

65787-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FILE COPY

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 6, 2011

Jeff Jones
Agent, Alcavis HDC, LLC
C/o Delta Analytical Corporation
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: Amuchina
EPA Reg.#: 65787-1
Amendment Date: March 25, 2011
Receipt Date: March 30, 2011

Dear Mr. Jones:

This acknowledges the receipt of your letter of March 25, 2011, in response to the Agency Letter dated December 9, 2010, regarding the label amendment for Amuchina, EPA Reg# 65787-1.

Proposed Amendment:

Label corrections made for "FIRST AID", "PRECAUTIONARY STATEMENTS", "DIRECTIONS FOR USE", and "STORAGE DISPOSAL" statements, are acceptable.

General Comments:

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

If you have any questions on this letter, please contact David Liem at 703-305-1284 or by email at liem.david@epa.gov

Sincerely

Wanda Y. Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobial Division (7510P)

AMUCHINA

[GENERAL PURPOSE HOSPITAL DISINFECTANT]
[HOSPITAL CLEANING DISINFECTANT]

- **pseudomonacidal**
- **salmonellacidal**
- **staphylocidal**
- **virucidal***
- **tuberculocidal**

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

Active Ingredient:

Sodium Hypochlorite.....	1.02%
Other Ingredients:	<u>98.98%</u>
TOTAL	100.00%

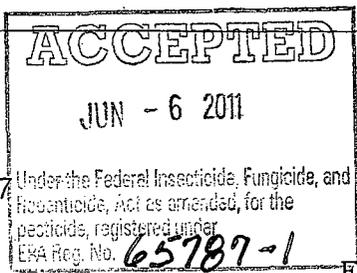
Keep Out of Reach of Children

CAUTION

See back panel for complete precautions

FIRST AID	
If in Eyes:	<ul style="list-style-type: none"> 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. Call a poison control center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none"> 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If on Skin or Clothing:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of emergency, call poison control center 1-800-222-1222 for treatment advice.</p>	

Distributed by:
Alcavis HDC, LLC
8322 Helgerman Court
Gaithersburg, MD 20877



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

EPA Reg. No. 65787-I

EPA Est. No. 65787-ITA-001

Net Content: 170 oz. (5 liters)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye irritation. May cause skin irritation. Harmful if swallowed. Avoid contact with eyes, skin and clothing. When handling the product, wear goggles, or face shield and rubber gloves. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Avoid breathing vapors. Vacate poorly ventilated areas as soon as possible. Do not return until strong odors have dissipated.

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*

Concentration	mL of Amuchina	mL of Deionized or Distilled Water	ppm Available Chlorine
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 or 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 *Trichophyton 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.

DIALYSIS: Amuchina may be used undiluted for routine sanitization of dialysis machines. Follow the machine supplier's instruction manual to perform disinfection. Usually Amuchina is automatically proportioned (diluted) to a 3% solution in the hemodialysis machine during the disinfection 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 disinfection, 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 an effective disinfectant 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 disinfection program which includes bacteriological monitoring of the hemodialysate delivery system. This product is NOT recommended for use in hemodialysate or reverse osmosis (RO) membranes. 25 ml of Amuchina introduced into the peritoneal dialysis sets, disinfects potentially contaminated peritoneal effluent before disposal.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

Pesticide Disposal: Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer.

Container Handling and Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or place in trash collection.

[Batch #]