



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 29 2001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of CSF for an Alternate Formulation of an End-Use Product (EP)
Containing Alkyl (50 % C₁₄, 40 %; C₁₂, 10 % C₁₆) 50 %; C₁₂, 40 %; C₁₆, 10 % C₁₄,
Dimethyl Benzyl Ammonium Chloride

TO: Velma Noble
PM Team No. 31

FROM: Chris Jiang, Chemist
Risk Assessment and Science Branch
Antimicrobials Division (7510C)

THRU: Winston Dang, Team Leader
Risk Assessment and Science Branch
Antimicrobials Division (7510C)

THRU: Norm Cook, Branch Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

Product Formulation for Lysol Pre-moistened Touch-ups

Active Ingredient(s)	% by wt.
----------------------	----------

Alkyl (50% C ₁₄ , 40 % C ₁₂ , 10 % C ₁₆) dimethyl benzyl ammonium chloride	0.28 %
PC Code: 069105	

DP Barcode: D277939

Reg. No. Or File Symbol: 777-68

Manufacturing-use [] OR

End-use Product [x]

Internet Address (URL) • <http://www.epa.gov>

Recycled/Recyclable • Printed with Vegetable Oil Based Inks on Recycled Paper (Minimum 25% Postconsumer)

Reviewed by: Chris Jiang Team: One, Date 10/18/01
Secondary Reviewer: Bob Quick *PM* Team: N/A, Date 10/25/2001
Branch: RASSB Team Leader: Winston Dang

DATA EVALUATION RECORD

STUDY TYPE: CSF
DP BARCODE: D277939
PC CODE: 069105
SUBMISSION CODE: S603461
CASE TYPE:/EPA File No: Registration/777-68
TEST MATERIAL: Alkyl (50% C₁₄, 40 % C₁₂, 10 % C₁₆) dimethyl benzyl ammonium chloride (0.28 %)
SPONSOR: Reckitt Benckiser Inc.
MRID#: N/A

DATA EVALUATION RECORD

BACKGROUND:

The registrant has submitted a package in support of an amendment to register an alternate formulation of a disinfectant wipe to be used in commercial, institutional, industrial and residential settings. The package contains a Confidential Statement of Formulas for an alternate formulation and a label.

FINDINGS:

1. The label of the product declares the formulation contains 0.28 % Alkyl (50% C₁₄, 40 % C₁₂, 10 % C₁₆) dimethyl benzyl ammonium chloride as the active ingredient.
2. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 8/27/01) is inconsistent with the concentration that is declared on the label.
3. The upper and lower certified limits for [REDACTED] should both be changed from [REDACTED] and from [REDACTED] respectively.
4. The percentages of the ingredients total 100.0.

RECOMMENDATIONS:

1. Risk Assessment and Science Support Branch finds this submission in support of registration for 777-68 to be unacceptable because of the inconsistency between the label and CSF with respect to the concentration of the active ingredient. The registrant must submit a new CSF that is consistent with the label to the Agency for review. On the resubmitted CSF, the registrant should also change the upper and lower certified limits for [REDACTED] from [REDACTED] and from [REDACTED].

Confidential Appendix:

DER Summary

cc: Chemfile: (069105)

INERT INGREDIENT INFORMATION IS NOT INCLUDED.