UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 25, 2002

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 9402-O / Kimtech Pre-Moistened Sanitizer Wipes
DP Barcode: D282428 / D282051
Case No: 71463

To: Velma Noble PM 31 / Tracy Lantz, Team Reviewer
Regulatory Management Branch I
Antimicrobials Division (7510C)

From: Robert A. Turpin, Scientist R. T.
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C) 5/14/02

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Kimberly-Clark Corp.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Octyl decyl dimethyl ammonium chloride	0.0120
Dioctyl dimethyl ammonium chloride	0.0048
Didecyl dimethyl ammonium chloride	0.0072
Alkyl (C_{14}, 50%; C_{12}, 40%; C_{16}, 10%) dimethyl benzyl ammonium chloride	0.0160
Other Ingredient(s):	99.9600
Total:	100%

BACKGROUND: The applicant has submitted toxicity data in support of its application for registration of its product, Kimtech Pre-Moistened Sanitizer Wipe. The studies are MRID #'s 456439-01 - Oral Toxicity; 456439-02 - Acute Dermal Toxicity; 456439-03 - Primary Eye Irritation; 456439-04 - Primary Skin Irritation; 456439-05 - Dermal Sensitization; and 456439-06 - Characterization of Active. The applicant has requested a waiver of the requirement for an Acute Inhalation study.

RECOMMENDATIONS (PSB findings):

The applicant must identify the test substance of each of the studies submitted to be the equivalent of the subject material of the registration application. The material of the studies is identified as C2000-1650 Code 7345-80 Wet Wipe.

The acute toxicity profile for Reg. No. 9402-O is currently:

acute oral toxicity	IV	Acceptable
acute dermal toxicity	IV	Acceptable
acute inhalation toxicity	IV	Waived
primary eye irritation	III	Acceptable
primary skin irritation	IV	Acceptable
dermal sensitization	Non-Sensitizer	Acceptable

LABELING:

The signal word is CAUTION.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: Velma Noble
MRID No.: 456439-01

Reviewer: R. Turpin
Study Completion Date: 3/29/2002
Report No.: 11705

Testing Laboratory : Product Safety Labs
Authors : George E. Moore

Quality Assurance (40 CFR §160.12): GLP statement provided.

Test Material: C2000-1650 Code 7345-80 Wet Wipe

Species: Rat
Age: 9 to 10 weeks
Weight: Males, 242-260 grams; Females, 181-190 grams
Source: Ace Animals, Inc.

Conclusion:

1. **LD_{50} (mg/kg):** **Males** = >5,000 mg/kg
   Females = >5,000 mg/kg
   Combined = >5,000 mg/kg
2. **The estimated LD_{50} is** >5,000 mg/kg
3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviations from §81-1): None noted other than sponsor requested use of expressed liquid from wipe.

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000 mg/kg	0/5	0/5	0/10

Observations: All animals survived and gained weight. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior.

Gross Necropsy: No gross abnormalities were observed.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: Velma Noble
MRID No.: 456439-02

Reviewer: R. Turpin
Study Completion Date: 3/29/2002
Report No.: 11706

Testing Laboratory: Product Safety Labs
Author: George E. Moore
Quality Assurance (40 CFR §160.12): GLP statement provided.

Test Material: C2000-1650 Code 7345-80 Wet Wipe

Species: Rat
Weight: Males, 260-285 grams; Females, 200-222 grams
Age: 9 to 10 weeks
Source: Ace Animals, Inc.

Summary:

1. **LD_{50} (mg/kg)**: **Males** = >5,000 mg/kg
   Females = >5,000 mg/kg
   Combined = >5,000 mg/kg

2. **The estimated LD_{50} is** >5,000 mg/kg

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2): None noted other than sponsor requested use of expressed liquid from wipe.

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000 mg/kg	0/5	0/5	0/10

Observations: All animals survived and gained weight. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior.

