

79630-1

3/7/2008

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

MAR 7 2008



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

K2 Concepts, Inc.  
805 Peachtree Street, Suite 614  
Atlanta, GA 30308

**AGENT: Steptoe and Johnson**  
**1330 Connecticut Avenue, N.W.**  
**Washington, D. C. 20036-1795**

Attention: Elizabeth Anne Brown, Agent

**Subject: Aquastat-HU**  
EPA Registration No. 79630-1  
Notification Dated February 7, 2008

This will acknowledge receipt of your notification to include additional optional marketing statements to the label, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

Conditions

The following optional marketing statement "Just as [gentle] [mild] as [soap] [and] [water]" must be deleted from the label.

General comments

The Notification dated February 7, 2008 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.


Sincerely

A handwritten signature in cursive script that reads "M Swindell".

Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> <b>Registration</b>	OPP Identifier Number
	<input type="checkbox"/> <b>Amendment</b>	
	<input checked="" type="checkbox"/> <b>Other</b>	

**Application for Pesticide - Section I**

1. Company/Product Number 79630-1	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aquastat-HU	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) K2 Concepts, Inc. 805 Peachtree Street, Suite 614 Atlanta, GA 30308  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> 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**

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

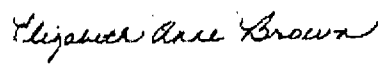
Notification of Labeling Changes per PR Notice 98-10 (Other Revisions (Section II.N)).

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:				2. Type of Container	
<input type="checkbox"/> Child-Resistant Packaging Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Unit Packaging Yes <input type="checkbox"/> No	<input type="checkbox"/> Water Soluble Packaging Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>cardboard box</u>		
*Certification must be submitted		If "Yes" Unit Packaging wgt. 0.035, 0.21, 0.28 or 0.35 oz	No. per container 1 or 2	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1x0.035, 1 x 0.21 oz, 1 x 0.28 oz, 1 x 0.35 oz 2x0.035, 2 x 0.21 oz, 2 x 0.28 oz, 2 x 0.35 oz		5. Location of label directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

**Section IV**

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Elizabeth Anne Brown	Title Step toe & Johnson, LLP Authorized Agent	Telephone No. (Include Area Code) 202-419-5166
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law		Date Application Received  <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: auto;"> <b>(Stamped)</b> </div>
2. Signature  	3. Title Step toe & Johnson, LLP Authorized Agent	
4. Typed Name Elizabeth Anne Brown	5. Date February 8, 2008	



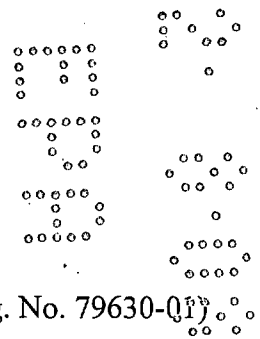
James C. Chen  
(202) 624-2570  
jchen@crowell.com

February 7, 2008

1757:  
103575-0000001

VIA HAND-DELIVERY

Marshall Swindell, PM 33  
Office of Pesticide Programs - Antimicrobial Division  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202



Re: Notification for Additional Claims on Aquastat-HU (EPA Reg. No. 79630-01)

Dear Mr. Swindell:

On behalf of K2 Concepts, Inc. ("K2" or the "Company"), we wish to express our appreciation for meeting with us earlier this week regarding K2's registered Aquastat-HU product. As noted in our meeting with you and others from the Antimicrobial Division, there are a number of issues associated with our registered product, not the least of which is the desire to seek approval for label claims similar to claims granted to other registered products.

In follow up to our meeting, and as agreed upon during our discussion, enclosed please find our notification for certain additional claims K2 wishes to make in association with the registered Aquastat-HU product (EPA Reg. No. 79630-01). The formal version of this submission has been sent to the Front End Processing Unit consistent with Agency requirements for notifications. The basis for many of the new claims sought comes from our discussion as well as originating from claims directly reviewed and approved by the Antimicrobial Division for Clorox's Emil registered product (EPA Reg. No. 5813-85) (sold under the commercial brand name "Clorox Anywhere"). We have attached a copy of that stamped approved label for your reference. As agreed during our meeting, we have included a statement on our notification that allows EPA to suggest additional changes as warranted. I would ask, however, that to the extent you believe such changes are necessary that you and I have the opportunity to discuss them by telephone prior to final processing.

