

AUG - 9 2012

Jeff Jones, Agent, Alcavis HDC, LLC
c/o Delta Analytical Corporation
12310 Prosperity Drive Suite # 160
Silver Spring, MD 20904

Subject AMUCHINA
EPA Registration No 65787-1
Notification Date July 09, 2012
EPA Receipt Date July 10, 2012

Dear Mr Jones,

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA section 3(c)9 and PR Notice 98-10

Proposed Notification

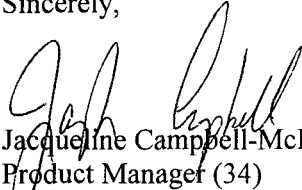
- Adding small size container label to the master label

General Comments

Based on a review of the submitted materials, your notification to add small size container label to the master label is acceptable A copy of this letter has been made a part of the record on file for future reference

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Lorena Rivas by telephone at (703) 305-5027 or by e-mail at rivas.lorena@epa.gov When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing

Sincerely,


 Jacqueline Campbell-McFarlane
 Product Manager (34)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL	75107						
SURNAME	J. Rivas						
DATE	8/09/12						



United States
Environmental Protection Agency
 Washington DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
NOTIF

Application for Pesticide - Section I

1 Company/Product Number 65787-1	2 EPA Product Manager Monisha Harris	3 Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4 Company/Product (Name) Alcavis HDC, LLC / Amuchina	PM# 32	
5 Name and Address of Applicant (Include ZIP Code) Alcavis HDC, LLC c/o Delta Analytical Corp 12310 Prosperity Dr Suite 160 Silver Spring MD 20904 <input type="checkbox"/> Check if this is a new address	6 Expedited Review In accordance with FIFRA Section 3(c)(3)(b)(i) my product is similar or identical in composition and labeling to EPA Reg No _____ Product Name _____	

Section - II

Amendment Explain below
 Resubmission in response to Agency letter dated
 Notification Explain below

Final printed labels in response to Agency letter dated
 Me Too Application
 Other explain below

Explanation Use additional page(s) if necessary (For section I and Section II)
Notification under PR Notice 98 10 re change in packaging and related labeling statements addition of small label accompanied by complete label

This notification is consistent with the provisions of pr notice 98 10 and epa regulations at 40 cfr 152 46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U S C Sec 1001 to willfully make any false statement to EPA I further understand that if this notification is not consistent with the terms of PR Notice 98 10 and 40 CFR 152 46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA

Section - III

1 Material this Product will be Packaged in

Child Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2 Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If Yes Unit Package wgt No per container	If Yes Unit Package wgt No per container

3 Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4 Size(s) of Retail Container 1 33 Gal (170 oz) (5 liters) 1 Qt (32 oz) (0 97 liters) 3 2 oz (97 ml)	5 Location of Label Direction <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
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6 Manner In Which Label Is Affixed to Product
 Lithograph Paper glued Stenciled Other _____

Section - IV

1 Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application)

Name Jeff Jones	Title Agent, Alcavis HDC, LLC	Telephone No (Include Area Code) 301 680 7971
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Certification

I certify that the statements I have made on this form and all attachments thereto are true accurate and complete I acknowledge that any kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law

2 Signature 	3 Title Agent, Alcavis HDC, LLC	6 Date Application Received (Stamped)
4 Typed Name Jeff Jones	5 Date July 9, 2012	



July 9 2012

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U S Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive Room S 4900
Arlington VA 22202

Attn Monisha Harris PM 32

**Re Notification per PR Notice 98-10 re change in packaging and related labeling statements
addition of small container label**

**Company Alcavis HDC, LLC
Product Amuchina
EPA Reg No 65787-1**

Dear Ms Harris

On behalf of Alcavis HDC LLC I am submitting a labeling notification for the product Amuchina EPA
Reg No 65787 1

