

73696-2

06/26/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 26 2003

Mr. Lawrence Culleen  
Counsel to Alistagen Corporation  
Arnold & Porter  
555 Twelfth Street, NW  
Washington, DC 20004-1206

Subject: Hydrated Lime Manufacturing Use Product  
EPA Registration No. 73696-2  
Amendment Date: October 17, 2002  
EPA Receipt Date: October 17, 2002

Dear Mr. Culleen,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- Addition of HVAC use site

**Conditions**

Revise the label as follows:

**Hydrated Lime Manufacturing Use Product Label Comments:**

1. According to PR Notice 2001-1, the "First Aid" statements must be organized so that the most severe routes of exposures demonstrated by toxicity category are listed first. Therefore, reorder the statements to reflect the following: "If in eyes, If on skin or clothing, If inhaled, If swallowed."
2. Revise the first statement under "IF on skin or clothing" to read "Take off *contaminated* clothing." The use of the term, "affected," is unacceptable.
3. Revise the "If Swallowed" statement under th "First Aid Statements" to state "*Call a poison control center or doctor immediately for treatment advice. Have a 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.*"
4. Under "Precautionary Statements" revise the last sentence to read "Remove *contaminated* clothing and wash clothing before reuse."

**CONCURRENCES**

SYMBOL							
SURNAME							
DATE							

**Technical Bulletin Label Comments**

1. Page 1 and 2: Delete the phrases, "registered by U.S. Environmental Protection Agency," and "EPA registered." Although these are true statements for this product, they have been taken out of context on supplemental and treated articles labels that directly or indirectly implies endorsement or recommendation of your pesticide by an Agency of the Federal Government which is considered false and misleading according to 40CFR 156.10 (a)(5)(v).
2. Page 2: Under Permitted Claims, revise the second bullet by deleting the phrase, "treated article," and replace it with "**Coatings.**"
3. The proposed precautions section of this label is unacceptable because this product's toxicity has been established. The format of the proposed labeling gives consumers the impression the product is not as hazardous as established on the actual label. Revise the "Precautionary Statements" Section to read as follows:

**Precautionary Statements**

**Hazard to Humans**

**Corrosive.** Causes irreversible eye damage and skin burns. May be fatal if inhaled. Do not breathe dust. Do not get in eyes, on skin, on clothing. Wear protective eyewear (goggles or face shield), protective clothing (long sleeve shirt, long pants), and gauntlet type gloves. Harmful if absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

May be fatal if inhaled. Do not breathe dust. Wear a MSHA/NIOSH approved dust/mist filtering respirator number TC-210, or a NIOSH approved dust mist filtering respirator number TC-21C, or a NIOSH approved respirator with any N, R, P, or HE filter. Wear a dust mask if you applying the latex or solvent based coating that has been formulated using Hydrated Lime MUP.

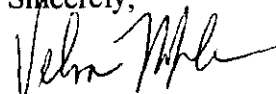
See label for additional information on proper personal protective equipment and handling instructions.

**General Comments**

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should 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)

# Hydrated Lime

## Manufacturing-Use Product

**ACTIVE INGREDIENT:**

Hydrated Lime (Calcium Hydroxide).....96.6%  
 OTHER INGREDIENTS..... 3.4%  
 TOTAL.....100.0%

**KEEP OUT OF REACH OF CHILDREN**

### DANGER

**FIRST AID**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move victim to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off affected clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>

**NOTE TO PHYSICIAN**

Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured by: [Name of Supplier] for the  
**Alistagen Corporation**  
**New York, NY 10019**

EPA Reg. No. 73696-2 EPA Est. No. [XXXXX-XX-001]  
 Net Contents: \_\_\_\_\_ lbs.

**WARRANTY AND LIMITATION OF DAMAGES**

The Manufacturer makes no warranties, expressed or implied, concerning this product or its use, which extend beyond the description on the label. Read all directions carefully.

