

79533-1

2/28/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FEB 28 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Abigail T. Downs, Agent for Wisconsin Pharmacal
c/o Technology Sciences Group
1150 18th Street NW, Suite 1000
Washington, D.C. 20036

Subject: Potable Aqua
EPA Registration Number 79533-1
Notification Date: February 25, 2014
Notification Pin Punch: February 25, 2014

Dear Ms. Downs:

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c) 9.

Proposed Notification


- Revisions of Pesticide Storage and Disposal statements and the addition of labeling claims including a company web site.

General Comment

- Based on a review of the material submitted, the Notification is acceptable. Should you wish to retain a reference to the company's website on your label, you are advised that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 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. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075 or Luminello.Tom@EPA.GOV.

Sincerely,

for 
Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

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	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 79533-1	2. EPA Product Manager Jacqueline Hardy	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wisconsin Pharmacal Company, LLC / Potable Aqua	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Wisconsin Pharmacal Company, LLC 1 Pharmacal Way Jackson, WI 53037 <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.)

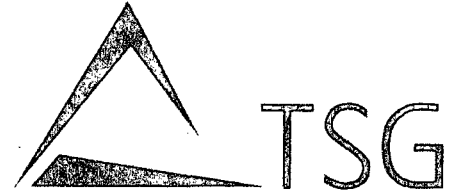
Notification to update product label per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is 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. Please confirm receipt with Abigail Downs: adowns@tsgusa.com or via phone (202) 828-8992.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container		
* Certification must be submitted			<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph Paper glued 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 Abigail Downs	Title Regulatory Consultant	Telephone No. (Include Area Code) 202-828-8992
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 both under applicable law.		6. Date Application Received (Stamped)
2. Signature 		
3. Title Regulatory Agent to Wisconsin Pharmacal Company, LLC		
4. Typed Name Abigail T. Downs		5. Date February 25, 2014



Technology Sciences Group Inc.

1150 18th Street, NW, Suite 1000
 Washington, D.C. 20036
 Direct: (202) 828-8992
 Fax: (202) 872-0745
 E-Mail: adowns@tsgusa.com

Jacqueline Hardy, PM 34
 Attn. Tom Luminello
 Antimicrobial Division (7504P)
 Office of Pesticide Products
 U.S. Environmental Protection Agency
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, VA 22202-4501

February 25, 2014

Re: Resubmission of Notification to Update Product Label per PR Notice 98-10
Company Name: Wisconsin Pharmacal Company, LLC
Product Name: *Potable Aqua*
EPA Registration Number: 79533-1

Dear Mr. Luminello,

Technology Sciences Group, Inc., on behalf of Wisconsin Pharmacal Company, LLC, is re-submitting the enclosed notification to update the Storage and Disposal language of the product label. This notification further adds several optional label claims to the product label and corrects a typo in the spelling of the term "cysts." This notification was initially submitted on January 24, 2014. The Agency rejected the notification on February 19, 2014 on the basis that, "the addition of "cysts" is too broad." In a February 25 phone call, I requested clarification of the Agency's concern as the change to the term "cysts" on the label was a correction of a typo, not the addition of the term. "Cysts" has been on the label, spelled "cycsts", since at least 2009 in this context. You agreed to re-do your review with this knowledge.

Please see the following enclosed in support of this submission:

1. EPA Form 8570-1;
2. Revised redline version of the label;
3. One clean revised copy of the proposed label.

Thank you for offering to re-do and expedite your review. Please do not hesitate to contact me with any questions via phone (202) 828-8992 or e-mail at adowns@tsgusa.com.

Sincerely,

Abigail T. Downs
 Regulatory Consultant

POTABLE AQUA®

Alternate Names:

- Potable Aqua Water Purification Technology 1
- Potable Aqua Water Purification Technology 1 2
- Potable Aqua Traveler
- Coleman® Drinking Water Purification Tablets
- Emergency Drinking Water Germicidal Tablets

Active Ingredient

Tetraglycine Hydroperoxide	16.7%
Other ingredients.....	<u>83.3%</u>
Total.....	100.0 %

Each Tablet Contains: 6.68% Titratable Iodine

WARNING:
KEEP OUT OF THE REACH OF CHILDREN

See First Aid and other Precautions on inside label (back panel).

[Peel Here→]

Back Panel/Inside panel

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

WARNING: Avoid eye contact. Will cause severe irritation to eyes and mucous membranes. Harmful if swallowed. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco

FIRST AID
<p>If in eyes:</p> <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 eyes.
<p>If swallowed:</p> <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
<p>Call a poison control center or doctor for further treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p>

GENERAL INFORMATION

POTABLE AQUA Drinking Water Germicidal Tablets are intended for emergency disinfection of drinking water.

Or

[Potable Aqua is] For use only when water is of questionable quality or known to be substandard.

Or

[Potable Aqua] is for use only when fresh drinking water is suspected or known to be bacteriological substandard.)

Not to be used on a continuous basis.

Or

[For short term or limited emergency use only.]

Potable Aqua (This product) has not been tested for effectiveness at inactivating Cryptosporidium cysts.

