

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NCH Corporation
2730 Carl Road
Irving, TX 75062

APR 16 2001

Subject: Chemene-X
EPA Registration No. 1769-227
Amendment Date: 2/22/01
EPA Receive Date: 3/01/01

Attention: Ms. Lisa Boynton

The amendment, referenced above, submitted in connection with registration under FIFRA, as amended, to update the label according to PR Notice 2001-1 and the July 1, 1999 Agency letter is acceptable provided you address the following comments before this product is release for shipment.

1. Under the "Disinfection" directions, you must indicate whether the surfaces should air dry or be wiped after the contact time.
2. The "Storage and Disposal" instructions for containers one gallon or less should be revised to reflect the following:

Storage and Disposal

Keep container closed when not in use. Store in original container in a cool, dry area inaccessible to children and pets. Do not reuse empty container. Securely wrap original container in several layers of newspaper and discard in the trash.

3. According to records on file for this product, the data requirements for this product were supported by citing BTC 2125M 10% data, a substantially similar product. The following "Precautionary Statements" revisions are based on cited product's acute toxicology profile.

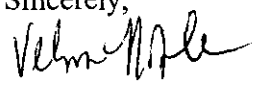
Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles/faceshield), protective clothing, and rubber gloves. Harmful if swallowed. Do not breath spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

CONCURRENCES

SYMBOL	2570C						
SURNAME	McFarlane						
DATE	4/16/01						

A stamped label is enclosed for your records. Submit one (1) copy of the final printed label prior to the release of this product for shipment. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

CHEMENE-X™

- ◆ Antimicrobial
- ◆ Disinfectant
- ◆ Sanitizer
- ◆ Deodorant

ACTIVE INGREDIENTS

n-alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl benzyl ammonium chlorides.....5.0%
 n-alkyl (68% C₁₂, 32% C₁₄) dimethyl ethylbenzyl ammonium chlorides.....5.0%

OTHER INGREDIENTS.....90.0%
TOTAL.....100.0%

(for 1 gallon containers)
 NET CONTENTS: 1 gallon/3.78 liters

(for 2 gallon containers and larger)
 NET CONTENTS: _____

KEEP OUT OF REACH OF CHILDREN

DANGER

(See side panels for additional precautionary statements.)

EPA REG. NO. 1769-227
 EPA Est. No. 4140 -
 CA-1 IN-1 NJ-1 PR-1 TX-1 TX-2

ACCEPTED
 with DISINFECTANTS
 in EPA Form 600-1-01

APR 16 2001

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

DIRECTIONS FOR USE

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 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.

GENERAL DISINFECTION OF HARD NON-POROUS ENVIRONMENTAL SURFACES AND OBJECTS SUCH AS FLOORS, WALLS, FURNITURE AND FIXTURES IN HOSPITAL ROOMS AND WARDS, OPERATING ROOMS, CORRIDORS, LAVATORIES FOR WASH BASINS, URINALS AND FLOORS AND SIMILAR AREAS IN SCHOOLS, MOTELS, HOTELS AND OTHER PUBLIC BUILDINGS:

CLEANING: Surfaces and objects must be thoroughly cleaned with a suitable detergent before application of this disinfectant.

DISINFECTION: To the clean surface, apply a solution of 3.5 ounces of CHEMENE-X in 5 gallons of water by mopping, swabbing or wiping on the surface. Contact time for disinfection should be at least 10 minutes. Effective against *Pseudomonas aeruginosa*.

FOR ROOM FOGGING: Do not use in food contact areas. To minimize the danger of cross-contamination to maintenance personnel, apply a solution of CHEMENE-X as a fog, as described below, before applying standard routine terminal cleaning and disinfecting practices.

1. Remove all human, animal and plant life from the room.
2. Open closet doors and drawers. Seal heating and air conditioning ducts.
3. Set up a 34-inch-high, 3-rpm revolving platform in the center of the room.
4. Mount an AEROFOG 300 generator, or other fogging device delivering an equivalent spray.
5. Fill the fogger reservoir with a solution of 1.5 ounces of CHEMENE-X in 1 gallon of water (1150 ppm active ingredients).
6. Set the fogger to deliver 1 gallon of solution in 15 minutes.

ACCEPTED
with COMMENTS
in EPA Better Dated:

- 7. Fog for 15 minutes for an average 2100 cubic foot room. For different room sizes, vary the fogging proportionately to achieve complete wetting of exposed surfaces.
- 8. Wait 2 hours before entering the room after treatment.
- 9. Rinse the fogging equipment thoroughly with clear water following use.

APR 16 2001
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

SANITIZING GLASSWARE, SILVERWARE, DISHES AND COOKING UTENSILS

- 1. Scrape and pre-wash utensils and glassware whenever possible.
 - 2. Wash with a good detergent or compatible cleaner.
 - 3. Rinse with clean water.
 - 4. Sanitize in a solution of 1 ounce of CHEMENE-X to 4 gallons of water (200 ppm). Immerse all utensils for at least 2 minutes or the contact time specified by the governing sanitary code.
 - 5. Place sanitized utensils on a rack or drainboard to air dry. A potable water rinse is not required.
- A solution of 1 ounce of CHEMENE-X to 4 gallons of water is effective up to 750 ppm hardness.

SANITIZING DAIRY EQUIPMENT: Remove all gross food particles by pre-cleaning or pre-scraping. Clean with a good detergent or other compatible cleaner and rinse the equipment thoroughly with potable water. Then apply a solution of 1 ounce of CHEMENE-X in 4 gallons of water (200 ppm) by flooding the surface, mopping or wiping on. The solution should remain in contact with the surface for at least 1 minute. Drain the solution from the surface and allow to air dry. No rinse is required.

SANITIZING EQUIPMENT IN FOOD PROCESSING AND MEAT PACKING PLANTS: Remove all gross food particles by pre-cleaning or pre-scraping. Clean with a good detergent or other compatible cleaner and rinse the equipment thoroughly with potable water. Then apply a solution of 1 ounce of CHEMENE-X in 4 gallons of water (200 ppm) by flooding the surface, mopping or wiping on. The solution should remain in contact with the surface for at least 1 minute. Drain the solution from the surface and allow to air dry. No rinse is required.

LAUNDRY RINSE SANITIZER: Add 3.5 ounces of CHEMENE-X per 100 pounds of laundry in no more than 50 gallons of final rinse water. This will impart residual bacteriostatic properties to treated fabric such as bed linens, diapers and blankets.

(for 1 gallon containers)

STORAGE AND DISPOSAL

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

STORAGE: KEEP CONTAINER CLOSED. Store in the original container in a cool, dry area inaccessible to children and pets.

PESTICIDE DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash.

CONTAINER DISPOSAL

PLASTIC CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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

(for 2 gallon containers and larger)

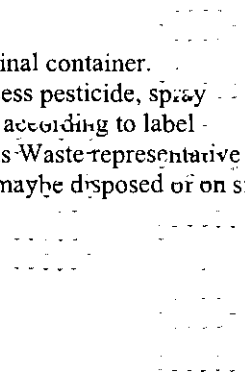
STORAGE AND DISPOSAL

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

STORAGE: Keep the container closed when not in use. Store in a cool, dry area in the original container.

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 instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional office for guidance. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL



676

Seattle-Atlanta-Honolulu
© 2001 NCH Corporation
www.chemsearch.com

TO REORDER
Call TOLL-FREE: 1-800-527-9921
FAX: 1-800-456-0010



ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 16 2001

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

Faint, illegible text at the bottom right of the page, possibly a routing slip or signature area.