



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

JUN 11 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Crowell & Moring LLP
Agent for K2 Concepts
1001 Pennsylvania Avenue, NW
Washington, DC 20005-2595

Attention: Mike Kelley
Regulatory Manager

Subject: Aquastat-XR
EPA Registration. No. 79630-2
Notification Dated April 7, 2010

This will acknowledge receipt of your notification, submitted under the provisions of FIRRA Section 3(c)(9). The company is submitting this notification to request the following:

- Label change to include new pests (i.e., mold and mildew)

The notification is in compliance with PR Notice 98-10 and is acceptable. This letter supersedes the previous correspondence (letter dated May 5, 2010) sent to your company. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

A handwritten signature in black ink that reads "M Swindell".

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

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



Office of Pesticide Programs

K2 Concepts Incorporated
114 N. Prince St. 3rd Floor
Lancaster, PA 17603

MAY - 5 2010

Attention: James C. Chen

Subject: Aquastat XR
EPA Registration No. 79630-2
Notification Dated April 7, 2010

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification:

- Label Change to include new pests (i.e., mold and mildew)

General Comments:

Based on a review of the submitted material, the following comments apply:

The Notification is not in compliance with PR Notice 98-10 and is not acceptable. This request must be handled under the Amendment process.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely

A handwritten signature in black ink, appearing to read "M Swindell".

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



EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other - Notification

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 79630-2	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aquastat XR	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) K2 Concepts Incorporated 114 N. Prince St. 3rd Floor Lancaster, PA 17603 <input checked="" 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. <u>N/A</u> Product Name <u>N/A</u>	

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 to include new pests (i.e., mold and mildew) pursuant to PR Notice 98-10 (Adding or Deleting Pests (Section II.B.)) This notification is consistent with the guidance in PR Notice 98-10 and the requirements of EPA's regulations at 40 CFR § 152.46. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 19 U.S.C. § 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 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	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name James C. Chen	Title Counsel for K2 Concepts, Inc. Crowell & Moring LLP	Telephone No. (Include Area Code) (202) 624-2570
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 	3. Title Counsel for K2 Concepts, Inc. Crowell & Moring LLP	
4. Typed Name James C. Chen	5. Date APRIL 7 2010	

JOSEPH R. PITTS
16TH DISTRICT, PENNSYLVANIA

GABE NEVILLE—WASHINGTON CHIEF OF STAFF
TOM TILLET—DISTRICT CHIEF OF STAFF

420 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2411

150 NORTH QUEEN STREET
SUITE 716
LANCASTER, PA 17603
(717) 393-0667

POST OFFICE BOX 837
UNIONVILLE, PA 19375
(610) 429-1540

www.house.gov/pitts

COMMITTEE ON
ENERGY AND COMMERCE

Congress of the United States
House of Representatives

Washington, DC 20515-3816

May 14, 2010

COMMISSION ON SECURITY AND
COOPERATION IN EUROPE

CONGRESSIONAL—EXECUTIVE
COMMISSION ON CHINA

ASSISTANT REPUBLICAN WHIP

Mr. David McIntosh
Associate Administrator for Congressional and Intergovernmental Relations
Environmental Protection Agency
1200 Pennsylvania Avenue, NW, Room 3426 ARN
Washington, DC 20460

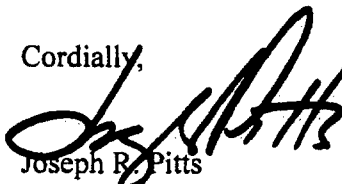
Dear Mr. McIntosh:

The attached communication is sent for your consideration. Your investigation of the statements contained therein would be helpful. In addition, I would greatly appreciate any information necessary to make a satisfactory reply to my constituent.

