

79630-1

12/28/2007

10f9

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

DEC 28 2007



Office of Pesticide Programs

Ms. Elizabeth Anne Brown
Authorized Agent for,
K2 Concepts, Inc.
2625 - 116 Piedmont Road, N.E.
Atlanta, GA 30324

Mail to: Steptoe and Johnson
1330 Connecticut Avenue, N.W.
Washington, D. C. 20036-1796

Subject: AquaStat-HU
EPA Registration No. 79630-1
Notification Dated November 29, 2007

This will acknowledge receipt of your notification to include optional instructions associated with a small sized application cartridge for use in very small capacity humidifiers, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to the file.

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

Sincerely

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

2009

Please read instructions on reverse before completing form

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



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

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) Aquistat-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. 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

<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 (Packaging Related Statement (Section IIE)).

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"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*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	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input checked="" type="checkbox"/> Other (Specify) <u>cardboard box</u>
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 Steptoe & Johnson, LLP Authorized Agent	Telephone No. (Include Area Code) 202-419-5166
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 knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law		6. Date Application Received (Stamped)
2. Signature <i>Elizabeth Anne Brown</i>	3. Title Steptoe & Johnson, LLP Authorized Agent	
4. Typed Name Elizabeth Anne Brown	5. Date November 29, 2007	

WRITER'S DIRECT DIAL
202.419.5166

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
Tel 202.429.3000
Fax 202.429.3902
steptoe.com

November 29, 2007

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

Attention: Marshall Swindell (PM 33)

Subject: AquaStat-HU, EPA Reg. No. 79630-1
Notification per PR 98-10 – Packaging Related Statements

Dear Marshall:

On behalf of K2 Concepts, Inc., enclosed please find notification consistent with PR 98-10 for product labeling notifications under Section IIE, to include optional instructions associated with a small sized application cartridge for use in very small capacity humidifiers. The change in size itself is considered to be a non-notification under PR 98-10, Section IVB.

Enclosed with this application please find the following:

1. EPA Form 8570-1
2. One copy of the label with the revisions highlighted

Please let me know if there are any questions or if anything else is needed.

Regards,

Elizabeth Anne Brown, Ph.D.
eabrown@steptoe.com

cc: K2 Concepts, Inc.

4089

Master Label

11/29/2007 Notification for Other Labeling

AQUASTAT-HU

Microbistatic [Antimicrobial] Treatment for Residential Humidifier Units

Active Ingredient:	
Silver (metallic)	1.4%
Other ingredients	98.6%
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: ~~0.35 oz (10 grams)~~
[one or two cartridges per package]

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

EPA approved: 11-13-2007

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 (≤ 500 ml capacity):

For Units with Capacity of ≤ 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.

STORAGE AND DISPOSAL

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

Pesticide Storage: Do not store in areas accessible to children. Keep product dry during storage.

Container and Pesticide Disposal: Do not reuse empty cartridge or outer carton. Securely wrap original container in several layers of newspaper and discard in trash.

6099

FIRST AID: Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
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 INHALED	<ul style="list-style-type: none"> • Move person to fresh air • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth, if possible • Call a poison control center or doctor for further treatment advice
IF SWALLOWED	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor • Do not induce vomiting unless told to do so by a poison control center or doctor • Do not give any liquid to the person. • 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
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.

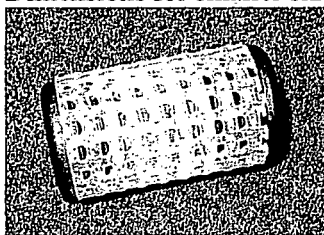
[Optional] Description of Cartridge [no more than one of these will appear on the printed label, but either/neither may be used]

Type 1: Cylinder

Cylinder composed of 100% polypropylene, with caps of 100% LDPE.

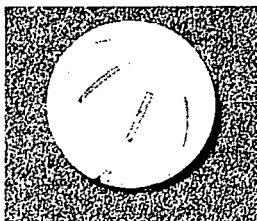
Dimensions: 2 inches (L) x 1.25" (D)

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)



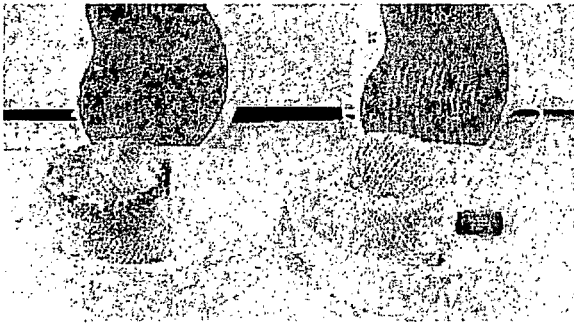
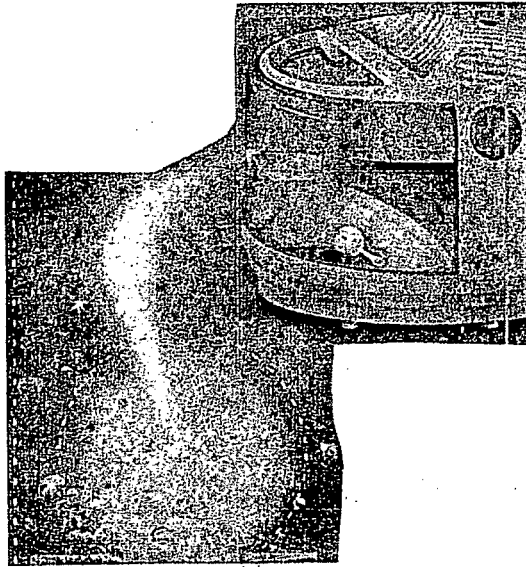
7099

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]

80f9

[The Following Two Optional graphics]



90f9

Optional Marketing Graphic

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

