

NOV 13 1997

Amuchina
 200 Orchard Ridge Drive
 Suite 220
 Gaithersburg, MD 20878

Attention: Adrian D. Ferguson
 Regulatory Affairs Manager

Subject: Amuchina
 EPA Registration Number 65787-1
 Your Submission Dated October 15, 1997

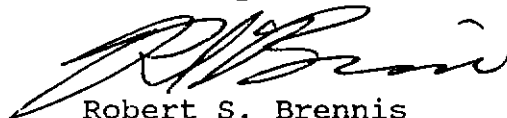
The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you make the labeling change listed below before you release the product for shipment bearing the amended labeling.

Revise the Dialysis "Use Directions" to reflect the available chlorine level at 600 ppm per the Sodium Hypochlorite Standard. It appears that a six percent solution should be indicated for this use.

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 me at (703) 308-6264.

Sincerely,



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

Enclosure

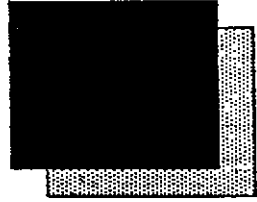
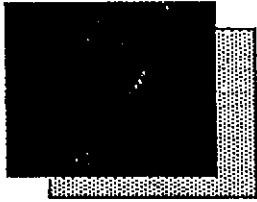
CONCURRENCES

SYMBOL	SURNAME	DATE					

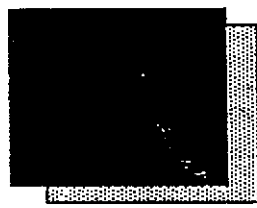
294

FRONT LABEL

GENERAL PURPOSE HOSPITAL DISINFECTANT



AMUCHINA



- pseudomonacidal
- staphylocidal
- salmonellacidal
- virucidal*
- tuberculocidal

*Kills HIV (AIDS virus) and Herpes simplex on pre-cleaned enviromental surfaces

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 13 1997

EPA Reg. No. 65787-1

EPA Est. No. 65787/ITA/001

Active Ingredient:
Sodium Hypochlorite
Inert Ingredients:
TOTAL

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No
1.02%
98.98% 65787-1
100.00%

Keep Out of Reach of Children
CAUTION

See back panel for complete precautions

Distributed by: Amuchina International Inc
200 Orchard Ridge Drive
Gaithersburg, MD 20878

Manufactured by: Amuchina S.P.A.
Casella, Genova
ITALY

Net Content: 170 oz. (5 liters)

BACK LABEL

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

PREPARATION OF USE DILUTION - To Prepare Dilutions of Amuchina*

<u>Concentration</u>	<u>mL of Amuchina</u>	<u>mL of Deionized or Distilled Water</u>	<u>ppm Available Chlorine</u>
2%	2	98	200
3%	3	97	300
5%	5	95	500
10%	10	90	1000

* Initial concentration of Amuchina is 1.02% or 10,000 ppm available chlorine

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES/OBJECTS SOILED WITH BLOOD OR BODY FLUIDS

*AMUCHINA Kills HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks or eye coverings. **CLEANING PROCEDURE:** Blood and other fluids should be thoroughly cleaned from surfaces and objects before application of the product. **DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal. **CONTACT TIME:** Leave surfaces wet for 30 seconds. This contact time will not control other types of bacteria.

DISINFECTION: Amuchina can be used in hospitals, nursing homes, daycare centers, schools and homes to disinfect instruments or devices prior to sterilization. floors, walls, medical equipment surfaces or other non-porous surfaces composed of glass, vinyl and stainless steel, teflon, plastics and other materials. Amuchina is a bactericidal germicide active against many pathogenic bacteria on inanimate non-porous surfaces that have been previously cleaned. Blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection. Amuchina will destroy vegetative microorganisms including *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* on inanimate non-porous surfaces at 3% in 15 minutes. The 3% dilution is virucidal against Herpes simplex-1 and Human Immunodeficiency Virus (HIV-1) in 15 minutes. The 5% use dilution is fungicidal against *Tricophyton mentagrophytes* in 15 minutes. When tuberculocidal activity is required, blood and other fluids should be thoroughly cleaned from surfaces and objects before use the 10% dilution for 25 minutes at 25°C (97°F).

USE ON NON-POROUS FOOD CONTACT SURFACES: Amuchina may be used on pre-cleaned food contact surfaces as a sanitizing rinse or as a disinfectant. A 2% solution of Amuchina is an effective sanitizing rinse against *Salmonella typhi* and *Staphylococcus aureus* in one minute at 20°C. A 5% solution of Amuchina is effective against these organisms in 1 minute at 20°C. The surfaces exposed to a 5% solution must be rinsed with potable water after use of Amuchina. A 3% solution of Amuchina may also be used as a disinfectant for Pre-cleaned food contact surfaces if applied to the surface for 15 minutes at 20°C. The surface must be rinsed with potable water after application of Amuchina, 3%.

CLEANING: Surfaces to be treated with Amuchina must be thoroughly rinsed and cleaned prior to its use. For Food Contact Surfaces: all equipment should be cleaned to remove gross food particles and soil using pre-flush, pre-scrape or pre-soak, if necessary. Surfaces or objects should be cleaned with a detergent or cleaner followed by a potable water rinse before application of Amuchina.

USE \ APPLICATION: Apply appropriate concentration with a thoroughly wet mop, cloth or sponge. Spread on surface and allow to remain wet for the indicated time. Remove excess fluid with sponge or cloth, if necessary, before rinsing.

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DIALYSIS: Amuchina may be used undiluted for routine sanitization of dialysis machines. Follow the machine supplier's instruction manual to sanitize the machine. Usually Amuchina is automatically proportioned (diluted) to a 3% solution in the hemodialysis machine during the process. This product is recommended for decontaminating single and multi-patient hemodialysate delivery systems. This process requires a minimum 20-minute contact time for efficacy at room temperature. After treatment, Amuchina must be rinsed from the machine, following the rinsing instructions included in the supplier's instruction manual. This product has been shown to be effective when tested by AOAC and EPA test methods. This product may not totally eliminate all vegetative microorganisms in hemodialysate delivery systems due to their construction and/or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. This product should be used in a treatment program which includes bacteriological monitoring of the hemodialysate delivery system. This product is NOT recommended for use in hemodialysate or reverse osmosis (RO) membranes. 25ml of Amuchina introduced into the peritoneal dialysis sets, disinfects potentially contaminated peritoneal effluent before disposal.

PRECAUTIONARY STATEMENTS :

CAUTION. Hazardous to humans and domestic animals. Causes eye and skin irritation. Harmful if swallowed.

STORAGE AND DISPOSAL

STATEMENT OF PRACTICAL TREATMENT

1. Keep out of direct sunlight.
2. Store upright in original closed container
3. Stable for 5 years when stored in original container.
4. Do not reuse empty container. Rinse and deposit in trash.

Eyes: Flush with plenty of water and get medical attention.
Ingestion: If swallowed, drink large quantities of water. Do not give vinegar or other acids. Do not induce vomiting. Get prompt medical attention

Lot #:
Expiration Date: