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WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

May 13, 2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
KIMTECH Pre-Moistened Sanitizer Wipes

DP Barcode: 282047 **Reg. No. Or File Symbol: 9402-O**
Manufacturing-use [ ] OR **End-use Product [X]**

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5/14/02

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Product Formulation

Active Ingredient(s)	**% by wt.**
n-Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	0.0416%
Octyldecyl dimethyl ammonium chloride	0.0313%
Didecyl dimethyl ammonium chloride	0.0187%
Dioctyl dimethyl ammonium chloride	0.0124%
	0.1040%

BACKGROUND:

The registrant has submitted an application for a new sanitizer wipe. The single-use wipe is designed to be used on both food-contact and non-food contact hard, non-porous surfaces. Submitted for review were Confidential Statements of Formula for the bulk sanitizer used in the

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wipe and the saturated wipe. Also submitted were 4 separate documents containing the applicable product chemistry data required to satisfy Series 830 Guidelines for registration (MRID Nos. 456171-01, -02, -03, and 456171-04). The wipe product consists of a roll of perforated impregnated sheets inclosed in a plastic canister with a lid thru which individual wipes are dispensed.

FINDINGS:

1. The Confidential Statement of Formula for the bulk sanitizer is presented to show the amount of active ingredient (0.104%) that is loaded into the [redacted] material to produce the wet wipe.

2. The second Confidential Statement of Formula is for the wipe product that is sold and lists the amount of active ingredient that can be expressed from the wipe (0.04%) after the active ingredient is absorbed into the wipe material.. This figure represents the amount that is available for sanitization.

3. All the ingredients have previously been approved for use in pesticides.

4. All the certified upper and lower limits are within the accepted range of Agency standards listed in 40 CFR, Part 158.175.

5. All the product chemistry which is required for registration, and that is applicable to this product, has been submitted. See attached below for a summary of the data.

RECOMMENDATIONS:

1. The product chemistry data submitted to satisfy registration requirements of Series 830 Guidelines are acceptable.

2. The Confidential Statements of Formula, dated February 11, 2002, for both the bulk sanitizer and the wipe product itself, are approved.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration
- Non-integrated formulation system [X]
- Are all TGAI used registered? Yes [X] No [ ]

- Integrated formulation system [ ]

- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [X] No [ ] NA [ ]

4c. Physical state of product: Liquid

4d. The chemical IDs and analytical information (including that for the TGAI), density, pH, and flammability are consistent with that given in 830.1000, Series A and 830.7300, .7000 and .6315 respectively: Yes [X] No [ ]

4e. NCs and CLs are acceptable: [X] Not acceptable [ ]

4f. Active ingredient (s)	NC	UCL	LCL
A. n-Alkyl (50% C_{14}, 40%C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	0.0160%	0.0176%	0.0144%
B. Octyldecyl dimethyl ammonium chloride	0.0120%	0.0132%	0.0108%
C. Didecyl dimethyl ammonium chloride	0.0072%	0.0079%	0.0065%
D. Dioctyl dimethyl ammonium chloride	0.0048%	0.0053%	00.0043%

4g. For products produced by an integrated formulation system:
- All impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [ ]

- All impurities of $\geq 0.1\%$ in the product have been identified?

  Yes [ ] No [ ] Not applicable [ ]

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC] is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No [ ]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [ ] No [ ] Not applicable [X]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [X] No [ ]

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [ ] No [ ] Pending

6 . **PRODUCT CHEMISTRY (Series 830 Part A)**

	Acceptance of Information	MRID No.
830.1550 Chemical ID (See Appendix)[1]	A	456171-01
830.1600 Description of Materials	A	456171-01
830.1620 Manufacturing Process[2]	A	456171-01
830.1650 Formulation Method[3]	NA	456171-01
830.1670 Discussion of Impurities[4]	A	456171-01
830.1700 Analysis[5]	A	456171-02
830.1750 Certified Limits[6]	A	456171-02
830.1800 Analytical Method for AIs[7]	A Titration	456171-02

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required, G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information

[2]For MP/EP products produced by an integrated formulation system.

[3]For products from a TGAI or MP.

[4]May be waived unless actual/possible impurities are of toxicological concern.

[5]Five batch analysis required for products produced by an integrated formulation system.

[6]If different from standard CLS recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR),

Physical and Chemical Characteristics (Series 830, Part B)

6b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Off-white	456171-03
830.6303 Physical State	A	Liquid	456171-03
830.6304 Odor	A	Slight quat. amine	456171-03
830.6314 Oxidation/Reduction	A	Formed brown p'itate. with $KMnO_4$. Pitted iron coupon and formed brown precipitate	456171-03
830.6315 Flammability/Flash Pt	NA	Not flammable	456171-03
830.6316 Explodability	NA	Not explosive	456171-03
830.6317 Storage Stability	A	Pending	456171-04
830.6320 Corrosion Character.	A	Pending	456171-01
830.7000 pH	A	11.83 (solution)	CSF
830.7100 Viscosity	A	0.964 mm^2/s (cSt)	456171-03
830.7300 Relative Density	A	1.002	456171-03

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= Not required G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25°C.

Note to Reviewer:

Kimberly-Clark is submitting two (2) Confidential Statement of Formula (CSF) for the product, "Kimberly-Clark KIMTECH Pre-Moistened Sanitizer Wipe".

The first CSF is for the bulk sanitizer solution prior to its addition to the absorbent wipe. The percent by weight for each ingredient is a straightforward calculation based on the amount added to the bulk solution.

The second CSF, which is for the finished product, is more complex. Since the accelerated storage stability study (Volume 4) clearly shows that the quaternary ammonium compounds present in the bulk sanitizer solution bind to the absorbent wipe, the concentrations assigned to the quaternary ammonium compounds are in terms of the amount actually expressed from the wipe. It should also be noted that the concentrations on the product label for the quaternary ammonium compounds are amounts in the liquid expressed from the wipe. Kimberly-Clark believes that both the CSF and product label should report quaternary ammonium compounds in terms of actual expressed amounts since any viable enforcement method will be based on the expressed solution. Moreover, it is highly unlikely that the bound material contributes to product efficacy, and, therefore, is characterized as an impurity.

The values for each of the components of the second CSF were derived as follows:

- The concentration of Bardac 208M is the amount in the bulk sanitizer solution (1.3 lbs or 0.13%) adjusted for the weight of the absorbent wipe (174 lbs or 17.4%):

  (1.3 lbs or 0.13%) (826 lbs or 82.6%)/1000 lbs or 100%) = 1.07 lbs. or 0.107%

- The concentration of the quaternary ammonium compounds is based on the data presented in Volume 4. The data showed that the concentration of the quaternary ammonium compounds in the liquid expressed from the wipe (i.e., "free" quat) is approximately 0.04% and the amount adsorbed out of bulk solution and bound onto the surface of the substrate (i.e., "bound" quat) is approximately 0.062%. As noted above, the bound quaternary ammonium compound is being reported as an impurity.

- The concentration of the inert ingredients, except for the absorbent wipe, are the amounts present in the bulk sanitizer solution adjusted for the absorbent wipe.

- The absorbent wipe concentration is based on the percentage of the finished product weight that is due to the absorbent wipe.