UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 4, 2000

MEMORANDUM

Subject: Secondary Review of Contractor's (Oak Ridge National Lab) Efficacy and Label Review for "Spruce-Ups™" (EPA Reg. No. 5813-58)
DP Barcode: D268126
Case No.: 061904

From: Emily Mitchell, M.S., Team Leader *Emily Mitchell 12/6/00*
Efficacy Evaluation Team
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To: Velma Noblel, PM 31/Jacqueline Campbell
Regulatory Management Branch I
Antimicrobials Division (7510C)

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

Applicant: The Clorox Co.
Pleasanton, CA, USA

Formulation From Label:

Active Ingredient(s)	% by wt
n-Alkyl (C_{14}, 60%; C_{16}, 30%; C_{12}, 5%; C_{18}, 5%) dimethyl benzyl ammonium chloride	0.145%
n-Alkyl (C_{12}, 68%; C_{14}, 32%) dimethyl ethylbenzyl ammonium chlorides	0.145%
Inert Ingredient(s)	99.710%
Total	100.000%

SUMMARY OF INFORMATION REVIEWED AND FINDINGS/CONCLUSIONS:

Product manager has requested review of new labeling and 10 efficacy studies (MRID Nos. 451711-01 thru 451711-10) to amend product labeling changes that include the addition of new or revised efficacy claims and new directions for sanitization of the registered product Spruce-Ups ™ (EPA Reg. No. 5813-58). The Oak Ridge National Laboratory's efficacy reviews have undergone secondary review by AD/PSB/EET. The contractor's reviews reflect EPA's Pesticide Assessment Guideline requirements and regulations and the findings/conclusions are scientifically sound. The efficacy data submitted under MRID Nos. 451711-01 thru 451711-10 demonstrates the product's effectiveness as a disinfectant against *Listeria monocytogenes* (ATCC 19117), *Campylobacter jejuni* (ATCC 29428), *Streptococcus pyogenes* (ATCC 19615), *Escherichia coli* 0157:H:7 (ATCC 51657), *Pseudomonas aeruginosa* (ATCC 15442), *Klebsiella pneumoniae* (ATCC 4352), *Staphylococcus aureus* (ATCC 6538), Salmonella cholerasuis (ATCC 10707) when tested undiluted, in the presence of an organic soil load (5% fetal bovine serum) for 4 minutes. The efficacy data also demonstrated the product's effectiveness as a virucide against Influenza virus type A_2, (ATCC VR-544, Strain Hong Kong) and Rotavirus, Strain WA when tested undiluted, in the presence of an organic soil load (5% fetal bovine serum) for 4 minutes at 22±2°C. The efficacy data demonstrated the product's effectiveness as a non-food contact surface sanitizer. ~~However, the product was not tested on all surfaces claimed on label. The registrant must specify which sample is 60 days old. Three product samples, representing 3 different preparations, one of which is at least 60 days old, should be tested against each bacterium on each test surface. The test surfaces(s) represent the type(s) of surfaces recommended for treatment on the label including, but not limited to glass, metal, unglazed ceramic tile, porcelain, or vitreous china. All surfaces claimed for use sites on label must be tested.~~

LABELING:

1. Sanitizing claims must state for hard non-porous glass surfaces. Data was not submitted to support claims for other hard non-porous surfaces.

2. Change statement "can help reduce the risk of cross-contamination during flu season and travel" to read "can help reduce the risk of cross-contamination on treated surfaces during flu season and travel."

3. Under "DEODORIZATION", delete terms such as lamps, light switch panels, and cabinet handles."

4. Change the statement "quickly disinfects" to read "disinfects in 4 minutes."

5. Delete all claims pertaining to bacteria that can live and grow in the refrigerator. Data was not submitted to support these claims. This product can not be used for the inside of appliances. It can only be used to disinfectant the outside of appliances.

6. Clarify which surface areas around the toilet. The term toilet areas is too broad. Also specify not to be used inside the toilet bowl.

7. For kitchens, specify for use on non-food contact surfaces.