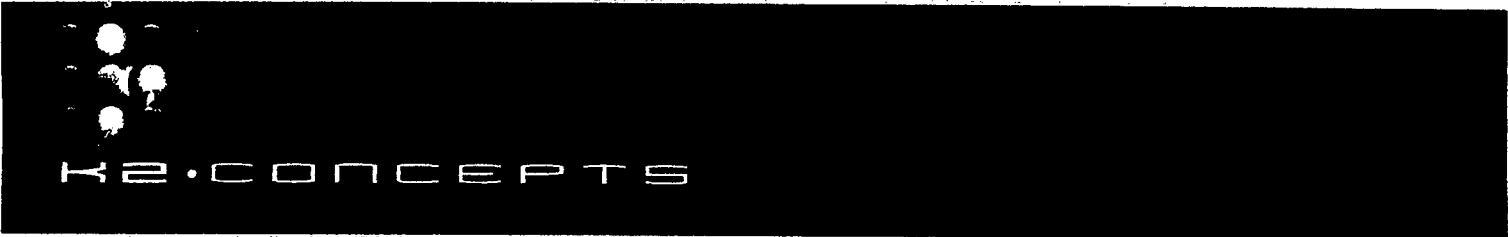
Thank you for your cooperation in this regard. I look forward to hearing from you at your earliest opportunity. Please respond to my Lancaster office at: 150 North Queen Street, Suite 716

Lancaster, PA 17603
717-393-0667

Cordially,


Joseph R. Pitts
Member of Congress

JRP/jmh



corporate office
114 N Prince Street, 3rd floor
Lancaster, PA 17603
USA

research center
Clark Atlanta University
223 James P Brawley Drive, SW
Atlanta, GA 30314
USA

US Congressman Joe Pitts
150 North Queen Street
Suite# 716 (7th floor)
Lancaster, PA 17603

RE: EPA Office of Pesticide Programs

sent via FEDEX

on the web
www.k2conceptsinc.com

May 13, 2010

main +1 717 207 0820
fax +1 717 207 0822
info@k2conceptsinc.com

Dear Congressman Pitts,

My name is Bryan Kepner. I am the President and CEO of K2 Concepts Incorporated, with our corporate office at 114 N. Prince St, Lancaster PA 17603. My company is in the business of developing and manufacturing environmentally friendly germ and mold control chemicals for use in the consumer products industry. Our list of customers includes companies such as Wal-Mart, Target, Kmart, Home Depot etc. In addition to our headquarters being located here, we have contracts with several local companies to produce products for us. We therefore are proud to directly and indirectly employ many people here in Lancaster County.

I could use your assistance regarding some recent dealings with the EPA's Office of Pesticide Programs (EPAOPP) in Washington DC.

In the past we have had a very good relationship with the above Federal agency as they have been instrumental at assisting us to meet the necessary regulatory requirements to bring our products to market in a timely manner, however, recently we have noticed a significant change in the level of cooperation and attentiveness by them. It has unfortunately gotten to the point where it is now affecting our financial sustainability.

Specifically, we manufacture patented eco-friendly mold and fungi controlling agents trade named "Aquastat XR and XRC". We are attempting to add additional marketing claims to the registered labels in order that our customers can state the mold and fungi controlling abilities of these products on the packaging. The Code of Federal regulations require that in order to add additional marketing claims to the registered labels of these products (on file with EPA), we must submit a formal notification to EPAOPP, allowing EPAOPP the ability to determine if the new claims are in compliance with the EPA's regs. In order to do this we submitted a formal "Notification" to the EPAOPP notifying them that we wish to make a marketing claim on the product stating that the Aquastat XR and XRC and fungi and mold control agents. This notification was submitted on April 7th, 2010 by our regulatory counsel and agent in Washington DC.

It is important to note that prior to submitting the notification, our agent contacted the EPAOPP directly to speak with them and get their "blessing" that we are taking the appropriate path by filing the notification and that the claims we are requesting meet the EPA's requirements for approval...He received this blessing. Unfortunately one month later we received a form document from the EPAOPP letting us know that our

request has been denied as it was "not in compliance with PR Notice 98-10 and is not acceptable" (copies of the letters have been attached herewith).

