

79533-1

1/5

January 28, 2004

Jean Killoren
Authorized Agent
Wisconsin Pharmacal Company, LLC
1 Pharmacal Way
Jackson, WI 53037

Subject: Potable Aqua
EPA Registration No. 79533-1
Application Date: December 22, 2003
Receipt Date: January 7, 2004

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 two (2) alternate brand names :
 "Potable Aqua Water Purification Technology 1"
 "Potable Aqua Water Purification Technology 1 2"

General Comments

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

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 Mitchell
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL	7510 C	7510C					
SURNAME	E. Berg	Mit H					
DATE	1/28/04	1-28-04					



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 79533-1	2. EPA Product Manager Robert Brennis	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 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 of Alternate Brand Names per PR Notice 98-10.

(1) Potable Aqua Water Purification Technology 1, (2) Potable Aqua Water Purification Technology 1 2

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.

Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
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		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		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 <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input 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 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. DLTJ Application Received (Stamped)
2. Signature 	3. Title Authorized Agent	
4. Typed Name Jean Killoren	5. Date December 22, 2003	

FRONT

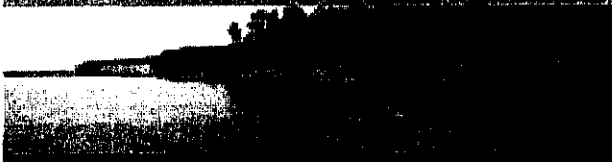
<p>PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS — WARNING: Avoid eye contact. Will cause severe irritation to eyes and mucous membranes. Do not ingest tablets. Avoid contamination of food. Wash after handling.</p>	<p>FPO Varnish Free Area</p>	<p>DIRECTIONS: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Add 2 tablets to 1 quart or liter of water and cap loosely to allow 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. RECAP BOTTLE TIGHTLY. KEEP TABLETS DRY.</p>	<p>FPO Varnish Free Area</p>	<p>potable aqua water purification technology EMERGENCY DRINKING WATER GERMICIDAL TABLETS</p> <p>Active ingredient: tetraglycine hydroperiodic acid 16.7% Other ingredients 83.3% Total 100.0%</p> <p>Each tablet contains 6.68% Titratable iodine WARNING: KEEP OUT OF THE REACH OF CHILDREN See First Aid and other precautions on inside label. Net Contents 0.21 oz (6g) 50 Tablets (For Solution) EPA Reg. No. 79533-1 EPA Est. No. 79533-WI-1</p>
<p>FIRST AID</p> <p>IF IN EYES: Hold eye open & rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</p> <p>Call a poison control center or doctor for further treatment advice. Have the product container with you when calling a poison control center or doctor, or going for treatment.</p>				

BACK

POTABLE AQUA™ is for use only when water is of questionable quality or known to be substandard. Not to be used on a continuous basis. This product has not been shown to inactivate *Cryptosporidium* cysts. For short term or limited emergency use only.

STORAGE AND DISPOSAL: Store in a cool, dry place. **IF EMPTY:** Do not reuse this container. Place in trash or offer for recycling if available. **IF PARTLY FILLED:** Call your local solid waste agency for disposal instructions.

potable aqua
 water purification technology



EMERGENCY DRINKING WATER GERMICIDAL TABLETS

iodine tablets
 water treatment

❓ Makes questionable water bacteriologically suitable to drink

☑️ Proven effective against *Giardia lamblia* when used as directed

Treats up to 25 quarts

effective water treatment made simple

potable aqua
 water purification technology
EMERGENCY DRINKING WATER GERMICIDAL TABLETS

GENERAL INFORMATION
POTABLE AQUA™ Drinking Water Germicidal Tablets are intended for emergency disinfection of drinking water. When used as directed, they make most water bacteriologically suitable for drinking. Used worldwide by campers, hikers, motorists, emergency organizations and anyone needing to drink water of questionable bacteriological quality. **POTABLE AQUA™** is for use only when drinking water is suspected or known to be bacteriologically substandard. Not to be used on a continuous basis. For short term or limited emergency use only.

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

- Iodine-based compound (no chlorine).
- No unpleasant taste.
- Easy to use.
- 2 tablets of **POTABLE AQUA™** makes 1 quart of most water bacteriologically suitable to drink.
- Uniform dosage per tablet assured — no guesswork.
- A must for first-aid and survival kits.
- Ideal for emergency use at home.
- **POTABLE AQUA™** Germicidal Tablets have 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. Add 2 tablets 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.