**DIRECTIONS FOR USE**  
**IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT**  
**IN A MANNER INCONSISTENT WITH ITS LABELING**

Use only for manufacture of or fabrication into antimicrobial pesticides for 1) the uses listed on this label or 2) uses for which EPA has approved the required data and/or citations of data that the formulator has submitted in support of a pesticide registration. Imparts antimicrobial activity by suppressing the growth of odor, discoloration, or deterioration causing bacteria, mold, mildew, algae and fungi on paint film or coatings. Formulations that incorporate this product may be used as coatings on, or components of, the following hard, inanimate surfaces and products: walls, floors, ceilings, tile, fixtures, tools, appliance exteriors, pipe exteriors, heating/cooling/ventilation (HVAC) equipment, duct work and related equipment (other than motors, fans and similar mechanical moving parts) interiors and exteriors, and concrete, stone, ceramic, plaster, wood, drywall substrates in residential dwellings, schools, day care centers, professional offices, commercial and industrial buildings, factories, animal housing facilities (barns, corrals, fences) and healthcare facilities (hospitals, medical offices, nursing homes). Applications to interior surfaces of HVAC equipment must be made only during construction, assembly, or installation of the unit and during periods where the HVAC system is not in operation and the building is unoccupied. Persons formulating this product into coatings for HVAC equipment must consult Alistagen's Technical Bulletin. This product is not for use in or on coatings or other antimicrobial pesticides that will be used on food contact, food preparation or food processing surfaces. Persons who formulate coatings, finished articles or other manufactured products incorporating this product may not make public health claims relating to the incorporation of hydrated lime without first obtaining an EPA registration for the product for which such claims are made. Formulations and antimicrobial coating products that incorporate hydrated lime are to be formulated to include 15 - 25% of this product.

**PRECAUTIONARY STATEMENTS**  
**Hazards to Humans**  
**DANGER**

Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield), clothing (long sleeve shirt, long pants), and gloves (gauntlet type). May be fatal if inhaled. Do not breathe dust. Wear a MSHA/NIOSH-approved dust/mist filtering respirator number TC-21C, or a NIOSH-approved respirator with any V, R, P or HE filter. Harmful if absorbed through the skin. Wash thoroughly with soap and water after handling. Remove and wash clothing before reuse.

**Environmental Hazards**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the Environmental Protection Agency.

**STORAGE AND DISPOSAL**

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

**Pesticide Storage** Keep container tightly sealed. Store in cool, dry area.

**Pesticide Disposal** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides, spray mixtures 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 hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**Container Disposal** Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

ACCEPTED  
 with COMMENTS  
 in EPA Letter Dated:

JUN 26 2003

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
 registered under EPA Reg. No. 73696-2

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TECHNICAL BULLETIN FOR ALISTAGEN HYDRATED  
LIME MUP WHEN USED IN LATEX- OR SOLVENT-BASED FORMULATIONS FOR  
APPLICATION UPON HEATING, VENTILATION  
AND AIR CONDITIONING EQUIPMENT

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**Read the product label first.** Refer to the product label and MSDS for complete directions on safety precautions, storage and handling.

**Product Description:**

Alistagen Hydrated Lime MUP contains approximately 96.6% by weight hydrated lime. Alistagen Hydrated Lime MUP is registered by the U.S. Environmental Protection Agency for use in (among other products) latex- or solvent-based coating formulations that may be used on hard, inanimate surfaces and products to impart a coating that is protected against deterioration caused by certain microorganisms. In latex- or solvent-based coatings that will be applied to Heating, Ventilation and Air Conditioning (HVAC) equipment and components (other than mechanical, moving parts), the antimicrobial additive is incorporated into a coating which will dry to form a surface on the paint film that resists the growth of odor causing bacteria and mold, mildew, fungi, and algae that can cause deterioration to the coating or film. This product is compatible with a variety of substrates and products listed on the label. Apply the coating product to HVAC interior surfaces only during periods prior to their installation in buildings or during periods when the equipment is not in operation and the building is unoccupied.

**Benefits:**

When formulated into a latex- or solvent-based coating product, Alistagen Hydrated Lime MUP imparts a durable antimicrobial activity to the coating surface when it is applied to a wide variety of substrates.

The hydrated lime MUP can be a coating against odor, discoloration, staining, deterioration or corrosion caused by bacteria, mold, mildew, fungi and algae.

**Permitted Claims:**

- Alistagen Hydrated Lime MUP is an EPA-registered antimicrobial agent that will effectively resist the growth of bacteria, mold, mildew, fungus and algae that can cause odors, deterioration and decay on coatings.
- Alistagen Hydrated Lime MUP can preserve treated articles.
- Alistagen Hydrated Lime MUP provides a coating that resists the deterioration, discoloration, decay and odor caused by the growth of bacteria, fungi, mold, mildew and algae.