PR Notice 98-10 specifically states:

"A claim against a pest that does not pose a threat to public health, except termites, **may be added to the label...** [acceptable pests include fungi and mold]

Also important to note is that we have another product registered with EPA that contains the same eco-friendly active ingredient (Aquastat XR). The device that contains the Aquastat XR is trade named "Protec Antimicrobial Cleaning Cartridge". The Protec Cartridge was approved several years ago by EPAOPP to carry the "mold and fungi control" claim. This decision was based purely on the fact that the cartridge contains the Aquastat XR fungi and mold control agent aforementioned above.

In conclusion:

1. The Notification our agent submitted on our behalf to EPAOPP falls squarely within the guidelines of PR Notice 98-10, which is contrary to the EPAOPP's statement on their letter(s).
2. Our agent took the proactive approach by "pre-clearing" our request with the EPA prior to formally submitting the notification yet still it was rejected.
3. Had the EPAOPP taken the time to look, they would have noticed that our company has already received approval from EPAOPP on this same active ingredient (Aquastat XR) in another registered product.

Representative Pitts, as you can imagine this lack of cooperation and diligence by EPAOPP burdens our company with significant additional costs and a heavy financial strain, which we cannot afford under any circumstance but especially in this difficult economy. We literally have hundreds of thousands of dollars and 2 local supply contracts riding on our ability to gain EPAOPP's approval on this product. If we are unable to resolve this issue in a timely manner with the EPAOPP we will lose the interest of our customers, the Wal-Mart's of the world, which could have a significant effect on our business and our local activities.

We simply are looking for an honest effort from the EPAOPP to help us bring this important product to the consumer under the guidelines that are set forth in the CFR. At this point we are incredibly frustrated and are pleading for any help you could offer.

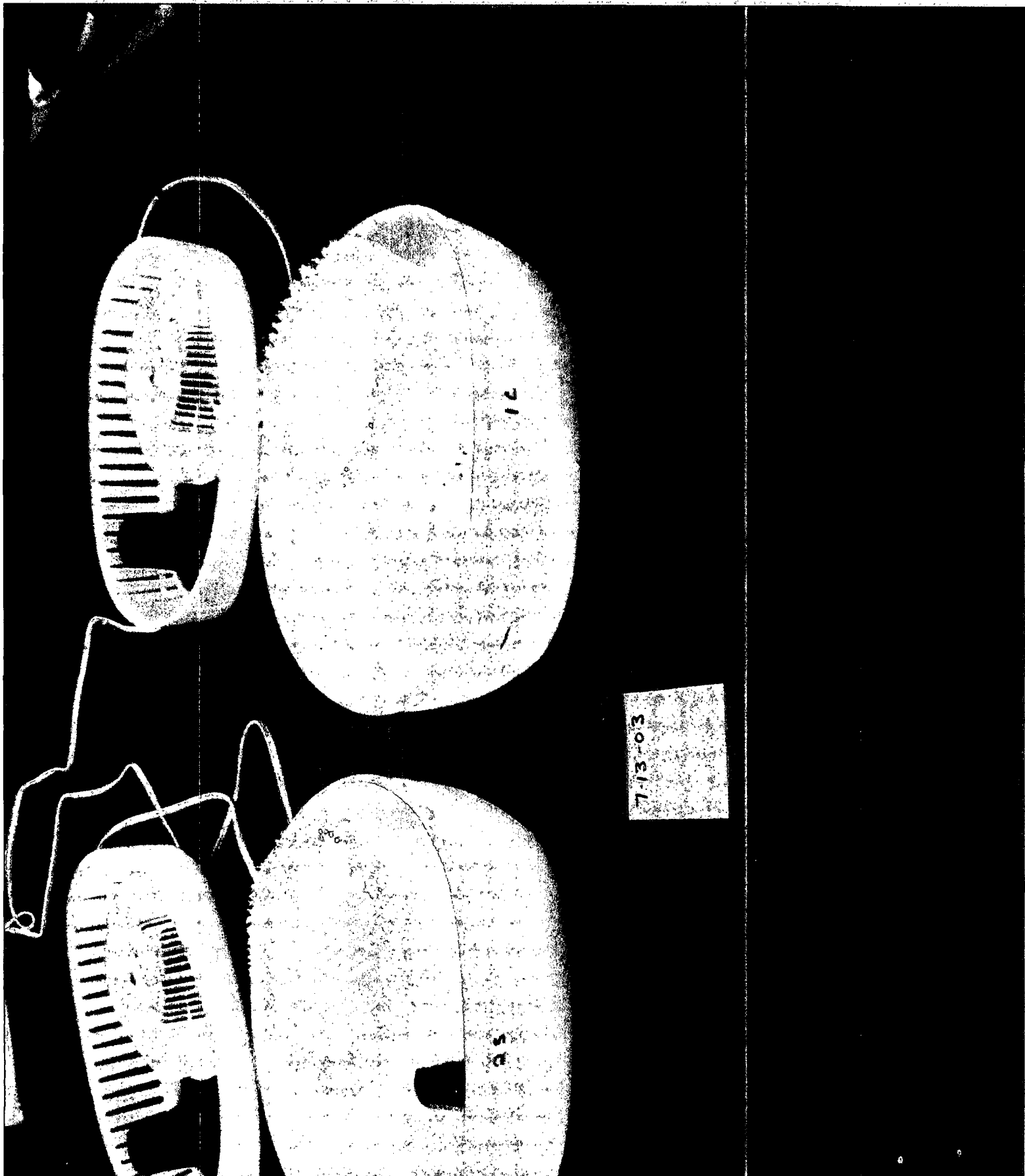
Thank you for your patience and thank you in advance for any aid you can offer.