RECAP BOTTLES TIGHTLY. KEEP TABLETS DRY.

STORAGE & DISPOSAL: Store in a cool dry place. **IF EMPTY:** Do not reuse this container. Place in trash or offer for recycling if available. **IF PARTLY FILLED:** Call your local solid waste agency for disposal instructions.


PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS. WARNING: Avoid eye contact. Will cause severe irritation to eyes & mucus membranes. Do not ingest tablets. Avoid contamination of food. Wash after handling.

FIRST AID

IF IN EYES: Hold eye open & 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 further treatment advice. Have the product container with you when calling a poison control center or doctor, or going for treatment.

Net Contents 0.21 oz. (6g) 50 Tablets
 E.P.A. Reg. No. 79533-1 E.P.A. Est. No. 79533-WI-1



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WISCONSIN PHARMACAL CO., LLC Jackson, WI 53037
 Questions or comments? Call 1.800.658.6614
 www.pharmaceuticalway.com Made in USA

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potable aqua
water purification technology
P.A. Plus Tablets (Per Solution)

2

Directions: Read directions carefully before use.
P.A. Plus Tablets neutralize the iodine taste and color AFTER water has been treated with POTABLE AQUA Emergency Drinking Water Tablets. Wait a minimum of 20 minutes after the addition of POTABLE AQUA before adding the P.A. Plus Tablets. Adding the P.A. Plus Tablets before 20 minutes may cause harmful organisms to remain in the drinking water. DO NOT ADD POTABLE AQUA AND P.A. Plus TABLETS AT THE SAME TIME.

Removes Iodine Taste & Color After Water Has Been Treated With POTABLE AQUA® Tablets 30 Tablets (Per Solution)

Active Ingredient:
Ascorbic Acid 45 mg per tablet
Wisconsin Pharmaceutical Co., LLC
Jackson, WI 53032
www.pharmaceuticalway.com

KEEP OUT OF REACH OF CHILDREN

FPO Varnish Free Area

potable aqua
water purification technology

EMERGENCY DRINKING WATER TETRAVICAL TABLETS WITH P.A. PLUS

Iodine tablets w/neutralizer
2 step water treatment

Takes questionable water bacteriologically suitable to drink with no iodine taste or color

Proven effective against *Giardia lamblia* when used as directed

2 steps: (1) Potable Aqua disinfects drinking water (2) P.A. Plus neutralizing tablets remove iodine taste and color

Treats up to 25 quarts

effective water treatment made simple

potable aqua
water purification technology

EMERGENCY DRINKING WATER TETRAVICAL TABLETS WITH P.A. PLUS

FIRST AID

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WISCONSIN PHARMACEUTICAL CO., LLC Jackson, WI 53032
Questions or comments? Call 1.800.958.6614
www.pharmaceuticalway.com Made in USA

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WISCONSIN PHARMACEUTICAL CO., LLC JACKSON, WI 53037
Divisions of companies? Call 1-800-888-8879
www.potableaqua.com Made in USA



FIRST AID
If you experience any allergic reactions, such as hives, difficulty breathing, or swelling of the face, lips, tongue, or throat, stop using the product immediately and seek medical attention. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe dizziness, fainting, or loss of consciousness. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe stomach pain, nausea, or vomiting. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe headache, dizziness, or confusion. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe rash, itching, or redness. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe sore throat, difficulty swallowing, or difficulty breathing. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe chest pain, difficulty breathing, or difficulty swallowing. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe weakness, fatigue, or dizziness. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe irritability, aggression, or changes in behavior. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in vision, such as blurred vision or double vision. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in hearing, such as ringing in the ears or hearing loss. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in taste, such as a metallic taste or loss of taste. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in smell, such as a metallic smell or loss of smell. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in skin, such as dry skin, itching, or redness. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in hair, such as hair loss or changes in hair texture. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in teeth, such as tooth pain or changes in tooth color. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in nails, such as nail pain or changes in nail color. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in menstrual cycle, such as irregular periods or changes in flow. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in fertility, such as difficulty getting pregnant or changes in menstrual cycle. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in pregnancy, such as miscarriage or stillbirth. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in breastfeeding, such as changes in milk production or changes in milk taste. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in lactation, such as changes in milk production or changes in milk taste. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in lactation, such as changes in milk production or changes in milk taste. If you experience any of the following symptoms, stop using the product immediately and seek medical attention: severe changes in lactation, such as changes in milk production or changes in milk taste.

