

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

29 NOV 1994

Wisconsin Pharmacal Company
1 Repel Road
P.O. Box 198
Jackson, WI 53037

Attn: Jean Killoren

Subject: Potable Aqua
EPA Registration No. 305-37
Your Resubmission of June 1, 1994

The materials forwarded in response to EPA's letter of April 19, 1994 concerning your proposed label amendment has been reviewed. Please note the following.

1. The proposal to add a reference on the product label for the use of "P.A. Plus", an ascorbic acid tablet for use in the treated water, is acceptable. The Material Safety Data Sheet (MSDS) on the P.A. Plus tablet will be recorded in your product file.

2. The revised product labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Submit five copies of the finished, printed labeling before releasing the product for shipment.

a. Delete the statement "Prevents most stomach and intestinal disorders caused by drinking bacteriologically unsuitable water.". This is an implied health or safety claim and is not acceptable.

b. Submit a complete and updated Confidential Statement of Formula (CSF) for the subject product formulation which is in compliance with PR Notice 91-2. (Blank CSF forms are enclosed.)

c. Submit a separate CSF for the P.A. Plus tablet. (In column 15 of this CSF, you may list "water neutralizer".

CONCURRENCES

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|---------|------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | | |
| SURNAME | | | | | | | | |
| DATE | 9 NOV 1994 | | | | | | | |

If you should have any questions concerning this letter, you may call Robert Travaglino on (703) 305-6909.

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

29 NOV 1994

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended by the pesticide
registered under EPA Reg. No. ~~305-307~~ 305-37

MADE IN USA

E.P.A. Reg. No. 305-37
E.P.A. Est. No. 305-WI-1

POTABLE AQUA[®] with P.A. Plus

Emergency Drinking Water
2 STEP TREATMENT

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, militaries, emergency organizations, and anyone needing to drink water of questionable bacteriological quality.

For use only when water is of questionable quality or known to be substandard. Not to be used on a continuous basis.

P.A. Plus are neutralizing tablets for use after water has been treated with POTABLE AQUA.

P.A. Plus neutralizes the iodine after-taste and color.

IMPORTANT INFORMATION ON POTABLE AQUA

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.

- Prevents most stomach and intestinal disorders caused by drinking bacteriologically unsuitable water.
- Iodine-based compound (no chlorine).
- 1 tablet of POTABLE AQUA makes 1 quart of most water bacteriologically suitable to drink (2 tablets if Giardia is suspected).
- Uniform dosage per tablet assured - no guesswork.

WARNING: POTABLE AQUA tablets may be harmful if swallowed. Avoid eye contact. Will cause severe irritation to eyes and mucous membranes. Avoid contamination of food. Wash after handling. **FIRST AID:** If POTABLE AQUA tablet is swallowed, drink freely a thin paste of starch or flour (2 tablespoons in water), or drink a sodium thiosulfate solution (approx. 1/2 teaspoon in water). In case of contact with eyes, flush thoroughly with water. Call a physician.

DIRECTIONS

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

STEP 1: Add 1 tablet of POTABLE AQUA to 1 quart or liter of water and cap loosely to allow a small amount of leakage. Wait 3 minutes. Shake container to allow screw threads on the closure to be moistened, then tighten cap. Wait 10 minutes before drinking. *For Giardia control, or if water is of poor quality or very cold, use 2 tablets of POTABLE AQUA per 1 quart or liter of water and wait 20 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 20 minutes after the addition of POTABLE AQUA before using the P.A. Plus tablets. Adding the P.A. Plus tablet before 20 minutes may allow harmful bacteria or viruses to remain in the drinking water. **DO NOT ADD POTABLE AQUA AND P.A. Plus TABLETS AT THE SAME TIME.**

Add 1 tablet of P.A. Plus for every tablet of POTABLE AQUA used (up to a maximum of 2 tablets) per quart of water. Shake container well. Wait 3 minutes before drinking. Tablet does not have to completely dissolve to be effective.

Recap bottles tightly. Keep tablets dry.

DISPOSAL: Do not reuse bottles. Wrap and discard in a safe place.

POTABLE AQUA Net Contents 0.21 oz. (50 Tablets)

P.A. Plus Net Contents 50 Tablets

WYSCON SIN PHARMACAL CO., INC., Jackson, WI 53037

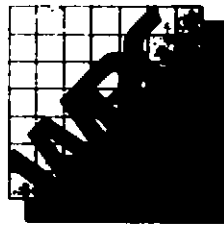


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Wisconsin Pharmaceutical Company

QUALITY ♦ INNOVATION

DIRECTIONS

Read directions carefully before use.
P.A. Plus tablets neutralize the sodium taste and odors AFTER water has been treated with FORMALIN® Emergency Drinking Water Tablets. Use a minimum of 20 tablets after the addition of FORMALIN® tablets using the P.A. Plus tablets. Adding the P.A. Plus tablets before 20 minutes may alter treated appearance in amount in the drinking water. DO NOT ADD FORMALIN AND P.A. Plus TABLETS AT THE SAME TIME.



Removes Sodium Taste and Odors After Water Has Been Treated With FORMALIN® Tablets
20 Tablets (Per Serving)

DIRECTIONS Cont.

20 minutes after treatment with FORMALIN, add 1 tablet of P.A. Plus to every gallon of FORMALIN and up to a maximum of 2 tablets per gallon of tap water. Refer amount used. Use 3 tablets before drinking. Tablets that are not used in completely sealed containers.
KEEP AWAY FROM REACH OF CHILDREN
Active Ingredient:
Ascorbic Acid 45 mg per tablet
WISCONSIN PHARMACEUTICAL CO., INC.
JACKSON, WI 53007

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