



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460

EPA Reg. Number:

74245-5

Date of Issuance:

SEP - 8 2005

Term of Issuance:

Conditional

Name of Pesticide Product:

DentaPure Model DP40  
Microbiological Water  
Purification Cartridge

NOTICE OF PESTICIDE:

     Reregistration  
  X   Registration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

MRLB International, Inc.  
2450 College Way  
Fergus Falls, MN 56537

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following label change:
  - a. Revise the EPA Registration Number to read, "EPA Reg. No.74245-5"
  - b. Revise the Ingredient statement as follows:

Active Ingredient:

Iodine\* .....46%

Other Ingredients ..... 54%

\*bound to strong base anion exchange resin

Signature of Approving Official:

*Emily Mitchell*

Date:

SEP - 8 2005

- c. Change the heading "Indications" to "Uses"
- d. Revise the Hazards to Humans and Domestic Animals statement to read:

CAUTION: May cause eye and skin irritation. Avoid direct contact with eyes, skin and clothing. Wear protective eyewear (goggles) and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

- e. Move the general directions for use statement "IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN ANY MANNER INCONSISTENT WITH ITS LABELING." above the Directions For Use
- f. Revise the Environmental Hazards to read "This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."
- g. Remove FDA510(K)992868 from the label.

Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

### INSTRUCTIONS FOR USE

### DENTAPURE® MODEL DP40

For Use As A Microbiological Dental Unit Water Purifier

#### ACTIVE INGREDIENT:

Iodine\*.....46%

#### OTHER INGREDIENT:

Inert.....54%

\*bound to strong base anion exchange resin 100%

### PLEASE SAVE THESE INSTRUCTIONS FOR FUTURE USE

Only selected information is contained on the cartridge packaging, therefore you should keep this sheet for future reference.

### KEEP OUT OF REACH OF CHILDREN

### CAUTION

Microbiological Dental Unit Water Purifier. Each Model DP40 cartridge contains 4.0 cc iodinated resin (3.6 grams iodine). USEPA registered.

EPA REG. NO. 74245-????? EPA EST. 74245 FDA510(K)992868

US PATENT # 5,370,534

**IMPORTANT!!** To obtain maximum bacteriological reduction, dental unit waterlines are to be cleaned with an approved dental unit waterline agent prior to initial installation of DentaPure® cartridges.

*USE* The DentaPure® cartridge is for use on dental unit waterlines attached to the dynamic dental instruments, i.e., high-speed hand piece, three-way air/water syringe and ultrasonic scaler. This cartridge, in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments reduces bacteria from the water supplied through the instruments to a level that will meet or exceed the current ADA recommendations for water quality having a maximum of 200 cfu/ml.

### PRECAUTIONARY STATEMENT: CAUTION

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Do not use DentaPure® cartridge for a patient who is known to be Hypersensitive to iodine. Safety and effectiveness in children under the age of two has not been established.

**CAUTION:** In the event of a rupture of the plastic cartridge housing, contact with the iodinated resin may result. Contact with the iodine resin may cause eye and skin irritation. Avoid direct contact with eyes, skin and clothing. Wear goggles and plastic gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

**CAUTIONS:** Use DentaPure® cartridge on dental unit waterlines only. Use DentaPure® purified water for dental procedures only, not for general consumption. Water used during dental treatment must be either aspirated or expectorated. Dental unit water must have a PH level of less than 8. Dental unit water must not have a chlorine level greater than 1 ppm. Dental unit water must not be over 100 degrees Fahrenheit. Water pressure must not exceed 45 psi. If package seal is broken or cartridge appears dry, properly dispose of cartridge.

### IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN ANY MANNER INCONSISTENT WITH ITS LABELING

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

SEP - 8 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 74245-5

**FIRST AID:** [REDACTED]

**IF IN THE EYES:** 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 eye. Call poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

**IF SWALLOWED:** Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish. Do not discharge into lakes, streams, ponds, or public waters, unless in accordance with an NPDES permit. For guidance, contact the regional office of the EPA.

**STORAGE:** Store at room temperature in original packaging, away from children, pets and direct sunlight. Avoid excessive heat. Do not allow cartridge to freeze. Do not store in open or unlabeled containers.

**DISPOSAL:** Securely wrap cartridge in newspaper and discard in trash.

**DIRECTIONS FOR USE FOR DENTAPURE® MODEL DP40**

Your DentaPure® cartridge has been installed on the pick-up tube in your bottle water system by a dental technician. The cartridge is held in place and retained by luer-loc fittings. One the cartridge is in place, the supply water will pass through the cartridge's iodinated resin bed, purifying the water delivered by the dental instrument. To maintain a continuous iodine presence with the dental tubing, install a new cartridge immediately after removing the used cartridge. The cartridge must be left in place during times that the dental unit is not used (weekends, vacations, etc). Adherence to CDC/ADA guidelines for aseptic procedures including a 2 minute morning flush, a 20-30 second flush between patients, and hand piece sterilization must be continued after the installation of the DentaPure® cartridge. The flushes maintain the iodine levels necessary for bacteriological control. The bottle must be emptied each night and the empty bottle replaced on the manifold. Prior to daily use, wash the inside of the bottle and rinse thoroughly. Wipe down the outside of the cartridge, and make sure the intake end is not obstructed. Fill with fresh water each morning before its first use. The DentaPure® cartridge must be changed after 40 liters of water usage, or if records of usage are not kept, after 60 calendar days of installation. When you add water to your bottle, be sure to check off the appropriate amount of water on your water usage check-off sheet. To change cartridge, simply untwist the luer-loc fitting and remove the cartridge. Re-install a new cartridge, operate the dental instrument to check water flow and the unit is ready for use. Install a new water check-off sheet. Discard the used cartridge properly. Shut off water to dental unit when not in use.

**TROUBLESHOOTING**

Slow or no water flows through cartridge-Make sure new cartridge was installed. Make sure air supply is turned on (maximum 45 psi). Make sure cartridge is off the bottom of the bottle. Air leak from luer fitting contact your dental dealer for replacement parts. Discoloration of the tubing from blue to green or black is normal and is not a concern.

Manufactured by MRLB International Inc.  
2450 College Way  
Fergus Falls, MN 56537  
218-739-2222 or fax 218-736-3241

**QUESTIONS OR COMMENTS?** Visit our website at [www.dentapure.com](http://www.dentapure.com) or e-mail us at [dentapure@dentapure.com](mailto:dentapure@dentapure.com). DentaPure® is a Registered Trademark of MRLB International Inc.

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