

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

October 5, 2001

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Spruce-Ups**

DP Barcode: 277151
Manufacturing-use [] OR

Reg. No. Or File Symbol: 5813-58
End-use Product [X]

TO: Velma Noble/Zenobia Jones
PM Team 31

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

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C) *Karen P. Hicks 10/9/01*

THRU: Michele E. Wingfield, Chief
Product Science Branch
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Product Formulation
Active Ingredient(s)

% by wt.

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chloride	0.145%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride	0.145%

BACKGROUND:

The registrant's consultant has submitted an application for an alternate formulation (A04) as an amendment to the registration of this cleaning and disinfecting wipe product. Two new

inert ingredients, [REDACTED] and [REDACTED], used as surfactants have been included in the new formulation. There were no other changes.

INERT INGREDIENT INFORMATION IS NOT INCLUDED
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FINDINGS:

1. The two new inert ingredients have not been approved for use in pesticides. Compositional data on these ingredients was not submitted in the data package, but was sent directly to the Registration Division for consideration. The consultant has been requested to re-submit that data directly to the Antimicrobial Division so that a Pesticide code can be requested by the normal protocol and processed in a timely manner. If these are truly "new inerts" it may require several months for approval to be granted, and additional data may be required from the suppliers.
2. The nominal concentrations of the active ingredients (0.145 %) for each of the two components) are not listed on the Confidential Statement of Formula. Certified upper and lower limits based on the nominal concentrations are listed, but they are wider than the Agency standard (+/- 10% of the nominal value if that amount is <1.0%) listed in 40 CFR, Part 175.158(b)(c).
3. The composition of the wipe material is not specified on the Confidential Statement of Formula, and there is no other designation on the suppliers' list. Based on a prior agreement between the registrant and the Agency, a variety of suppliers may be used, but all components in the wipe materials must have previously been approved for use. No wipe material will contain components that are not approved. A matrix for those suppliers and the components of the approved materials is attached to the Confidential Statement of Formula.

RECOMMENDATIONS:

1. The registrant, or the consultant, must ascertain that all compositional data on inert ingredients are submitted to the Antimicrobial Division for approval of new ingredients. Information sent directly to the Registration Division will not be processed unless accompanied by a Confidential Statement of Formula and a written request from the Product Science Branch of the Antimicrobial Division.
2. The certified limits of the active ingredient must be corrected to meet Agency standards.
3. The Confidential Statement of Formula, dated August 1, 2001 is unacceptable until all ingredients are approved for use, and a revised Confidential Statement of Formula with corrected certified limits is received and reviewed by the Agency.