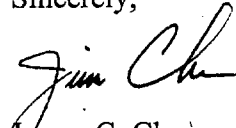
Also in accordance with our discussion, the new proposed claims set forth in the attached notification avoid use of the term "safe" in any context as we understand that the Agency disapproves of the use of this adjective. Although the Company very much would value making such claims with respect to the safety of the product on humidifier components, K2 has avoided including such claims even though there are a number of similar approved claims on the Clorox

Marshall Swindell, PM 33  
February 7, 2008  
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Emil registration that allow use of the term "safe." K2 agrees to avoid such claims because we understand that EPA will be taking action to have such claims removed from Clorox's registration. We encourage the Agency to act on modifications EPA deems necessary to the Clorox Emil registration as soon as possible since their current allowed use places K2 and other competitors at an unfair and significant market disadvantage.

Thank you again for your time and attention. If you have any questions or comments, please feel free to contact me. Otherwise, I look forward to hearing from you.

Sincerely,

  
James C. Chen  
Counsel for K2 Concepts, Inc.



Enclosures  
4924582

cc: Bryan Kepner, President, K2 Concepts, Inc.  
Elizabeth A. Brown, Agent for K2, Steptoe & Johnson, LLP

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# AQUASTAT-HU

Microbistatic [Antimicrobial] Treatment for Residential Humidifier Units

Active Ingredient:	
Silver (metallic)	1.4%
Other ingredients	<u>98.6%</u>
TOTAL	100.0%

## KEEP OUT OF REACH OF CHILDREN

### CAUTION

See other panel for First Aid statements and additional precautionary wording.

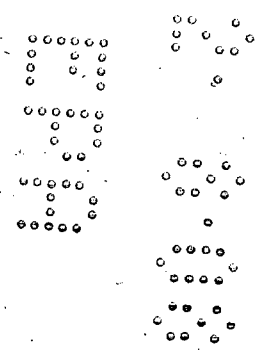
EPA Establishment No. 79630-GA-001

EPA Registration No. 79630-1

Net weight each cartridge:  
[one or two cartridges per package]

K2 Concepts, Inc.  
2625-116 Piedmont Rd. NE  
Atlanta, GA 30324

[EPA stamped label: 11-13-2007; Notifications accepted 12/28/2007]



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**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS**

**CAUTION.** Causes eye irritation. May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Remove outer package before placing cartridge into humidifier. Do not open or attempt to empty the cartridge. Retain this label for reference.

For use in the following sizes of residential humidifiers: Small portable humidifier units, Console humidifer units, Central humidifier units. For use in the following types of residential humidifiers: ultrasonic, cool mist (impeller), evaporative, steam vaporizer.

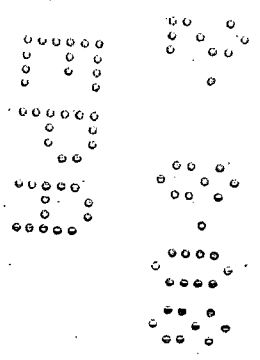
1. For every 2 gallons of water contained in the humidifier tank, use 1 AQUASTAT-HU cartridge.
2. For best results, before using for the first time, it is recommended that you clean your humidifier according to the humidifier manufacturer's instructions to remove any buildup that may have accumulated.
3. After humidifier has been cleaned, drop one (1) AQUASTAT-HU cartridge per 2 gallons of water capacity into the humidifier water reservoir and fill tank with fresh water.
4. Operate humidifier according to the manufacturer's directions and replace AQUASTAT-HU cartridge every 30 days. For deep-well reservoir tanks, shut off water and drain tank in order to retrieve the AQUASTAT-HU cartridge.

Alternate Wording for 1 gram (0.035 oz) cartridges for very small units ( $\leq 500$  ml capacity):

For Units with Capacity of  $\leq 500$  ml:

1. For every 500 ml (17 fl oz) of water contained in the humidifier tank, use 1 AQUASTAT-HU cartridge.
2. For best results, before using for the first time, it is recommended that you clean your humidifier according to the humidifier manufacturer's instructions to remove any buildup that may have accumulated.
3. After humidifier has been cleaned, drop one (1) AQUASTAT-HU cartridge per 500 ml (17 fl oz) of water capacity into the humidifier water reservoir and fill tank with fresh water.
4. Operate humidifier according to the manufacturer's directions and replace AQUASTAT-HU cartridge every 30 days. For deep-well reservoir tanks, shut off water and drain tank in order to retrieve the AQUASTAT-HU cartridge.

