

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 5 1997

Alcide Corporation
8561 154th Avenue, NE
Redmond, Washington 98052

Attention: David R. Joy
Regulatory Counsel

Subject: Exspor 4:1:1 Sterilant-Disinfectant
EPA Registration Number 45631-03
Your Amendment Dated August 4, 1997

This is in response to your amendment on the above product to revise the product labeling by removing reference to technical bulletin and modifying the directions for use.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comment listed below.

Place the heading "Precautionary Statements" above the phrase "Hazards to Humans" and revise "Hazards to Humans" to read: "Hazards to Humans and Domestic Animals".

A stamped copy is enclosed for your records. Submit one copy of the final printed label before you release the product for shipment bearing the amended label.

If you have any questions concerning this letter, please contact Delores Williams at (703) 308-6372.

Sincerely,



Robert S. Brennis
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7504C)

CONCURRENCES

| SYMBOL | | | | | | | |
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| SURNAME | | | | | | | |
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EXSPOR BASE LABEL - FRONT PANEL

Alcide® Brand EXSPOR®

Part 1

Base Concentrate

4:1:1 Sterilant-Disinfectant

The 3-Minute System for Controlling Cross-Contamination from Treated Hard, Non-Porous Inanimate Surfaces

For use with EXSPOR® Activator Concentrate (Part 2)

Bactericidal - Virucidal - Fungicidal - Tuberculocidal - Pseudomonacidal - Sporocidal

Disinfecting level - Kills all bacteria including *Pseudomonas aeruginosa* and *Mycobacterium* sp., pathogenic fungi and viruses*+ on hard, non-porous environmental surfaces in 3 minutes (SEE DIRECTIONS FOR USE).

Sterilizes laboratory equipment and other non-medical immersible items in 10 hours at 20°C. (See directions for use. See side panel for precautionary information.)

*Kills Influenza Virus Type A2 (Hong Kong); Herpes Simplex Virus Types 1 and 2; Poliovirus Type 1; Coxsackievirus; Adenovirus Type 2; Echovirus Type 2; Vaccinia Virus and Vesicular Stomatitis Virus (VSV).

+Currently, there is no established test for hepatitis viruses.

| | |
|-------------------------------------|---------------|
| Active Ingredients: Sodium Chlorite | 1.52% |
| Inert Ingredients: | <u>98.48%</u> |
| TOTAL: | 100.00% |

Keep Out of Reach of Children
CAUTION — See Side Panel
For Additional Precautionary Statements

Contents: 1 Gallon (3.785 Liters)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 5 1997

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

45631-3

CAUTION

This product is not to be used as a terminal sterilant/high level 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 membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

HAZARDS TO HUMANS:

CAUTION

Harmful if absorbed through the skin.
Causes eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

FIRST AID

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush with plenty of water. Call a physician if irritation persists.

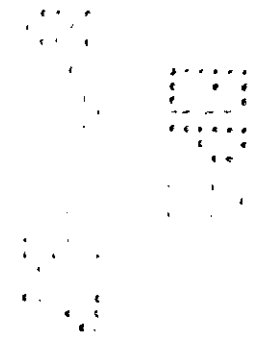
OTHER PRECAUTIONS

Use of mixed solutions in a confined or large volume area may lead to respiratory irritation. If irritation occurs, leave the area immediately, and seek medical attention if irritation persists.

U.S. Patent No. Re. 31,779
Foreign Patents

EPA Reg. No. 45631-03
EPA Est. No. 035-347-CA-001

Alcide Corporation
Redmond, Washington 98052



EXSPOR BASE LABEL - BACK PANEL

Alcide® Brand EXSPOR®

Part 1

Base Concentrate

4:1:1 Sterilant-Disinfectant

EXSPOR Sterilant-Disinfectant is recommended for use as a disinfectant in schools, hospitals, medical, dental, industrial and institutional facilities to control human health-related microorganisms on hard, non-porous environmental surfaces and for sterilizing laboratory and other non-medical immersible items.

