

75829-1

9/30/2008

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



Office of Pesticide Programs

Garrison Dental Solutions
110 DeWitt Lane
Spring Lake, MI 49456

SEP 30 2008

Attention: Clarke Reberg, Director
Product Development

Subject: H2Pro Maintenance Treatment
EPA Registration No. 75829-1
Amendment Dated August 1, 2008

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to add the following new package sizes, is acceptable.

- Clean Start Bottle A: adding a one gallon size – one to a lot
- Clean Start Bottle B: adding a one gallon size – one to a lot
- Maintenance Treatment: adding a 24 ounce size – 10 to a lot

A stamped copy of the “accepted” product labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

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

Enclosure

H₂Pro™ Bulk Clean Start™ Guide

Thank you for choosing H₂Pro Dental Waterline Treatment for your office. H₂Pro has been specially formulated and clinically proven to control odor-causing bacteria and clean dental unit waterlines. It is the **FIRST** product approved by the EPA for continuous use in dental units. It is designed for closed systems with self contained water bottles only.

The Clean Start™ treatment, with colloidal silver and hydrogen peroxide, is designed to power through accumulated build up. The Maintenance Treatment contains a controlled, minute amount of colloidal silver to keep things clean.

Our special formulation gives you the piece of mind of knowing that you are using the best possible product for your patients. This is all accomplished without adding any taste or scent to your treatment water, without any adverse affects to bond strength, while treating your sensitive equipment as mildly as distilled water.

Use of the following Clean Start™ process will give you the best, most rapid results.

STEP 1: For best results begin the Clean Start™ treatment at the end of the last business day of the week for your office.

IMPORTANT!!! Do not treat patients with the red Clean Start™ solution!

- After treating the last patient of the day, remove the water bottle from the dental chair to be treated and completely empty it.
- Using the manual dispenser pump provided, place four (1 oz.) pumps of both H₂Pro Clean Start Bottles A and B into empty dental chair water bottle.
- Reattach the water bottle to the chair and run all lines attached to the dental chair until the red coloration of the treatment solution appears exiting the lines. Place this card on dental chair during Clean Start™ treatment to prevent accidental ingestion.
- For best results allow the lines to sit unused for a minimum of 12 hours.
- Prior to returning the chair to patient use, remove the water bottle from the treated chair and completely drain remaining Clean Start™ Treatment solution from lines. (Discard solution accordingly.)

Re-treatment parameters: Proper H₂Pro Clean Start™ treatment followed by continuous use of Maintenance Treatment solution should be adequate to keep your lines clean. If there is a return of noticeable odor or if there appears to be any debris in the dental water effluent, re-treat with Clean Start. Part #HPCSB1

STEP 2: Begin H₂Pro™ Maintenance Treatment now to keep your lines clean.

Preparation and use of H₂Pro Maintenance Treatment

- Pour the entire contents of one (1) H₂Pro Maintenance Treatment bottle (Blue label) into dispensing container provided.
- Add seven (7) US gallons (26.5 liters) of distilled¹ or deionized¹ water (32:1 dilution) to the indicated on the dispenser container.
- Fill the dental chair water bottle with the prepared Maintenance Treatment from the dispenser container and reattach the water bottle to the chair.
- Run all lines attached to the dental chair until the blue coloration of the Maintenance Treatment is seen exiting the lines.
- The dental chair is now ready for patient use.
- Use prepared H₂Pro Maintenance Treatment continuously in the dental chair instead of distilled, deionized or tap water.

¹Use of tap water or bottled "Drinking" or "Spring" water is not recommended. Water quality from these sources varies and your results with H₂Pro may vary accordingly.

ORDERING GUIDE

HPM4-2 - 10 Maintenance Treatment refills

Garrison
Dental Solutions

We put ideas into practice.

150 DeWitt Lane
Spring Lake, MI USA
49456

phone 616.842.2244
toll free 888.437.0032 USA
fax 616.842.2430

web www.garrisondental.com
email gds@garrisondental.com

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

PESTICIDE STORAGE

Store at room temperature out of direct sunlight. Do not contaminate water, food or feed by storage or disposal.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Improper disposal of excess pesticide is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER DISPOSAL

Securely wrap original container in several layers of newspaper and discard in trash.



To reorder call 888.437.0032 or visit us at www.garrisondental.com



Bottle A

Dental Water Line Treatment

H₂Pro has been specially formulated and clinically proven to control odor causing bacteria and clean dental unit water lines.

Active Ingredient:	
Silver	0.0015%
Inert Ingredients:	99.9985%
Total	100.0000%

This product contains 0.0001245 lbs of silver per gallon.

Keep Out of Reach of Children

CAUTION

See First Aid Statements on Side Panel

Manufactured by Garrison Dental Solutions
Spring Lake, MI 49456

EPA Registration No. 75829-1
EPA Establishment No. 075829-MI-001
Net Contents: 1 gal. (3.78 liters)

DIRECTIONS FOR USE:

For additional instructions see enclosed Bulk Clean Start Guide.

FOR PROFESSIONAL USE ONLY

A general-purpose cleaner for use in self contained dental unit water line systems. Use only in combination with H₂Pro Clean Start Bottle B (EPA Reg. No. 75829-2).

INITIAL TREATMENT

Using the manual dispenser pump provided, place four (1 oz.) pumps of both H₂Pro Clean Start Bottles A and B into empty dental chair water bottle.

Run all lines attached to the dental chair until red coloration appears exiting the lines. Allow lines to sit unused for a minimum of 12 hours.

Prior to chair use completely drain remaining Clean Start Treatment solution from the dental chair reservoir. Prepare and use H₂Pro Maintenance Treatment (alternate formula of EPA Reg. No. 75829-1) according to the Maintenance Treatment directions on the enclosed card.

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MAINTENANCE TREATMENT

After initial dental unit water line treatment using H2Pro Clean Start Bottles A plus B, pour entire contents of H2Pro Maintenance Treatment (alternate formula of EPA Reg. No. 75829-1 Bottle A) into the 7 gallon dispensing container provided. Add 7 US gallons (26.5 liters) of distilled or deionized water (32:1 dilution). Dispense from container into self contained dental unit water bottle. Run all lines attached to the dental chair until blue coloration appears exiting the lines. Use continuously in dental water lines instead of distilled, deionized or tap water.

U.S. Patent No. 6,544,427
Additional Patents Pending

DIRECTIONS FOR USE

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