<p><b>STORAGE AND DISPOSAL</b></p> <p>Do not contaminate water, food or feed by storage and disposal.</p> <p><b>Pesticide Storage:</b> Do not store in areas accessible to children. Keep product dry during storage.</p> <p><b>Container and Pesticide Disposal:</b> Do not reuse empty cartridge or outer carton. Securely wrap original container in several layers of newspaper and discard in trash.</p>
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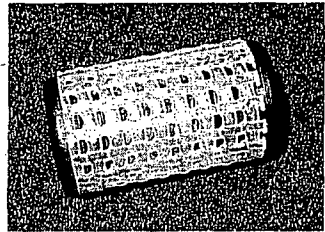
<b>FIRST AID:</b> Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>IF IN EYES</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, 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 INHALED</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth, if possible</li> <li>• Call a poison control center or doctor for further treatment advice</li> </ul>
<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>• Immediately call a poison control center or doctor</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor</li> <li>• Do not give any liquid to the person.</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul>
<b>IF ON SKIN OR CLOTHING</b>	<ul style="list-style-type: none"> <li>• Take off contaminated 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>
FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL THE NATIONAL POISON CONTROL CENTER 1-800-222-1222	

Notice: Customer is responsible for ensuring compliance with applicable laws and regulations. Any use of this product for purposes other than what is intended is strictly prohibited. Results may vary according to water quality.

[Optional] Description of Cartridge [no more than one of these will appear on the printed label, but either/neither may be used]

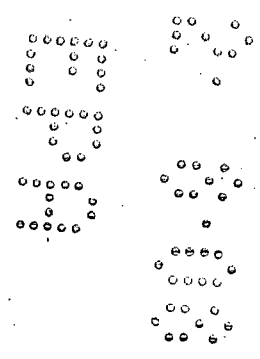
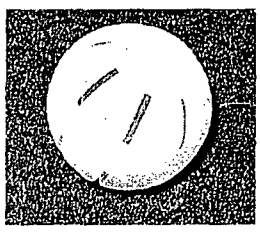
Type 1: Cylinder

Cylinder composed of 100% polypropylene, with caps of 100% LDPE.  
 Dimensions: 2 inches (L) x 1.25" (D)  
 Dimensions for smaller size units ( $\leq$  500 ml capacity): 12 mm (L) x 8 mm (D)



Type 2: Sphere

Sphere composed of 100% polystyrene. Dimensions: 30 mm (D)



Optional Marketing Statements:

- Kills bacteria [microorganisms] that cause unpleasant odors
- [Controls] [continually inhibits] [[prevents] growth [and buildup] of bacteria, mold and algae in the water tank
- [Controls] [continually inhibits] [prevents] growth of [bacteria] [mold] and [algae] [microorganisms] in the mist of cool-mist humidifiers [vaporizers] during the life of the cartridge.
- Prevents the growth of bacteria, mold and algae in the water and on the inside of the humidifier [vaporizer] tank
- Prevents the buildup of slime on the inside of the humidifier [vaporizer] tank
- Improves humidifier [vaporizer] performance by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]
- Extends the life of the humidifier [vaporizer] by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]
- Extends the life of the humidifier [vaporizer] filter/components [wick] by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]
- Provides fresh mist
- Provides both continuous cleaning and protection against odor [slime] causing [microorganisms] [bacteria] [mold] [fungi] [algae]
- Continuously cleans and protects humidifiers [vaporizers] against [bacteria] [mold] [algae]
- Keeps working [cleaning] for 30 days
- Simply drop in tank for fresh, clean mist
- Your humidifier [vaporizer] stays cleaner, longer
- You can actually see the difference!
- Continuously works to control [prevent] [inhibit] growth of [bacteria] [mold] [slime] [buildup of slime] in the water and humidifier [vaporizer] surfaces
- Uses the same antimicrobial that has been used for years in drinking water filters to prevent objectionable odors, tastes and colors
- Works in all residential humidifiers [vaporizers]
- Continuous protection against slimy build-up in humidifier [vaporizer]

[NOTE: EPA may make revisions as necessary to the following 7 optional marketing statements submitted under this notification but should contact the registrant in case of any needed revisions]

- ~~Just as [gentle][mild] as [soap] [and] [water]~~
- [Gentle][mild] cleaning action for your humidifier
- [Contains] no [harsh][harmful][lingering][cleaning] chemicals
- Contains no [abrasives] or [harsh acids]
- Leaves no [harsh] [harmful][lingering][corrosive] residues
- Non-[corrosive][corroding]
- [Will not harm][Non-harmful] to [metal][plastic][humidifier] components



Optional Marketing Graphic

Virtually no odor and slime causing bacteria found in humidifier using Aquastat HU