Gross Necropsy Findings: No gross abnormalities were observed.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: Velma Noble
MRID No.: 456439-03

Reviewer: R. Turpin
Study Completion Date: 3/29/2002
Report No.: 11707

Testing Laboratory: Product Safety Labs
Author(s): George E. Moore

Quality Assurance (40 CFR §160.12): GLP statement provided.

Test Material: C2000-1645 Code 7345-80 Wet Wipe
Dosage: 0.1 ml
Species: Rabbit
Sex: 2 males; 1 female
Weight: N/A
Source: Davidson's Mill Farm

Age: Young adults

Summary:

1. **Toxicity Category**: III
2. **Classification**: Acceptable

Procedure (Deviations From §81-4): None noted

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	—	—	—	---
Iritis	0/3	0/3	0/3	0/3	—	—	—	---
Conjunctivae								
Redness	3/3	1/3	0/3	0/3	—	—	—	---
Chemosis	---							
Discharge	---							

--- = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Velma Noble
MRID No.: 456439-04

Reviewer: R. Turpin
Study Completion Date: 3/29/2002
Report No.: 11708

Testing Laboratory: Product Safety Labs
Author: George E. Moore

Quality Assurance (40 CFR §160.12): GLP statement provided

Test Material: C2000-1645 Code 7345-80 Wet Wipe
Dosage:
Species: Rabbit
Age: Young adults
Sex:2 males; 1 female
Source: Davidson's Mill Farm

Weight: N/A

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-5): Test substance was cut into 1 inch squares and applied to as received to the test site.

Results: All animals appeared active and healthy. There were no signs of gross toxicity, dermal irritation, adverse pharmacologic effects or abnormal behavior.

Special Comments: None

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: Velma Noble
MRID No.: 456439-05

Reviewer: R. Turpin
Study Completion Date: 3/29/2002
Report No.: 11709

Testing Laboratory: Product Safety Labs
Author: George E. Moore

Quality Assurance (40 CFR §160.12): GLP statement provided.

Test Material: C2000-1650 Code 7345-80 Wet Wipe
Positive Control Material:1-Chloro-2,4-dinitrobenzene (DNCB)

Species: Guinea pig
Weight: 390-477 grams
Source: Elm Hill Breeding Labs

Age: Young adults

Method: Buehler

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification**: Acceptable

Procedure (Deviation From §81-6): The test substance was cut into circles (20-22 mm prior to application. The circles are not required to be moistened, as they are pre-moistened..

Procedure: The test sites on four animals was prepared by clipping. The wipres were cut into 20-22 mm circles and applied as received to each animal using an occlusive 25 mm Hill top Chamber. After six hours the chambers were removed and wiped with water and a clean towel. Approximately 24 hours after application, each site was evaluated for local reactions.

In the Induction Phase the above procedure was preformed on the test animals and they were observed after 24 and 48 hours for reactions to exposure. In the Challenge Phase, 28 days after the first induction dose, a 20-22 mm circle of test substance was applied to a naive site of each animal using the procedures, above. These sites were evaluated.

Results: The test substance was determined to be a non-sensitizer.

ACUTE TOX ONE-LINER

1. PC CODE: 69105 / 69165 / 69166 / 69149

2. CURRENT DATE: 4/25/2002

3. TEST MATERIAL: C2000-1645 Code 7345-80 Wet Wipe

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
acute oral toxicity /Rat/Product Safety Labs(PSL)/11705/3-29-02	456439-01	LD_{50} (mg/kg) = >5,000	IV	A
acute dermal toxicity /Rat/PSL/11706/3-29-02	456439-02	LD_{50} (mg/kg) = >5,000	IV	A
acute inhalation toxicity /	Waived	LC_{50} (mg/L)		
primary eye irritation /Rabbit/PSL/11707/3-29-02	456439-03	Minimally irritating, all symptoms cleared at the 48 hr. observation	III	A
primary skin irritation /Rabbit/PSL/11708/3-29-02	456439-04	No dermal irritation was observed at any time during test period	IV	A
dermal sensitization /Guinea pig/PSL/11709/3/29/02	456439-05	Not a sensitizer	---	A

A = Acceptable
U = Unacceptable
S = Supplementary
V = self-Validated