

PM-32

Reg # 65787-1

104

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75767) WASHINGTON, DC 20460	EPA REGISTRATION NO. 65787-1	DATE OF ISSUANCE MAR 31 1995
	TERM OF ISSUANCE	
NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION <i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i>	NAME OF PESTICIDE PRODUCT Amuchina	

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Amuchina International Inc.
 200 Orchard Ridge Drive, Suite 220
 Gaithersburg, MD 20878

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Add the phrase, "EPA Registration No. 65787-1" to your label before you release the product for shipment.
3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
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294

A stamped copy of the label is enclosed for your records.

Sincerely,



Ruth G. Douglas
Product Manager 32
Antimicrobial Program Branch
Registration Division (7505C)

Enclosures

374

Hospital Cleaner / Disinfectant

AMUCHINA

* pseudomonacidal
* staphylocidal

* salmonellacidal
* virucidal

* tuberculocidal

EPA Reg. No. 000.000/00

Active Ingredient:
Sodium Hypochlorite
Inert Ingredients:
TOTAL

EPA Est. No 000.000/00

1.02%
98.98%
100.00%

Available Chlorine 0.97% w/w

Keep Out of Reach of Children
CAUTION

See back panel for complete precautions

Distributed by:
Amuchina International Inc.
200 Orchard Ridge Drive
Suite 220
Gaithersburg, MD 20878

Manufactured by:
Amuchina S.p.A.
Via Pontasso
Casella, Genova
ITALY

Net Content: 170 oz. (5 liters)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 31 1995

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

77321

4

PAGE 02

AMUCHINA INT. INC.

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484

BEST COPY AVAILABLE

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 into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate prior to sterilization or high level disinfection.

PREPARATION OF USE DILUTION

Add 3 ml of Amuchina to 97 ml of distilled or deionized water in an appropriate container (polyethylene). This use dilution when diluted as directed. Amuchina is a potent bactericidal germicide active against many pathogenic bacteria.

DISINFECTION

AMUCHINA will destroy vegetative microorganisms including *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *S. aureus* surfaces in 15 minutes. It is virucidal against Herpes simplex and Human Immunodeficiency Virus (AIDS Virus) after 15 minutes after 25 minutes.

CLEANING

Amuchina is an effective cleaner at its use dilution.

HEMODIALYSIS

Amuchina may be used undiluted for routine disinfection of dialysis machines. When used in this manner, the AMUCHINA provide a 3 percent solution by the hemodialysis machine during the disinfection process.

This product is recommended for decontaminating single and multi patient hemodialysis systems. This product has been tested (virucide, fungicide, bactericide, pseudomonicide) when tested by AOAC and EPA test methods. This product may not kill microorganisms in hemodialysis delivery systems due to their construction and/or assembly, but can be relied upon to meet acceptable levels when used as directed. This product should be used in a disinfectant program which includes bactericidal delivery system. This product is NOT recommended for use in hemodialysis or reverse osmosis (RO) membranes.

This product degrades with age. Use a chlorine test kit and increase dosage, as necessary, to obtain the required level of disinfection.

STORAGE AND DISPOSAL

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS
CAUTION: Causes eye and skin irritation. Harmful if swallowed.

lot:
Expiration date:

STATEMENTS

Eyes: Flush with water for 15 minutes.
Ingestion: Drink large amounts of water.

ACCEPTED with COMMENTS
in EPA Letter Dated:
MAR 31 1995

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