. Fenters, Life Sciences Research, Illinois Institute of Technology Research Institute, Chicago, Illinois 60616, dated 01-28-83.

b. Effectiveness Data - UW. Report by Elliott C. Dick, Respiratory Virus Research Laboratory, Dept. of Preventive Medicine, University of Wisconsin Medical School, Madison, Wisconsin 53706, dated 01-11-83.

c. Effectiveness Data - KC. Report by Jeffrey D. Holz and Thomas W. Schafer, Pioneering Research & Development, U.S. Consumer Products Co., Kimberly-Clark Corp., Neenah, Wisconsin 54956, dated 02-08-83.

d. Report IV - Final Report - Time Course of Rhinovirus Inactivation on Virucidal Kleenex Tissue. Report by Elizabeth Wills and Roland R. Rueckert, Biophysics Laboratory, University of Wisconsin, Madison, Wisconsin 53706, dated 12-28-82.

e. Additional Effectiveness Data.

1. Evidence That Human Rhinovirus 14 Is Completely Dissociated by Virucidal Tissues by K. C. Medappa and R. R. Rueckert, Biophysics Laboratory, University of Wisconsin, Madison, Wisconsin 53706; report prepared by K. R. Smith, Kimberly-Clark Corp., Neenah, Wisconsin 54956, undated.

2. Virucidal Tisse Inactivates Human Rhinovirus 14 Within Seconds by G. S. Fout and R. R. Rueckert, Biophysics Laboratory, University of Wisconsin, Madison, Wisconsin 53706, dated 06-14-82.

3. Exploratory (Virucidal) Studies by Elliott C. Dick, Respiratory Virus Research Laboratory, Dept. of Preventive Medicine, University of Wisconsin Medical School, Madison, Wisconsin 53706, undated.

201.2 Test Summaries.

a, b, and c. Effectiveness Data - IITRI, UW, and KC.

1. Method: Undiluted virus suspension (0.1 ml) was inoculated onto a 1-1/8-inch diameter disc of treated tissue in a plastic petri dish. The virus was added to the disc in a manner which permitted the solution to be absorbed into the disc, completely wetting it, but without overflowing. After the specified exposure time, 5.0 ml of neutralizing solution (KC-NS-11) was added to the petri dish and mixed gently with the disc for 3 seconds using a pipette tip. Then the entire contents of the dish including the disc were rapidly transferred to a wide-mouth tube and vigorously agitated on a vortex mixer for 30 seconds. Serial dilutions are then made and the virus is assayed by conventional tissue culture methods. The following controls were also performed: (i) Untreated control disc + virus + neutralizer (virus control); (ii) Virucide-treated disc + neutralizer + virus (neutralization control); (iii) Untreated control disc + neutralizer + virus (neutralizer toxicity control); (iv) Virucide-treated disc + neutralizer (cytoxicity control); and (v) Untreated control disc + neutralizer (cytotoxicity control).

2. Samples: Two batches of virucide-treated tissues (H315-133-1 and H315-134-1) and untreated control tissues otherwise identical to the treated discs.

3. Dilution: As is.

4. Exposure: 1 and 10 minutes at room temperature.

5. Neutralizer: KC-NS-11 consisting of 5.0 ml bovine serum albumin, fraction 5 (7.5%), 0.125 ml HEPES buffer (1.0 M), and 0.5 ml sodium hydroxide solution (0.1 N).

6. Test Viruses: Rhinovirus 1A, Poliovirus Type 1 Attenuated, Coxsackievirus A7 and B4, Echovirus 11, Reovirus Type 3, Influenza virus Types A/Port Chalmers (H3N2) and B/Maryland, Parainfluenza virus Types 1, 2, and 3, Respiratory Syncytial virus, and Herpes Simplex virus Types 1 and 2. All viruses were grown and assayed by appropriate conventional tissue culture techniques.

7. Results: The raw data were evaluated and found to be accurately represented in the attached summary table "Summary - Virucide-Treated Disc In Vitro Test Results From Three Laboratories".

8. Conclusions: Product showed satisfactory performance as a virucide against the respiratory viruses Rhinovirus Type 1A, Influenza virus Type B/Maryland, Parainfluenza virus Types 1 and 3, and Respiratory Syncytial virus, and against the non-respiratory viruses Herpes Simplex Types 1 and 2, at a contact time of 1 minute; it also showed satisfactory performance as a virucide against the respiratory virus Parainfluenza virus Type 2 at a contact time of 10 minutes.

d. Report IV - Final Report - Time Course of Rhinovirus Inactivation on Virucidal Kleenex Tissue.

1. Method: Research study designed to evaluate inactivation rate of high-titer (ca. 10^8) rhinovirus inoculated onto virucide-treated tissue at ultra-short exposure times (5 to 60 seconds).

2. Results: Rhinoviruses displayed first order inactivation kinetics with very short half-lives, on the order of 0.8 to 0.9 seconds. Inactivation after 5 seconds exposure to the tissue was 99.9% for Rhinovirus 14 and about 98% for Rhinovirus 1A. About 0.05% of Rhinovirus 14 and 0.5% of Rhinovirus 1A was relatively resistant to inactivation by the tissue. The nature of this resistance was not established but the experiments indicate that resistance was not due to survival of infective RNA or to genetic variants in the virus population.

3. Conclusions: Although designed as a research study rather than as an efficacy evaluation in accordance with EPA virucidal testing guidelines, the results additionally show satisfactory performance of the product as a virucide against Rhinovirus 14 at a contact time of 1 minute.

e. Additional Effectiveness Data.

1. These data were summarized in the previous review of a pre-registration submission for this product by TSS (Efficacy), DB, RD, dated 12-02-82.

Claimed confidential by submitter

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 9402-G

Date Division Received 03-17-83

Data Accession No(s). 249743

Product Manager No. 32 (Castillo)

Product Name Kleenex Virucidal Tissue

Company Name Kimberly-Clark Corporation

202.0 Recommendations.

202.1 Efficacy Supported by the Data.

The submitted data meet current requirements to support efficacy of the product as virucidal against Rhinovirus Types 1A and 14, Influenza Type B/Maryland, Parainfluenza Types 1 and 3, and Respiratory Syncytial virus within 1 minute when deposited on the tissue in the presence of moisture; and against Parainfluenza Type 2 at a contact time of 10 minutes.

The data also support efficacy of the product as virucidal against the non-respiratory viruses Herpes Simplex Types 1 and 2 at a contact time of 1 minute. However, these viruses do not appear appropriate for the pattern of use intended for this product.

202.2 Efficacy Not Supported by the Data.

The submitted data do not meet current requirements to support efficacy of the product as virucidal against Adenoviruses.

203.0 Labeling.

The label must bear a clear statement as to the effectiveness of the product as an antimicrobial pesticide on an inanimate surface, e.g., "The tissues have been chemically treated to be virucidal within 1 minute against viruses deposited on the tissue in the presence of moisture". on back panel

The "Virucidal" claim must be keyed (e.g., by an asterisk) to the specific viruses and types tested, e.g., Rhinovirus Types 1A and 14, Influenza virus Type B/Maryland, Parainfluenza virus Types 1 and 3, and Respiratory Syncytial virus. appearing on front panel

Add a statement such as "Not a Bactericide".

The claim "Kills major cold and influenza viruses" is too broad and must be deleted.

Delete "Adenoviruses".