Or

(Potable Aqua (This product) has not been shown to inactivate Cryptosporidium cysts.)

DIRECTIONS

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

Note to reviewer: Directions will be based on how Potable Aqua is sold, by itself, with PA Plus or with a filter.

[● Potable Aqua Only]

Add 2 tablets of Potable Aqua to 1 quart or liter of water and cap loosely to allow a small amount of leakage. Wait 5 minutes. Shake container to allow screw threads on the closure to be moistened, then tighten cap. Wait 30 minutes before drinking.

[○ Potable Aqua with PA Plus]

Step 1: Add 2 tablets of Potable Aqua to 1 quart or liter of water and cap loosely to allow a small amount of leakage. Wait 5 minutes. Shake container to allow screw threads on the closure to be moistened, then tighten cap. Wait 30 minutes before drinking.

Step 2: P.A. Plus neutralizing tablets are for use AFTER water has been treated with Potable Aqua. Wait a minimum of 30 minutes after the addition of Potable Aqua before using P.A. Plus tablets. Adding the P.A. Plus tablet before 30 minutes may allow harmful bacteria to remain in the drinking water. DO NOT ADD POTABLE AQUA AND PA PLUS TABLETS AT THE SAME TIME.

Add 2 tablets of P.A. Plus per quart of water. Shake container well. Wait 3 minutes before drinking. Tablets do not have to completely dissolve to be effective.

[◆ Potable Aqua with Filter Bottle]

- [1. FILL:] Remove filter cap and fill bottle with water.
- [2. ADD] Add two Potable Aqua® Water Purification Tablets (included) and cap loosely to allow a small amount of leakage. Wait 5 minutes.
- [3. SHAKE] Replace filter cap and shake container to allow screw threads on the closure to be moistened, then tighten cap
- [4. DRINK] After 30 minutes, just squeeze for great tasting drinking water.

[Directions Graphic]

STORAGE & DISPOSAL

Pesticide Storage: Store in a cool dry place. **Pesticide Disposal and Container Handling:** Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions.

Net Contents:

[Potable Aqua] 0.21 oz. (6 g) (50 Tablets)

50 Tablets (For Solution)

[P.A. Plus 50 Tablets]

[Water Bottle with 2 micron filter]

Wisconsin Pharmacal Company, LLC

1 Pharmacal Way, Jackson WI 53037

Questions or Comments call 1-800-558-6614

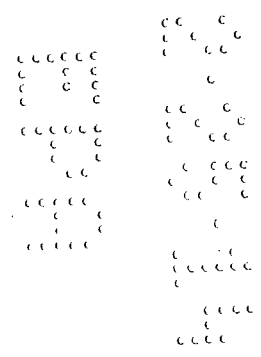
[www.pharmacalway.com]

Made in USA

[Filter and Bottle Made in United Kingdom]

EPA Reg. No.: 79533-1

EPA Est. No.: 79533-WI-1



Note to reviewer: the following is considered optional marketing language.

IMPORTANT INFORMATION ON POTABLE AQUA

Keep cap on [Potable Aqua] bottle tightly sealed. Humidity, moisture and exposure to air will reduce effectiveness of tablets. We recommend that you do not keep an open bottle for more than one year. Unopened bottles should remain effective up to four years.

Recap bottle tightly. Keep tablets dry.

IMPORTANT INFORMATION ON BOTTLE AND FILTER

To avoid accidental leakage protect bottle from jarring impact, and ensure nozzle is closed and cap secure. Store bottle upright.

Retain packaging for instructions.

Filter Maintenance and Storage: When the Potable Aqua® Traveller™ will not be in use for long periods, flush the bottle and cap assembly with tap water. Replace the filter cap and store in an upright position. The useful life of the filter cartridge is variable dependent upon usage and water contamination. The cartridge is rated to filter up to 350 liters, but should be replaced when the bottle becomes too difficult to squeeze (i.e. the filter is blocked).

Optional statements

- For Advanced Water Purification Technology, you don't have to look further than the brand outdoor enthusiasts, travelers and militaries from around the world have been trusting for years.
- Where are you going?
- Can you trust hotel water?
- Will there be drinking water available on your travels?
- Run out of water on your hike?
- Got a survival kit?-What about water?
- Ideal for: Camping, International Travel, Hunting, Homeland Emergency, Hiking, Fishing Cycling, Sports, Day Trips, Expeditions and more.
- Potable Aqua® Emergency Drinking Water Germicidal Tablets Make Questionable Water Bacteriologically Suitable to Drink
- Emergency Drinking water
- When used as directed, they make water bacteriological suitable for drinking.
- Used worldwide by campers, hikers, military, emergency organizations, and any needing to drink water of questionable bacteriological quality.
- Effective against water of questionable bacterial quality
- Effective against cyst such as Giardia lamblia and bacteria such as Vibrio cholera.
- Potable Aqua has been proven effective against Giardia lamblia and Vibrio cholera when used as directed.
- Potable Aqua water purification tablets.
- Iodine-based compound (no chlorine)
- 2 tablets of Potable Aqua makes 1 quart of most water bacteriological suitable to drink.
- Uniform dosage per tablet assured - no guesswork.

