US ERA ARCHIVE DOCUMENT

AMENDMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION EFFICACY REVIEW

ANTIMICROBIAL PROGRAM BRANCH

IN 09/19/91 OUT 11/03/91

EPA Reg. No. No. or File Symbol 777-75
EPA Petition or EUP No. None
Date Division Received 02-07-91
Type Product Hospital Disinfectant/Household Laundry Sanitizer
MRID No (s) 415230-01 and 415230-02
Product Manager PM 32 (Douglas)
Product Name Barrage Pine Action Cleaner
Company Name Lehn & Fink Products
Submission Purpose Resubmission in response to Agency letter dated 4/16/90 with additional data/information and revised label with phrases "Fresh Pine Scent", "Hospital disinfectant", "Meets AOAC Standards", "New and Improved Barrage Pine Action Cleaner is now stronger than ever! It Kills household germs and cleans with a fresh pine scent!" and "contains no phosphates"
Type Formulation Liquid
Active Ingredient (s):%
Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides
Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides

Recommendations:

Efficacy Not supported By the Data

"Laundry Sanitizing Test Disinfectant TZ-1771-4 In the Presence of Organic Soil" by Joseph Rubino and Diane Albano, Lehn & Fink Products Group, Microbiology Laboratory, 225 Summit Avenue, Montvale, NJ 07645, dated 05-12-88 (MRID No. 415230-02)

Compatibility of the product with other laundry additives (e.g. soaps, detergents, bleach, starch, bluing, sours, fabric softeners) were not determined in the testing.

In the absence of this data, label should address non-compatibility of the product with other common laundry additives. Refer to DIS/TSS-13 enclosure, item (b).

Labeling:

The labeling submitted in connection with registration under the FIFRA Act, is not acceptable for the reasons given below. It should be corrected or amended in accordance with these comments and resubmitted in quintuplicate.

On the <u>Front of Label</u> change the product name from "BARRAGE PINE ACTION CLEANER" to read "BARRAGE PINE SCENT CLEANER" (Pine Oil is used for the purpose of pine scent in this formulation)

On the <u>Front of Label</u> change "MEETS AOAC STANDARDS" to read "MEETS AOAC USE-DILUTION TEST STANDARDS"

On the <u>Front of Label</u> delete the phrase "New and Improved!". The word "New" may be claimed only for a period of six months following approval of the label.

On the <u>Front of Label</u> delete the phrase "Now Stronger Than Ever"

On the <u>Back of Label</u> revise the statement "Barrage Pine Action Cleaner meets AOAC efficacy standards for hospital disinfectants" to read "Barrage Pine Scent Cleaner meets AOAC Use-Dilution efficacy test standards for hospital disinfectants"

On the <u>Back of Label</u> delete the phrase "NOW STRONGER THAN EVER!"

On the <u>Back of Label</u> delete the word "NEW". The word "New" may be claimed only for a period of six months following approval of the label.

On the <u>Back of Label</u> revise the statement "Kills household germs, athlete's foot fungus, dangerous Staphylococcus aureus and

Streptococcus faecalis germs, Pseudomonas aeruginosa, and prevents mold and mildew" to read "Kills household germs, athlete's foot fungus, Staphylococcus aureus, Streptococcus faecalis, Pseudomonas aeruginosa, and controls the growth of mold and mildew on hard, non-porous surfaces"

On the <u>Back of Label</u> revise the statement "...Herpes Simplex Type 1 and 2 on hard non-porous surfaces" to read "...Herpes simplex Type 1 and 2 on hard, non-porous, inanimate environmental surfaces"

There are two strains of "Influenza A2 (Japan)". Specify.

Specify Herpes simplex Type 1 strain.

Specify Herpes simplex Type 2 strain.

Under the heading "DISINFECTING/TO CONTROL MOLD AND MILDEW" include instructions to remove gross filth or heavy soil prior to application of the product.

Under the heading "DISINFECTING/TO CONTROL MOLD AND MILDEW" include the methods of application (e.g. "by sponge, mop, or spray" or "by immersion in the solution", followed by a statement such as "to wet all surfaces thoroughly"). The directions must also indicate if, and how, the product should be removed from the surfaces after the recommended exposure period.

Under the heading "DISINFECTING/TO CONTROL MOLD AND MILDEW" include the type of surfaces, objects, or items intended for treatment (e.g. floors, walls, bathrooms fixtures), in additions to any description of surface composition (e.g. stainless steel, chrome, glass, vinyl).

Under the heading "DISINFECTING/TO CONTROL MOLD AND MILDEW" include the statement "Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled"

Change "LAUNDRY" to read "HOUSEHOLD LAUNDRY"

Under the heading "LAUNDRY" include dosages for front-loading automatics (e.g. 8-10 gallon water capacity) and top-loading automatics and wringer-type washers (e.g. 12-15 gallon water capacity).

Under the heading "LAUNDRY" the directions for Pre-soaking must specify complete immersion in an adequate volume of soaking solution (at least 5:1 w/w solution to fabric ratio, e.g. half a washload in a 3-gallon pail) at the recommended use dilution for a specified contact time prior to the laundering operation.

Reviewed by Srinivas Gowda Date 11/03/91

3