

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

June 27, 2008

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 May 8, 2008

This will acknowledge receipt of your notification to include additional optional marketing statements to the label, submitted under the provisions of F1FRA 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]" to humidifier surfaces and components" is acceptable

General comments

The Notification dated May 8, 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

Marshall Swindell Product Manager (33)

Regulatory Management Branch 1 Antimicrobials Division (7510P)

Please read instructions on reverse	befor	e completing form				F	orm A	Approve	d, OMB	No. 2070-	-0060, Approval expires 5-31-98		
*			Reg	istratio	on	OPP Identifier Number							
Environmental Protection A					Δασ	anicv		Amo	endme	nt			
Washington, DC 20460						alloy	X	Oth	er				
Application for Pesticide – Section I													
1. Company/Product Number		ДРР	· · ·	011 101	Ť	2. EPA Product N				3. Pro	posed Classification		
79630-1 4. Company/Product (Name)					-	M. Swindell PM # X None Restricted							
Aquastat-HU						33							
Name and Address of Applicant (Include ZIP Code) K2 Concepts, Inc.						Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling							
805 Peachtree Street, Suite 614						to:							
Atlanta, GA 30308						EPA Reg No.							
Check if this is a new add		Product Name											
Section - II													
Amendment – Explain below Final printed labels in response to													
,						Agency letter dated							
Resubmission in response to Agency letter dated "Me Too" Application													
Natification Front - Lat													
Notification - Explain bei	X Notification Explain below Other Explain below												
Explanation: Use additional p	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 consisted													
have been made to the label U.S.C. Sec. 1001 to willfully													
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													
Material This Product Will b	e Pac	kaged in			ecu	On III							
Child-Resistant Packaging					ater Soluble Packaging 2. T					ype of Container			
Yes	X	X Yes				Yes					Metal Plastic		
X No		No ·			X	No					Glass		
*Certification must	If "Y		1	per	ı	es"	T	No. pe		1回	Paper		
be submitted		Packaging wgt. 35, 0.21, 0.28 or	con 1 or	tainer · 2	Pad	ckage wgt		contai	ner	×	Other (Specify) <u>cardboard</u> box		
	0.35	oz		· 	<u> </u>								
3. Location of Net Contents In	_	ation Container				Container oz, 1 x 0.28 oz, 1	x 0.3	35 oz		cation o On Labe	f label directions		
				.035, 2	∢0.2	oz, 2 x 0.28 oz, 2		35 oz	X		el accompanying product		
l l					Lithograph Other Paper glued								
x Stenciled													
Section IV													
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to procedure. Name Title Telephone Telephone									s this application.) o. (Include Area Code)				
				Stepto	Steptoe & Johnson, LLP Authorized Agent				202-419-5166				
Certification						- gon		···		· · · · · · · · · · · · · · · · · · ·	6. Date Application		
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								Received					
both under applicable law						sname by line or im							
2. Signature	3. Title	e		(Stamped)									
Elizabet and Brown					e & J	lohnson, LLP							
				Author	_								
4. Typed Name				5. Date									
Elizabeth Anne Brown					May 8, 2008								

STEPTOE & JOHNSON LLP

ATTORNEYS AT LAW

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

May 8, 2008

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 – Optional Marketing Statements

Dear Marshall:

On behalf of K2 Concepts, Inc., enclosed please find a notification consistent with PR 98-10 for product labeling notifications under Section II, to add optional marketing statements for this product.

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,

Heigener and Brown

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

cc:

K2 Concepts, Inc.

Master Label 5/8/2008

AQUASTAT-HU

Microbistatic [Antimicrobial] Treatment for Residential Humidifier Units

Active Ingredient:
Silver (metallic)
Other ingredients
TOTAL

98.6% 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, 3/7/2008]

Master Label 5/8/2008

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 humidifier 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.
- 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 AOUASTAT-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.
- 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.

FIRST AID:	
Have the product contained	r or label with you when calling a poison control center or doctor, or going for treatment.
IF IN EYES	 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	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	Immediately call a poison control center or doctor
	 Do not induct 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	Take off contaminated clothing
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 EME	RGENCY 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.

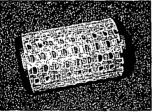
[Optional] Description of Cartridge [no more than one of these will appear on the printed label, but either/neither may be used]

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)

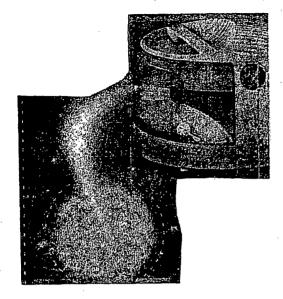


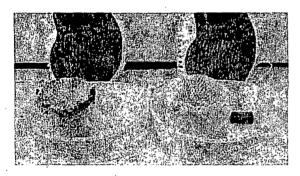
Optional Marketing Statements:

- 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] [microoganisms] 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]
- [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
- Just as [gentle][mild] as [soap] [and] [water] to humidifier surfaces and components

Master Label 5/8/2008

[The Following Two Optional graphics]





Optional Marketing Graphic

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

