

75100-2

10/29/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

October 29, 2008

J. Bruce Jaeger  
Health & Environmental Horizons, Ltd.  
U.S. Agent for  
VA & G Bioscience, Inc.  
2851 South Haven Road  
Annapolis, MD 21401

Subject: Product Name: ChitoSante MUP  
EPA Reg. Number: 75100-2  
Application Date: 08-Aug-2008  
EPA Receipt Date: 02-Sep-2008

Dear Mr. Jaeger:

The following amendments in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

**Proposed amendments**

- Primary Eye Irritation study: Submitted to satisfy the conditional registration requirements.
- MUP Master Label.

**General comments:**

The submitted Eye Irritation study is acceptable.

**Other comments:**

There still exists a data gap with respect to the Acute Inhalation data requirement.

- 1) This product is a relatively low density solid which is most likely a light powder which might easily become airborne and capable of being inhaled.
- 2) No data or studies have been made available for review to determine the inhalation toxicity of this product.

3) The toxicity category IV designated as acceptable for the requested waivers of the Acute Oral, Dermal, and Skin Irritation can not be used to infer anything specific about the toxicity via the inhalation exposure route.

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The acute toxicity profile for 75100-2 ChitoSante' MUP is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	Waive/Cite	IV	Acceptable
Acute Dermal Toxicity	Waive/Cite	IV	Acceptable
Acute Inhalation Toxicity	None	?	Data-Gap
Primary Eye Irritation	475266-01	III	Acceptable
Primary Skin Irritation	Waive/Cite	IV	Acceptable
Dermal Sensitization	Waive/Cite	Non-Sensitizer	Acceptable

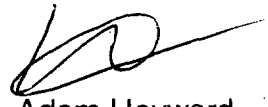
For detailed information and consideration, please refer to the enclosed AD/PSB acute toxicity data review dated September 26, 2008.

**Labeling comments:**

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

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or by email at: [heyward.adam@epa.gov](mailto:heyward.adam@epa.gov), or Stacey Grigsby by telephone at (703) 305-6440 or by email at [grigsby.stacey@epa.gov](mailto:grigsby.stacey@epa.gov).

Sincerely,



Adam Heyward  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosure: [Acute Tox review & stamped label]

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ChitoSante' MUP  
8/28/08 Section 3 Registration MASTER Label  
Page 1 of 4  
(front panel)

# ChitoSante'™ MUP

## FOR MANUFACTURING/FORMULATING USE ONLY

<b>ACTIVE INGREDIENT:</b>		% w/w
Chitosan		99%
<b>OTHER INGREDIENTS:</b>		1%
<b>Total</b>		100%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION  
PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION**  
Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**FIRST AID STATEMENTS**

<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.</li> <li>• 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>
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Have the product container or label with you when calling a poison control center or doctor, or going for treatment.. For emergency information call the **National Pesticides Information Center** at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.

Net Contents:

EPA Reg. No. 75100-2  
EPA Est. No. 075100-TWN-001

VA & G Bioscience, Inc.  
No. 29 Chang-an Street, Bade City  
Taoyuan, Taiwan 33465, R.O.C.

**ACCEPTED**  
OCT 29 2008

Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide, registered under  
EPA Reg. No. **75100-2**

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of 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 without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or regional Office of the EPA.

**PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Applicators and other handlers must wear: Long-sleeved shirt and long pants. Waterproof gloves. Shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Formulators using this product are responsible for obtaining an EPA Registration for their formulated product. Chitosan, the active ingredient in ChitoSante' MUP, inhibits the growth of non-health related organisms such as bacteria, mold, mildew and fungus that cause odor, stains, discoloration, decay and deterioration of the treated materials. Distributors of products containing ChitoSante' MUP may not make claims of antimicrobial activity other than the protection of the treated material against the growth of bacteria, mold, mildew and fungi in or on the treated product. See 40 C.F.R.152.25(a) for further guidance about treated article claims. ChitoSante' MUP may be incorporated into products used in the finishing process of manufacturing textiles, including carpet. It may used for surface applications to floor coverings, textiles, paper, leather, textile wall partitions, vinyl, upholstery, wallboard, hard contact surfaces, and vehicle interiors. It may be used in home use products, used in washing machines, for consumer use (on surfaces such as apparel, shoes and insoles, curtains, mattresses, upholstery, carpet, exercise equipment and air filters), textile covers (boat, car, sofa). ChitoSante' MUP may be used in agricultural products in accordance with 40CFR 180.1072.

**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE:**

Store in original container in a cool, dry place, away from sunlight and out of the reach of children and pets.

**PESTICIDE DISPOSAL:**

Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:**

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration; or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**BULK CONTAINERS:**

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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**NOTICE OF WARRANTY**

VA & G Bioscience, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with the label directions under normal conditions of use. VA & G Bioscience, Inc. makes no other express or implied warranties either of merchantability or fitness for a particular use. Handling, storage and use of the product by Buyer or User are beyond the control of VA & G Bioscience, Inc. and Seller. Risks such as ineffectiveness or other unintended consequences resulting from, but not limited to, failure to follow label directions will be assumed by the Buyer or User. In no case will VA & G Bioscience, Inc. or Seller be held liable for consequential, special or indirect damages resulting from the handling, storage or use of this product.

The terms of this Limited Warranty and Disclaimer cannot be varied by any written or verbal statements or agreements. No employee or agent of the seller is authorized to vary or exceed the terms of this Limited Warranty and Disclaimer in any manner.

Produced by  
VA & G Bioscience, Inc.  
No. 29 Chang-an Street, Bade City  
Taoyuan, Taiwan 33465, R.O.C.