

NOV 21 1994

Genlabs
5568 Schaefer Avenue
Chino, CA 91710

Attention: Robert Munion
Vice President

Subject: Strike Bac Step One Disinfectant
EPA Registration No. 37265-37
MOU Compliance Amendment dated September 6, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes listed below before you release the product for shipping bearing the amended label.

1. After "DIRECTIONS FOR USE", remove the wording "GENERAL CLASSIFICATION".
2. Under "DIRECTIONS FOR USE", revise the statement: "This product is not to be used as a terminal sterilant/high-leveling disinfectant..." to read, "This product is not to be used as a terminal sterilant/high-level disinfectant..."

A stamped copy of the labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

STRIKE BAC® STEP ONE DISINFECTANT

Disinfectant-Cleaner-Sanitizier-Fungicide-
Mildewstat-Virucide-Deodorizier with Organic Soil Tolerance for
Hospitals, Institutions and Industrial Use

ACTIVE INGREDIENTS:

Octyl Decyl Dimethyl Ammonium Chloride.....	1.14%
Diocetyl Dimethyl Ammonium Chloride.....	0.57%
Didecyl Dimethyl Ammonium Chloride.....	0.57%
Alkyl (C14 50%, C12 40%, C16 10%)	
Dimethyl Benzyl Ammonium Chloride.....	1.52%
INERT INGREDIENTS:.....	96.20%
TOTAL:.....	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

Statement of Practical Treatment in case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call physician immediately.

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

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

E.P.A. EST. NO. 37265-CA-01

EPA REG. NO. 37265-37

Manufactured By: Genlabs

5568 Schaefer Ave., Chino, CA 91710 • (909) 591-8451

NET ONE GALLON (3.78 LITERS)

Strike Bac Step One Disinfectant has been formulated to aid in the reduction of cross-contamination in institutions, schools and hospitals.

Strike Bac Step One Disinfectant cleaner is effective against a broad spectrum of bacteria, is virucidal, fungicidal, and will prevent the growth of mold and mildew and their odors when used as directed. Strike Bac Step One Disinfectant is an effective one step sanitizer-cleaner for use on non-food contact surfaces.

When used as directed, Strike Bac One Step Disinfectant will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacteria growth can cause mal odors.

Precautionary Statements Hazardous to Human and Domestic Animals

DANGER

Keep out of reach of children. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Avoid contamination of food.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place away from any moisture or direct sunlight. Do not stack over 4 cases high. Open containers carefully followed by immediate closure once diluted. If leaked or spilled, soak up material separate and away from other pesticides, fertilizer, food and feed.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Pesticide, spray mixture, or rinse water that cannot be used according to Federal or approved State procedures under subtitle C of the Resource Conservation and Recovery Act. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Do not reuse empty container. Plastic Containers: Triple rinse (or equivalent) then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities. If burned, stay away from smoke.

Directions For Use GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is not to be used as a terminal sterilant/high-leveling disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membrane; but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 21 1994

BEST AVAILABLE COPY

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

37265-37

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

Strike Bac Step One Disinfectant is a proven one-step cleaner-disinfectant-sanitizer-fungicide-mildewstatic-virucide in the presence of moderate amounts of organic soil.

Apply Strike Bac Step One Disinfectant to walls, floors and other hard (inanimate) non-porous surface such as tables, chairs, countertops, sinks and bedframes with a cloth, mop, or mechanical spray device so as to thoroughly wet all surfaces. For heavily soiled areas a primary cleaning is required. Prepare a fresh solution daily, or when solution becomes visibly dirty.

Disinfection: To disinfect hard, non-porous surface in hospitals, add 2 ounces per gallon of water. Treated surfaces must remain wet for 10 minutes. At this use-level, Strike Bac Step One Disinfectant is also virucidal, fungicidal, and mildewstatic. At 1 ounce per gallon Strike Bac Step One Disinfectant will disinfect hard non-porous surfaces in schools, industry and non-medical institutions.

Sanitizing: To sanitize porous or non-porous, non-food contact surface, add 1/2 ounce per gallon of water. Treated surfaces must remain wet for 60 seconds.

For Hospitals and nursing homes: Add 2 oz. per gallon of water. The broad spectrum of Strike Bac Step One Disinfectant has been evaluated in the presence of 5% serum and found to be effective against the following organisms by the AOAC Use-Dilution test:

Pseudomonas aeruginosa-Escherichia Coli-Enterobacter Aeregebes-Shigella Dysenteriae
Staphylococcus Aureus-Serratia Marcescens-Salmonella Schottmuelleri

Brevibacterium Ammonigenes-Salmonella Choleraesuis-Klebsiella Pneumoniae-Streptococcus Faecalis
AOAC Fungicidal Test

Strike Bac Step One Disinfectant at one ounce per gallon is effective fungicide against Trichophyton Mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, etc.

Mold and Mildew Control

At 1/2 oz. per gallon Strike Bac Step One Disinfectant will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces (as indicated in general instructions above). Allow to dry on surface and repeat when mildew growth returns.

Virucidal Performances

*At 1 oz. per gallon use-level Strike Bac Step One Disinfectant was evaluated in the presence of 5% serum and found to be effective against influenza A-Brazil Virus on manmade environmental surfaces.

For schools, non-medical institutional and industrial surfaces (such as floors, walls, tables, etc.)

At 1 oz. per gallon of water Strike Bac Step One Disinfectant is an effective sanitizer against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on porous and non-porous environmental surfaces.

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