DIRECTIONS
1. Fill a clean container with water.
2. Add 1 Potable Aqua tablet to the water.
3. Stir the water for 1 minute.
4. Let the water stand for 15 minutes.
5. Drink the water.

IMPORTANT INFORMATION ON POTABLE AQUA
Potable Aqua is a water purification tablet that kills bacteria, viruses, and protozoa. It does not remove chemicals, heavy metals, or nitrates. It is not intended for use in areas with high iron or manganese content. It is not intended for use in areas with high turbidity. It is not intended for use in areas with high salinity. It is not intended for use in areas with high hardness. It is not intended for use in areas with high pH. It is not intended for use in areas with high acidity. It is not intended for use in areas with high alkalinity. It is not intended for use in areas with high conductivity. It is not intended for use in areas with high total dissolved solids. It is not intended for use in areas with high total suspended solids. It is not intended for use in areas with high total phosphorus. It is not intended for use in areas with high total nitrogen. It is not intended for use in areas with high total organic carbon. It is not intended for use in areas with high total organic nitrogen. It is not intended for use in areas with high total organic phosphorus. It is not intended for use in areas with high total organic nitrogen. It is not intended for use in areas with high total organic phosphorus. It is not intended for use in areas with high total organic nitrogen. It is not intended for use in areas with high total organic phosphorus.

EMERGENCY DRINKING WATER
Potable Aqua is a water purification tablet that kills bacteria, viruses, and protozoa. It does not remove chemicals, heavy metals, or nitrates. It is not intended for use in areas with high iron or manganese content. It is not intended for use in areas with high turbidity. It is not intended for use in areas with high salinity. It is not intended for use in areas with high hardness. It is not intended for use in areas with high pH. It is not intended for use in areas with high acidity. It is not intended for use in areas with high alkalinity. It is not intended for use in areas with high conductivity. It is not intended for use in areas with high total dissolved solids. It is not intended for use in areas with high total suspended solids. It is not intended for use in areas with high total phosphorus. It is not intended for use in areas with high total nitrogen. It is not intended for use in areas with high total organic carbon. It is not intended for use in areas with high total organic nitrogen. It is not intended for use in areas with high total organic phosphorus. It is not intended for use in areas with high total organic nitrogen. It is not intended for use in areas with high total organic phosphorus.

potable aqua
water purification technology

GENERAL INFORMATION
Potable Aqua is a water purification tablet that kills bacteria, viruses, and protozoa. It does not remove chemicals, heavy metals, or nitrates. It is not intended for use in areas with high iron or manganese content. It is not intended for use in areas with high turbidity. It is not intended for use in areas with high salinity. It is not intended for use in areas with high hardness. It is not intended for use in areas with high pH. It is not intended for use in areas with high acidity. It is not intended for use in areas with high alkalinity. It is not intended for use in areas with high conductivity. It is not intended for use in areas with high total dissolved solids. It is not intended for use in areas with high total suspended solids. It is not intended for use in areas with high total phosphorus. It is not intended for use in areas with high total nitrogen. It is not intended for use in areas with high total organic carbon. It is not intended for use in areas with high total organic nitrogen. It is not intended for use in areas with high total organic phosphorus. It is not intended for use in areas with high total organic nitrogen. It is not intended for use in areas with high total organic phosphorus.

potable aqua
water purification technology

potable aqua
water purification technology

EMERGENCY DRINKING WATER
GERMICIDAL TASTE - PROTECTIVE KIT
and P.A. PLUS



iodine tablets w/neutralizer + 2 step water treatment

	25 uses questionable water for emergency use. Suitable to drink with no iodine taste or color.		2 steps: 1) Potable Aqua disinfects drinking water (2) P.A. Plus neutralizing tablets remove iodine taste and color.
	Remain effective against Giardia Lamblia when used as directed.		Includes 1 liter collapsible bottle.

treats up to 25 quarts
effective water treatment made simple

- KIT CONTAINS:
- 1 liter collapsible bottle
- 50 Potable Aqua tablets
- 50 P.A. Plus tablets

CHOICE OF TRAVELERS,
CAMPERS & HIKERS

