

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB - 6 2002

Ruth Trager  
Manager, Regulatory Services  
H&S Chemicals Division  
c/o Lonza Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

Subject: SAK-64L Cleaner  
EPA Registration No: 47371-46  
Application Date: December 6, 2001  
Receipt Date: December 7, 2001

Dear Ms. Trager:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

- revised label language

**Conditions**

Delete the claims for "germs." Revise the label to state "With all the news about bacteria, just looking clean..." and "Kitchen floors collect both traffic dirt and odor causing bacteria." deleting the word "germs" from both statements. The term "germs" has been interpreted to be broader than non-public health organisms.

**General Comments**

We recognize that a claim of disinfectant level against odor causing bacteria has been allowed in the past. We are not asking that the claim on your label be revised at this time. There have been discussions regarding the acceptability of such claims under present day standards. The Agency's position is further articulated in the proposed antimicrobial rule (60 FR 50672) under section 156.443(b). This sections states that the Agency will consider a product to make public health claims if a claim is made for the product as a disinfectant regardless of the use site

**CONCURRENCES**

SYMBOL	TRC							
SURNAME	J. Trager							
DATE	2/6/02							

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or microorganism listed on the label. Again, this is only a proposed rule and the Agency is not requiring any change based on this rule.

Regarding data review, our Office of General Counsel has consistently informed us that anytime a change requiring data is made to a label data compensation is required. A change in signal word, as per your amendment of August 22, 2001, requires supporting data. Since your product is not eligible for the formulator's exemption, you must address both generic and product specific data. Our Office of General Counsel has also consistently informed us that the data required would be all of the data needed to support registration of the product. Thus from a product specific standpoint, this would include chemistry, acute toxicity and efficacy, if required. We could not find any data supporting the use of this product as a disinfectant and wanted to bring this to your attention. Such data could be required in the future.

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

7510C:T.Lantz:2/5/02:47371-46b

CONCURRENCES

SYMBOL								
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**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER:** Causes irreversible eye damage and skin irritation. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(Note to reviewer: If the container size is 5 gallons or larger, use the following Environmental Hazards Statements.)

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**SAK-64L CLEANER**

CLEANER, DEODORANT AND DISINFECTANT

Active Ingredient:

n-Alkyl (C<sub>14</sub>, 50%; C<sub>12</sub>, 40%; C<sub>16</sub>, 10%)

dimethyl benzyl ammonium chloride..... 2.84%

Inert Ingredients: ..... 97.16%

Total ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See side / back / right / left panel for Precautionary Statements and First Aid.

EPA Reg. No. 47371-46

EPA Est. No. (as indicated on the container)

NET CONTENTS (as indicated on the container)

H&S Chemicals Division  
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Fair Lawn, NJ 07410

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 06 2002

Under the Federal Insecticide  
Fungicide and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 47371-46

(Note to reviewer: The following is optional marketing language:)

- Is effective against odor-causing bacteria on hard, nonporous, environmental surfaces.
- Prevents mold and mildew.
- For use in the home, schools and colleges, day care facilities, office buildings and federally inspected meat and poultry plants.
- Big job(s) size
- dilutable
- fresh scent
- sunny citrus scent
- fresh lemon scent
- lemon power®
- citrus fresh scent
- clean citrus scent
- not just clean, microscopically clean
- cuts grease
- cleans & shines
- kills odor-causing bacteria (for the entire house).

With all the news about germs and bacteria, just looking clean isn't enough. SAK-64L Cleaner does it all - cleans, shines, disinfects, and deodorizes - for a complete clean.

Unlike ordinary cleaners and disinfectants, this advanced cleaner not only wipes out tough grease and grime; [plus] it kills odor-causing bacteria all around the house. There's nothing left behind but a brilliant, streak-free shine, plus a light fresh scent.

SAK-64L Cleaner brings a combination of powerful cleaners plus antibacterial disinfectants, so you can be sure your home is completely clean.

With this product, you can be sure your home doesn't just look clean, it's microscopically clean.

Cleans, deodorizes and disinfects with a streak-free shine and a light fresh scent.

Ideal for big jobs like tile or no-wax floors, pet areas, garbage cans, sinks, tubs, showers, countertops and appliances.

On finished wood or painted surfaces, spot test in a small inconspicuous area first. Letter Dated:

ACCEPTED

FEB 06 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

SAK-64L CLEANER  
EPA REG. NO. 47371-46  
EPA REVISED LABEL 12-6-01

47371-46

DILUTION: 1:64 2 oz. (¼ cup) per gallon of water

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**FOR DISINFECTING and DEODORIZING:** Apply use- solution to walls, floors, garbage cans and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, shower doors, door knobs, handles and sinks, with a cloth, mop or coarse mechanical spray device so as to thoroughly wet surfaces for a contact time of 10 minutes. For heavily soiled areas, a preliminary cleaning is required. Wipe or allow to air dry. Food contact surfaces must be thoroughly rinsed with potable water after disinfecting. Do not use this product to clean utensils, glassware and dishes. Prepare a fresh solution daily or more often if the use-solution becomes visibly dirty or diluted.

