



Office of Pesticide Programs

APR 3 2009

Jean Killoren
Agent for Wisconsin Pharmacial Company
c/o Killoren Regulatory Consulting
316 Highland Ave.
Hartford, WI 53027

FILE COPY

Subject: Potable Aqua
EPA Registration No. 79533-1
Application Date: March 13, 2009
Receipt Date: March 19, 2009

Dear Ms. Killoren:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Addition of alternate brand name: "Coleman Drinking Water Purification Tablets"
- Addition of "non-refillable container" and "Do not reuse or refill this container"
- Addition of marketing claims

General Comments

Based on a review of the material submitted, the following comment applies:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6345.

Sincerely,

Wanda Y. Henson
Product Reviewer (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)



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 79533-1 | 2. EPA Product Manager Emily Mitchell | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Potable Aqua | PM# 32 | |
| 5. Name and Address of Applicant (Include ZIP Code) Wisconsin Pharmacal Company, LLC c/o Killoren Regulatory Consulting 316 Highland Ave. Hartford, WI 53027 <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 label change per PR-Notice 2007-4 and PR Notice 98-10. This notification is consistent with the guidance in PR Notice 2007-4, PR Notice 98-10 and the requirement of EPA regulations at 40 CFR 152.46, 156.10, 156.140, 156.144, 156.146, and 153.156. 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 the amended label is not consistent with the terms of 40 CFR 152.46, 156.10, 156.140, 156.144, 156.146, and 153.156 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.

ALL CHANGES ARE CLEARLY MARKED.

NOTIFICATION OF: Addition of "non-refillable container" and "Do not reuse or refill this container." per PR-Notice 2007-4;
 NOTIFICATION OF ALTERNATE BRAND NAME: Coleman Drinking Water Purification Tablets; per PR-Notice 98-10.
 NOTIFICATION OF ALTERNATE NON-FIFRA MARKETING CLAIMS: Ready in just 35 minutes, Powered by Potable Aqua, Emergency Drinking Water Germicidal Tablets.

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 |
| | | | | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| * Certification must be submitted | | | | <input type="checkbox"/> Other (Specify) _____ | |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 50 tablets | | 5. Location of Label Directions <input checked="" type="checkbox"/> on label | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph 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 Jean Killoren | Title Authorized Agent | Telephone No. (Include Area Code) (262) 844-7623 |
| 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 Authorized Agent | |
| 4. Typed Name Jean Killoren | 5. Date March 9, 2009 | |

3/17

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 Hydroperiodide 16.7%

Other ingredients..... 83.3%

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).

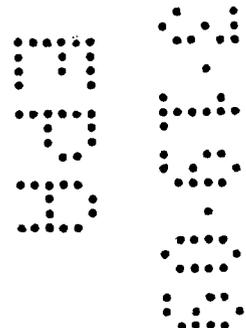
[Peel Here →]

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 | |
| 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 eyes. |
| If swallowed: | <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. |
| 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. | |



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 of 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 of 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 P.A. 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: Store in a cool dry place. **If empty:** Nonrefillable container. Do not reuse or refill this container. 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]

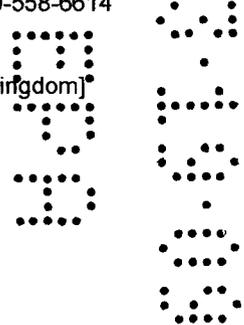
Wisconsin Pharmacal Company, LLC Jackson WI 53037

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

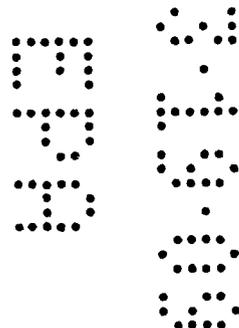
To avoid accidental leakage protect bottle from jarring impact, and ensure nozzle is closed and cap secure. Store bottle upright.

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 fist-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



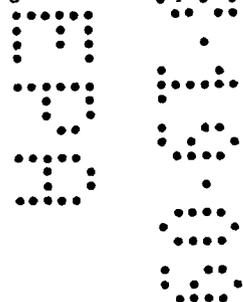
6/7

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

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

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



3/1

KEY

Optional statements for:

- ◆ Water bottle and filter packages with Potable Aqua only
- P.A. 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.

Italicized and underlined

new text

~~Strikethrough~~

text deleted