**Note:** Alistagen Hydrated Lime MUP can be blended into a coating that resists the deterioration, discoloration, decay and odor caused by the growth of bacteria, fungi, mold, mildew, and algae. HVAC systems must be kept clean and well-maintained in accordance with manufacturer's directions and industry standards. Manufacturers as well as professional trade associations have prepared guidance and written standards that address cleaning and maintenance of HVAC systems.

**Technical Data:**

Active Ingredient:	96.6% hydrated lime
Color:	White
Physical State:	Solid (powder)
Flammability:	Not flammable
Specific Gravity	2.24 g/cm <sup>3</sup>
pH:	12.4 (saturated aqueous solution at 25 °C)
Thermal Stability:	Decomposes to yield CaO and water above 580 °C

**Approved Uses:**

For use in latex- or solvent-based coatings and adhesives that can be applied to, or incorporated within:

Heating, Ventilation and Air Conditioning (HVAC) systems and related components (including air handlers, ducts, heat exchangers, drain pans and liners thereof, air filters, air purifiers, diffusers, humidifiers and parts and components thereof) other than mechanical moving parts. Apply coatings to the interior surfaces of HVAC equipment only prior to its installation in buildings or when the equipment is not in operation and the building is unoccupied.

**Mixing Coating Formulations:**

Incorporate Alistagen Hydrated Lime MUP directly into latex- or solvent-based coating formulations that are alkaline compatible and that have been developed for the coating of typical metals used in duct work manufacture. Alistagen Hydrated Lime MUP must comprise at least 15% and not more than 25% of the final coating formulation, consistent

with the recommended loading levels for inorganic fillers, pigments, and alkaline constituents.

Application of Mixed Coatings:

Before applying the coating to the HVAC system, you must inspect the system for microbial contamination. Then the system must be cleaned in accordance with manufacturer's directions and industry standards. Then, apply a single coat of the latex- or solvent-based coating with brush, roller, spray or other technology to the hard, inanimate nonporous HVAC surface or related equipment (other than moving parts) at a rate to achieve a smooth even surface having a dry film thickness of approximately 2.5 mil. Applicators of the latex- or solvent-based paint formulations should wear dust mask, long shirt and pants, goggles or face shield, and gauntlet type gloves to protect the skin and eyes against sprayed, splashed or dripped coating.

**Contact Alistagen to confirm optimum application technology and drying conditions, such as time and temperature, for each application before use in a commercial process.**

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

<b>FIRST AID</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move victim to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off affected clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
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<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>NOTE TO PHYSICIAN</b>	
Probable mucosal damage may contraindicate the use of gastric lavage.	

**Hazards to Humans: Corrosive.**

Hydrated Lime can be corrosive to the eye and cause skin burns on unprotected skin if not treated immediately and properly. Hydrated Lime can be fatal if inhaled. Do not breathe dust.

**Personal Protective Equipment and Handling Instructions: Also see label instructions for additional information and proper protection and warnings.**

To protect eyes, wear protective eyewear (goggles or face shield); clothing (long sleeve shirt, long pants) and gauntlet type gloves should be worn when handling Hydrated Lime MUP to protect your skin. Harmful if absorbed through skin. Wash thoroughly with soap and water after handling. Remove and wash clothing before reuse.

Do not breathe Hydrated Lime MUP dust. Wear a MSHA/NIOSH-approved dust/mist filtering respirator number TC-216, or a NIOSH-approved dust/mist filtering respirator number TC-21C, or a NIOSH-approved respirator with any N, R, P or HE filter if you are handling Hydrated Lime MUP. Wear a dust mask if you are applying a latex- or solvent-based coating that has been formulated using Hydrated Lime MUP.

**Environmental Hazards:**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the Environmental Protection Agency.

**Pesticide Storage:** Do not store in areas accessible to children. Keep containers tightly sealed. Store in a cool, dry area.

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides, spray mixtures 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 hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**Container Disposal: Inner Plastic Bag:** Completely empty plastic bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.



**MSDS Information:**

Refer to the Material Safety Data Sheet for this product for complete handling and safety information.

**Transportation Information:**

Consult MSDS and the U.S. Department of Transportation for rules concerning transportation of Alistagen Hydrated Lime MUP.

**Regulatory Information:**

Alistagen Hydrated Lime MUP is registered by the U.S. Environmental Protection Agency as EPA Reg. No. 73696-02

**For technical assistance or questions contact: [TBD]**

Alistagen Corporation  
New York, NY 10019

**WARRANTY AND LIMITATION OF DAMAGES**

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