SUBJECT: PRODUCT CHEMISTRY REVIEW OF: MAQUAT® 86-M
DP Barcode: D323563
Reg. No. or File Symbol 10324-85

TGAI/Manufacturing-use Product [ ] OR End-use Product [x]

TO: Velma Noble / Tracy Lantz
PM Team 31

FROM: Juan F. Negrón, Chemist
Product Science Branch, CT Team
Antimicrobial Division (7510C)

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

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

APPLICANT: Mason Chemical Company

Action: 307
Due out date: 03/02/06

Product Formulation
Active Ingredient(s) % by wt.
n-Alkyl (50%C₁₄, 40% C₁₂, 10% C₁₆) 0.034
dimethyl benzyl ammonium chloride
Octyl decyl dimethyl ammonium chloride 0.026
Diocetyl dimethyl ammonium chloride 0.013
Didecyl dimethyl ammonium chloride 0.013
BACKGROUND:

The registrant, Mason Chemical Company, is submitting a study entitled “Evaluation of Vinyl and Crypton for Hydrostatic Resistance” for review. The registrant is adding another non-porous surface, crypton barrier fabric, which can be applied using the MAQUAT® 86 - M product. The non-integrated end-use product, MAQUAT® 86 - M, is a disinfectant, cleaner, sanitizer, fungicide, mildewstat, virucide, and deodorizer.

FINDINGS:

1. The Product Chemistry Reviewer received the following documents:
   • Confidential Statement of Formula (CSF), dated 06/20/1988, for the basic formulation.
   • A label, dated 09/16/2005, pin punch.
   • A letter, dated 09/08/2005.

2. The document, MRID #466802-01, indicates that the study does not meet the requirement for the GLP. The registrant indicates that the GLP does not apply to the study according to the 40 CFR 160.135.

3. The 40 CFR 160.135 includes a list of studies that are not required to harmonize with the GLP guideline. However, the study mentioned above is not included in such list.

RECOMMENDATION:

1. The registrant needs to update the GLP statement. The study reveals that the document does harmonize with the GLP guidelines.

CONCLUSION:

The study title, “Evaluation of Vinyl and Crypton for Hydrostatic Resistance,” dated 05/2004. MRID #466802-01 is partially acceptable. The study reveals that the crypton fabric shows similar characteristics to the twelve non-porous surfaces, which exhibits fluid barrier properties.