



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

September 29, 2015

Karen E. Wakentien  
Consultant to K2 Concepts Inc.  
114 North Prince Street, 3<sup>rd</sup> Floor  
Lancaster PA, 17603

Subject: Notification per PRN 98-10 – To add alternate brand names  
Product Name: Aquastat-HU  
EPA Registration Number: 79630-1  
Application Date: August 21, 2015  
Decision Number: 508863

Dear Ms. Warkentien;

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

The following alternate brand names have been added to the product record:

- Protec Humidifier Cleaning Ball
- Protec Humidifier Cleaning Fish

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If you have any questions, you may contact Zebora Johnson at (703) 308-7080 or via email at [johnson.zebora@epa.gov](mailto:johnson.zebora@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao". The signature is fluid and cursive, with a large initial "J" and "C".

Julie Chao, Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

# AQUASTAT-HU

ABNs:

Protec Antimicrobial Cartridge

Aquastat-HUC for CPAP

Protec Humidifier Cleaning Ball

Protec Humidifier Cleaning Fish

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

Do not allow children to play with the AquaStat-HU cartridge

EPA Establishment No. 79630-GA-001

EPA Registration No. 79630-1

Lot/Batch Number:

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

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

### NOTIFICATION

79630-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

9/29/2015

## **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.
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.

## **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal.  
Nonrefillable container. Do not reuse or refill this container.

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

**Pesticide Disposal:** Do not reuse empty cartridge. Securely wrap cartridge in several layers of newspaper and discard in trash.

**Container Disposal:** Securely wrap outer carton in several layers of newspaper and discard in trash or offer for recycling, if available.

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.

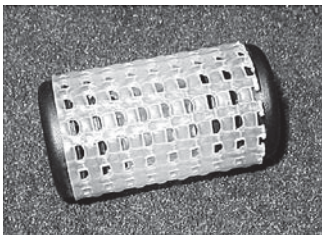
[Optional] Description of Cartridge [no more than one of these will appear on the printed label, but either/neither may be used]

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

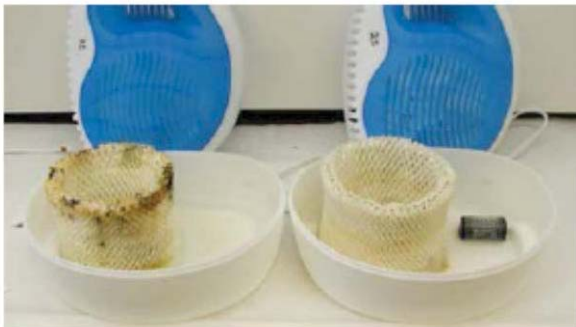
Sphere composed of 100% polystyrene. Dimensions: 30 mm (D)



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]
- [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
- Kills up to 99% of odor-causing bacteria
- Continually inhibits the growth of up to 99% of odor-causing bacteria, unsightly mold and algae on humidifier surfaces
- Inhibits the growth of up to 99% of odor-causing bacteria, unsightly mold and algae keeping your humidifier cleaner, longer
- Reduces up to 99% of odor-causing bacteria, unsightly mold and algae growth versus untreated humidifier surfaces)

[The Following **Five** Optional graphics]



(will be placed adjacent to the current claim: *Reduces up to 99% of odor causing bacteria, unsightly mold and algae growth versus untreated humidified surfaces.*)



(will be placed adjacent to the current claim: *Just drop in humidifier tank.*)



(will be placed adjacent to the Directions for Use section)

Optional Marketing Graphic

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