**KITCHENS:** Kitchen floors collect both traffic dirt and germs. Use ¼ cup per gallon of water, or full strength anywhere greasy dirt is a problem. Follow Disinfecting directions.

**BATHROOMS:** Great for cleaning and deodorizing basins, tubs and tiles. Leaves everything bright and clean. Kills odor-causing household bacteria. Odors disappear instantly. Use ¼ cup per gallon of water, or full strength where odors are a problem. Follow Disinfecting directions.

**TO CLEAN AND DISINFECTANT TOILET BOWLS:** Remove or expel over the inner trap the residual bowl water prior to applying solution. Remove heavy soil prior to disinfection. Use 3 ounces of concentrate in toilet bowl. Apply (squeeze) around bowl and under rim. Brush thoroughly over exposed surfaces and under rim with a cloth, mop, brush or sponge. Allow to stand for 10 minutes, then flush. When used as directed, this product will not harm white or colored bowls or inanimate, hard surfaces. Close cap on container after use.

**FOR CLEAN, FRESH, HYGIENIC LAUNDRY / DIAPERS:** For extra cleaning power plus deodorizing action, add ½ cup to regular soap or detergent. Make laundry fresh and odor free; especially good for grimy work clothes. For stubborn stains and spots, pre-dampen with full strength before adding to wash load. To kill odor-causing bacteria in diapers, presoak in ½ cup per gallon of water.

**MILDEWSTATIC INSTRUCTIONS:** Will effectively inhibit the growth mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors and table tops. Apply solution of ¼ cup to 1 gallon of water with a mop, cloth or sponge, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears.

**FOR USE IN FEDERALLY INSPECTED MEAT AND POULTRY PLANTS** as a general cleaning agent on all surfaces, or for use with steam or mechanical cleaning device in all departments. Before use of this compound, food products and packaging materials must be removed from the room or carefully protected. After use of this compound, all surfaces in the area must be thoroughly rinsed with potable water.

*(Note to reviewer: The following statement to be used when applicable:)*  
Bottle made of 25% Post-Consumer recycled plastic.

*(Note to reviewer: If the container size is one gallon or less, the following Storage and Disposal Statements will be used:)*

**STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

*(Note to reviewer: If the container size is greater than one gallon, the following Storage and Disposal Statements will be used:)*

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal.

**PESTICIDE STORAGE**

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

**PESTICIDE DISPOSAL**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL**

*(PLASTIC CONTAINERS:)* Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

*(FIBER DRUMS WITH LINERS:)* Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner

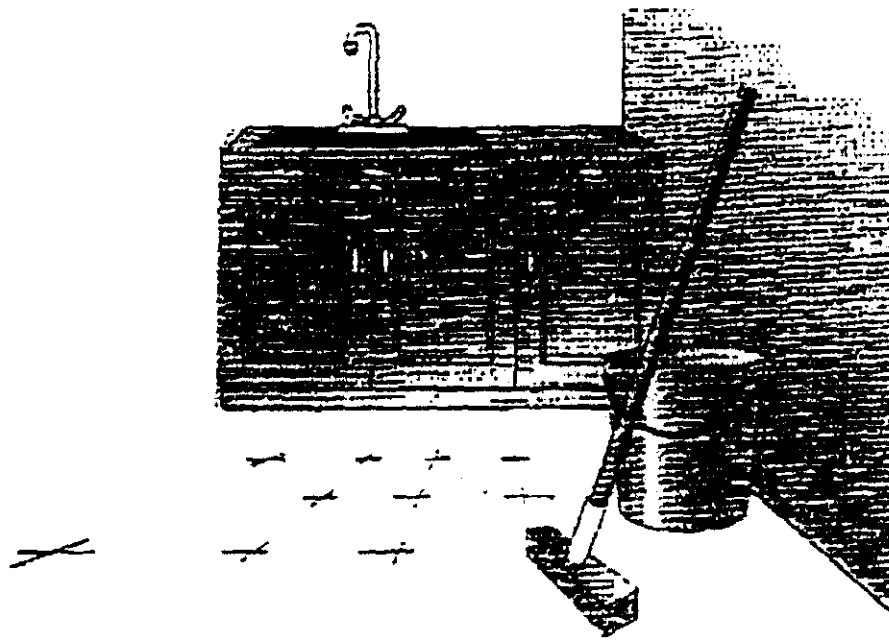
*(METAL CONTAINERS:)* Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures approved by state and local authorities.

**GENERAL:** Consult Federal, state or local authorities for approved alternative procedures such as limited open burning.

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