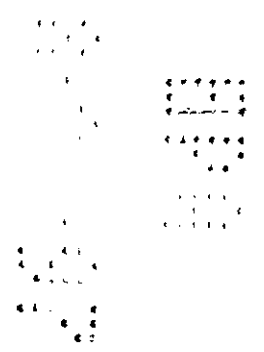
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with the labeling. USE IN A WELL-VENTILATED AREA. AVOID BREATHING FUMES. Base Concentrate must be diluted with water prior to adding Activator Concentrate. Improper preparation can result in excessive generation of chlorine dioxide fumes.

PREPARATION:

1. Measure 1 part EXSPOR Base Concentrate (Part 1) into a clean, empty, NON-METALLIC container.
2. Add 4 parts cool tap water (at or below 25°C).
3. Add 1 part EXSPOR Activator Concentrate (Part 2) and stir.

The final solution should appear colorless or pale yellow. Variations in local water hardness may result in dark color and/or strong odor. Deionized or distilled water may be substituted to minimize these effects.



EXSPOR BASE LABEL - BACK PANEL (CONT'D)**STERILIZATION OF LABORATORY AND OTHER NON-MEDICAL EQUIPMENT:**

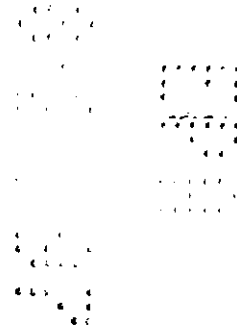
Prepare EXSPOR solution as described above.

Moderate amounts of organic load, such as soil, will not lower the efficacy of EXSPOR solutions. However, to ensure best results, surfaces should be rinsed and, if possible, equipment dismantled and rinsed free of heavy soil and gross debris. Hollow objects must be flushed and filled.

Immerse equipment for a minimum of 10 hours at 20°C to destroy resistant pathogenic spores as represented by *Clostridium Sporogenes* and *Bacillus subtilis*.

Remove equipment from Exspor solution using sterile technique and rinse thoroughly with sterile water prior to drying

Mix and use right away; do not reuse. Discard solution after each use.



EXSPOR BASE LABEL - BACK PANEL (CONT'D)

DISINFECTION:

Prepare EXSPOR solution as described above. Disinfection is not affected by water hardness up to 400 ppm (calculated as CaCO₃).

Discard used solution after each use and mixed, unused solution within 24 hours. Although efficacy at a 30-second contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms.

EXSPOR solution will inactivate bacteria (including M. tuberculosis), fungi and viruses in 3 minutes at 20°C.

Soaking is the best method of application. However, the solution may be sprayed or wiped on by any convenient means (mop, cloth, sponge, etc.). The surface should be thoroughly wet with solution. To minimize potential for oxidation or corrosion, a contact time of 3 minutes on metal surfaces or equipment should be exceeded.

NOTE: EXSPOR solution may be safely used on most plastics, ceramic, and glass. Never soak items in metal vessels. Prolonged or repeated exposure will oxidize metals, including aluminum and stainless steel. Do not use on copper, brass or bronze. Do not apply to surfaces containing residues from bleach, strong acids, or other chemicals, without first rinsing surface thoroughly with water.

Ventilation: Always use in a well-ventilated area. Avoid breathing fumes. When used in a confined or large-volume area, the quality of chlorine dioxide in the air may exceed OSHA Permissible Exposure Limits (PEL's) and may require respiratory protection. Limits are defined as 0.1 ppm for an 8-hour time weighted average, and 0.3 ppm for a 15-minute short term exposure limit (29 CFR Part 1910.134 and Section 1910.1000, Air Contaminants, Table Z-1). Personnel should contact their resident safety officer or Alcide Corporation for information on appropriate protective gear when such application is undertaken.

STORAGE AND DISPOSAL

Store unmixed concentrates in a cool, dark, dry place in the original containers. Always replace covers. Keep upright. Thoroughly wash empty concentrate containers with water and discard in a safe place. Do not reuse containers. Used and outdated EXSPOR solution may be flushed down the drain.

See Part 2 Activator Concentrate Label for Warranty Limitation and Disclaimer.