- Easy to use
- Treats up to 25 quarts
- A must for first aid and survival kits
- Ideal for emergency use at home
- Use in emergency drinking water situations
- Makes questionable water bacteriological suitable to drink
- Iodine tablets water treatment
- Water Purification Technology (1)
- Effective water treatment made simple
- Do not ingest tablets. (Tablets not to be swallowed.)
- Includes Potable Aqua® Water Purification Tablets
- Trusted water purification technology used worldwide
- Potable Aqua® Water Purification Tablets are EPA registered.
- Ready in just 35 minutes
- Powered by Potable Aqua
- Emergency Drinking Water Germicidal Tablets

Note to reviewer: the following is considered optional marketing language.

- NSN 6850016181533
- MFD (date)
- EXP (date)
- Coleman® The Outdoor Company™
- www.potableaqua.com

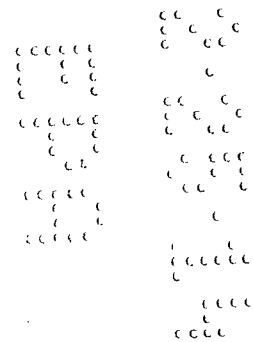
- Two Step Water Purification System
- 2 step treatment
- Eliminates undesirable color, taste and odor.
- No iodine taste.
- Includes Potable Aqua® Water Purification Tablets
- Removes undesirable odors, colors and tastes
- Great tasting water is produced ready to drink!
- No unpleasant taste

- P.A. Plus are neutralizing tablets for use after water has been treated with Potable Aqua.
- P.A. Plus [tablets] neutralize[s] the iodine after-taste and color.
- Germicidal Tablet Purification Kit with P.A. Plus
- Includes 1 liter collapsible bottle
- 2 steps: (1) Potable Aqua disinfects drinking water (2) P.A. Plus neutralizing tablets remove iodine taste and color
- Water Purification Technology 1 2
- Water Purification Technology

◆ Leading technology developed through the research of aerospace scientists, medical researchers and water purification specialists, this easy to use lightweight filter removes bad tastes, sediment, and waterborne pathogens.

◆ Both simple and effective, now you can produce bottle quality water from any fresh water source.

- ◆ Replacement filters and purification tablets available
- ◆ A gentle squeeze forces the water through the 2 micron unique filtration system of absorbing materials.
- ◆ Advanced Water Purification Technology
- ◆ The Potable Aqua® Traveller™ is a personal water filter in the form of a convenient water bottle.
- ◆ Fill the Potable Aqua® Traveller™ from ANY fresh water source and you will be able to enjoy palatable, clear and odorless drinking water.
- ◆ Potable Aqua® delivers bottled water quality in a simple to use hand held purification system.
- ◆ The filter removes bacteria and protozoa such as Giardia and Cryptosporidium.
- ◆ Removes Pathogens like Giardia and Cryptosporidium
- ◆ Potable Aqua® Traveller™ is approved by the International Survival Instructors Association.
- ◆ Endorsed by the Hospital for Tropical Diseases London. (with logo)
- ◆ Approved by Wilderness Medicine Institute (NOLS) (with logo)
- ◆ Potable Aqua® Traveller™ Water Purification System
- ◆ 3 Easy Steps to purified water
- ◆ Effective against cysts and bacteria -including Giardia lamblia, Vibrio cholera and Cryptosporidium
- ◆ Eliminates Color, Taste, Odor- Filters trace iodine and other sediment.
- ◆ Purification not just filtration! Don't confuse the Potable Aqua® Traveller™ with an ordinary filter. This unique purification system provides you with drinking water wherever your travels take you.
- ◆ Advanced Design
- ◆ Easiest and fastest water purification system available! Flow rates up to 30 ml per second!
- ◆ Exclusive easy-flow filter design draws water on all sides, allowing you to drink the entire bottle before filling*
- ◆ Perfect center of gravity creates an easy-grip surface to help pump water fast.
- ◆ Precision-engineered bottle is designed to protect the filter from damage.
- ◆ Compact size is perfect for bike cages and backpack pouches.
- ◆ *More Drinking water per fill than most bottle systems on the market.
- ◆ Great tasting drinking water wherever your travels take you.
- ◆ The Potable Aqua® Traveller™ is a water purifications system in a convenient, hand-held water bottle. This easy-to -use system combines the trusted quality of Potable Aqua® Water Purification Tablets with a proprietary filtration cap and unique bottle design. Together, these elements remove bacteria, cysts and sediment and provide palatable, clear, odorless, and bacteriologically suitable drinking water from any fresh water source.
- ◆ Nothing else to carry! No tiresome pumping!
- ◆ Up to 450 refills (350 liters) from each filter!
- ◆ Replacement filters sold separately.
- ◆ Purification and Filtration in one system
- ◆ Filtration]



KEY

Optional statements for:

- ◆ Water bottle and filter packages with Potable Aqua only
- PA Plus with Potable Aqua packages only
- Potable Aqua containing packages

[text in brackets] indicates optional text
 (text in parentheses) indicates alternate text which may be used in place of adjacent text.