Alcavis is planning to produce its product in a 3 2 oz bottle Since the complete product label is too large
for this bottle size Alcavis is adding a small container label that contains all required label text as indicated
in the Label Review Manual Chapter 18 Unique Product Labeling Section V Small Containers The
complete label will appear on the product box There has been no change to the currently approved label
The only new text is the addition of statements to the small label referring the user to complete labeling
information on the box

Enclosed please find
EPA form 8570 1
• 2 copies of label

If you have any questions regarding this submission please contact me at (301) 680 7971 or
jjones@delta ac com

Sincerely

Jeff Jones Agent
Alcavis HDC LLC

Small bottle label

AMUCHINA

Electrically generated sodium hypochlorite made from water and salt

Active Ingredient

Sodium Hypochlorite*

1.02%

Other Ingredients

98.98%

TOTAL

100.00%

*electrically generated

Keep Out of Reach of Children

CAUTION

See label on box for complete precautions

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 Refer to master label on box

EPA Reg No

EPA Est No

Net Content 3.2 oz

NOTIFICATION
Data Reviewed 8/2/12
Reviewed By [Signature]

AMUCHINA

[Alternate Brand Name **ALCAVIS 100**]

[GENERAL PURPOSE HOSPITAL DISINFECTANT]

[HOSPITAL CLEANING DISINFECTANT]

[FOOD SERVICES DISINFECTANT]

[Bactericidal] [Virucidal] [Tuberculocidal] [Fungicidal]
[Pseudomonacidal] [Salmonellacidal] [Staphylocidal]**

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

[Electrolytically or [electrically] generated sodium hypochlorite made from water and salt]

Active Ingredient	
Sodium Hypochlorite[*]	1 02%
Other Ingredients	<u>98 98%</u>
TOTAL	100 00%
[(*Electrolytically or [electrically] generated)]	

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
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	

Manufactured by
Alcavis HDC LLC
8322 Helgerman Court
Gaithersburg MD 20877

EPA Reg No 65787-1
EPA Est No 65787 ITA-061
Made in Italy

Net Content [1 33 Gal , [170 oz][(5 liters)]]
[1 Qt , [32 oz][(0 97 liters)]] [3 2 oz] [97 ml]

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

[See back panel for additional directions for use]

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 [this product] [see reader s note below] 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 and eye coverings

CLEANING PROCEDURE Blood and other fluids must 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

[Reader s note [This product] can be substituted for product name throughout label]

DISINFECTION Amuchina can be used in [list one or more of the following] hospitals, nursing homes, dental offices, doctor offices, veterinary offices [clinics][hospitals][facilities], health club facilities, 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 enterica on inanimate non-porous surfaces at 3% or [10%] in 15 minutes The 3% or [10%] dilution is virucidal against Herpes simplex-1 in 15 minutes and Human Immunodeficiency Virus (HIV-1) in 30 seconds The 5% or [10%] 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 using the 10% dilution for 25 minutes at 25 C (97 F) [A 10% (1:9 dilution with water) solution contains 1000 ppm of available chlorine]

[Reader's note If any veterinary site is included in the list of use sites the following directions need to appear on the label]

VETERINARY OFFICES [clinics] [hospitals] [facilities] Use to clean and disinfect hard, nonporous surfaces such as veterinary care surfaces, instruments, animal equipment, cages, reception counters [desks] [areas], floors, walls or other nonporous surfaces (e.g. stainless steel, chrome, glass, vinyl, etc.) Remove all animals from premises Pre-clean all surfaces with soap or detergent and rinse with water Saturate all surfaces with a 3% or [10%] use dilution of Amuchina and let stand for 15 minutes Allow surface to dry before reuse

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 must 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 decontaminates 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 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 must be used in a disinfection program which includes bacteriological monitoring of the hemodialysate delivery system Do not use this product 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

Storage Store 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

Product Disposal Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer

Container Handling Nonrefillable container Do not reuse or refill this container Fill the container ¼ full with water and recap Shake for 10 seconds and dispose of rinsate in a sanitary sewer Offer container for recycling if available or reconditioning if appropriate or place in trash

[Batch #]

