May 13, 2002

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

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

TO: Velma Noble/Tracy Lantz
PM Team No. 31

FROM: Nancy Whyte, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

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

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%
Diocetyl dimethyl ammonium chloride 0.0124%
1.040%

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
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)
   
<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>NC</th>
<th>UCL</th>
<th>LCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. n-Alkyl (50% C_{14}, 40%C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride</td>
<td>0.0160%</td>
<td>0.0176%</td>
<td>0.0144%</td>
</tr>
<tr>
<td>B. Octyldecyl dimethyl ammonium chloride</td>
<td>0.0120%</td>
<td>0.0132%</td>
<td>0.0108%</td>
</tr>
<tr>
<td>C. Didecyl dimethyl ammonium chloride</td>
<td>0.0072%</td>
<td>0.0079%</td>
<td>0.0065%</td>
</tr>
<tr>
<td>D. Diocetyl dimethyl ammonium chloride</td>
<td>0.0048%</td>
<td>0.0053%</td>
<td>0.0043%</td>
</tr>
</tbody>
</table>

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
<table>
<thead>
<tr>
<th>Acceptance of Information</th>
<th>MRID No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>456171-01</td>
</tr>
<tr>
<td>A</td>
<td>456171-01</td>
</tr>
<tr>
<td>A</td>
<td>456171-01</td>
</tr>
<tr>
<td>NA</td>
<td>456171-01</td>
</tr>
<tr>
<td>A</td>
<td>456171-01</td>
</tr>
<tr>
<td>A</td>
<td>456171-02</td>
</tr>
<tr>
<td>A</td>
<td>456171-02</td>
</tr>
<tr>
<td>A Titration</td>
<td>456171-02</td>
</tr>
</tbody>
</table>

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

1See Confidential Appendix A for additional information

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

3For products from a TGAI or MP.

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

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

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

7Abbreviate method used as follows: gas chromatography (GC), infrared (IR),
Physical and Chemical Characteristics (Series 830, Part B)

<table>
<thead>
<tr>
<th>6b. Physical/Chemical Properties*</th>
<th>Acceptance of data</th>
<th>Value or qualitative description</th>
<th>MRID No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>830.6302 Color</td>
<td>A</td>
<td>Off-white</td>
<td>456171-03</td>
</tr>
<tr>
<td>830.6303 Physical State</td>
<td>A</td>
<td>Liquid</td>
<td>456171-03</td>
</tr>
<tr>
<td>830.6304 Odor</td>
<td>A</td>
<td>Slight quat. amine</td>
<td>456171-03</td>
</tr>
<tr>
<td>830.6314 Oxidation/Reduction</td>
<td>A</td>
<td>Formed brown p’itate. with KMnO₄. Pitted iron coupon and formed brown precipitate</td>
<td>456171-03</td>
</tr>
<tr>
<td>830.6315 Flammability/Flash Pt</td>
<td>NA</td>
<td>Not flammable</td>
<td>456171-03</td>
</tr>
<tr>
<td>830.6316 Explodability</td>
<td>NA</td>
<td>Not explosive</td>
<td>456171-03</td>
</tr>
<tr>
<td>830.6317 Storage Stability</td>
<td>A</td>
<td>Pending</td>
<td>456171-04</td>
</tr>
<tr>
<td>830.6320 Corrosion Character.</td>
<td>A</td>
<td>Pending</td>
<td>456171-01</td>
</tr>
<tr>
<td>830.7000 pH</td>
<td>A</td>
<td>11.83 (solution)</td>
<td>CSF</td>
</tr>
<tr>
<td>830.7100 Viscosity</td>
<td>A</td>
<td>0.964 mm²/s (cSt)</td>
<td>456171-03</td>
</tr>
<tr>
<td>830.7300 Relative Density</td>
<td>A</td>
<td>1.002</td>
<td>456171-03</td>
</tr>
</tbody>
</table>

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* 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%):

  $\frac{1.3 \text{ lbs or } 0.13\%}{174 \text{ lbs or } 17.4\%} \times 100\% = 0.7\% \text{ or } 0.007$ lbs

- 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.