With Sincere Regards,

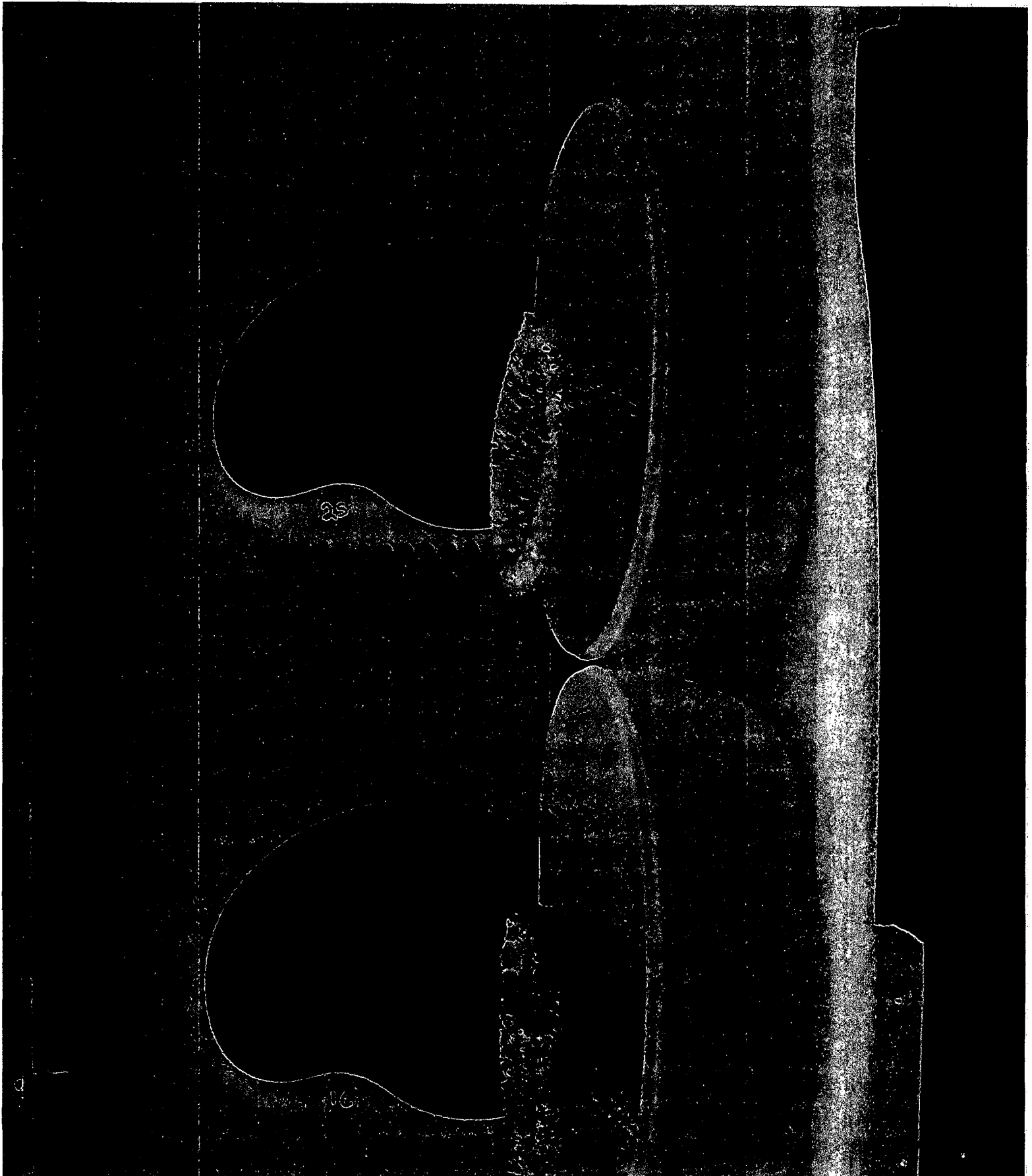


Bryan E. Kepner

Pres./CEO
K2 Concepts Incorporated



713-03



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9/11



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

April 7, 2010

1757:
103575-000001

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

Re: Aquastat-XR, EPA Reg. No. 79630-2
Notification Per PR 98-10 – Labeling Notification: Adding or Deleting Pests

Dear Marshall:

On behalf of K2 Concepts, Inc. (“K2” or “the Company”), enclosed please find a notification consistent with PR Notice 98-10 for product labeling notifications under Section II, to add new pests to the product registration referenced above. As mandated in PR Notice 98-10, the pests proposed for addition are not-public health related. Moreover, K2 has conducted and will maintain efficacy testing in accordance with the EPA’s Pesticide Assessment Guidelines, Subdivision G, Series 93: Efficacy of Fungicides.

Enclosed with this application please find the following:

- 1. EPA Form 8570-1
- 2. One copy of the label with the proposed revision highlighted in yellow.

If you have any questions or comments regarding this application, please feel free to contact me.

Sincerely,

James C. Chen, Counsel to K2 Concepts, Inc.

cc: Bryan Kepner, K2 Concepts, Inc.

10/11

[] denotes alternate and/or language



K2 Concepts, Inc
2625 Piedmont Rd. NE
Atlanta, GA 30324
(404) 452-9010

AQUASTAT® - XR

An antimicrobial agent for manufacturing or fabricating bacteriostatic [and][or] fungistatic water filters

Active Ingredient:	
Silver (as elemental)	1.4%
Other ingredients	98.6%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

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 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 poison control center or doctor for 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 poison control center or doctor for treatment advice
FOR MEDICAL ASSISTANCE, CALL 1-800-222-1222	

EPA Reg. No. 79630-2

EPA Establishment No. 79630-GA-001

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.

ENVIRONMENTAL HAZARDS

- This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a 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 to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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

- AQUASTAT-XR is to be used only for manufacturing or fabricating bacteriostatic [and] [or] fungistatic water filters. Filter manufacturers or formulators who use this product are responsible for providing data to US EPA to support any necessary registrations. AQUASTAT-XR is to be used to protect the water filter itself against the growth of bacteria, [mold] [and] [or] [mildew] and to prevent odors and unpleasant tastes or discoloration.

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STORAGE AND DISPOSAL

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

- **Pesticide storage:** Do not store in areas accessible to children. Keep product dry and containers covered during storage.
- **Pesticide disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility
- **Container disposal:** [only one will appear, based on the container type]

Plastic containers: Triple rinse (or equivalent). Then offer for recycling or recondition, 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.

Fiber drums with liners: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residues into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state authorities. If drum is contaminated and cannot be reused, dispose of it in the manner required for the liner.