

74245-5

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

April 24, 2007

Bob MacDonald
Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: MRLB International, Inc.
DentaPure Model DP40 Microbiological
Water Purification Cartridge
EPA Reg. No.: 74245-5
Application Date: February 5, 2007
Receipt Date: February 6, 2007

Dear Mr. MacDonald:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is accepted with conditions.

Conditions

1. The following instructions were omitted on the proposed label. Please re-insert "The DentaPure cartridge must be changed after 40 liters of water usage, or if the records of usage are not kept, after 60 calendar days of installation."
2. The following instruction must be added to the **First Aid** section "Have product container or label with you when calling a poison control center or doctor, or going for treatment."
3. Remove the first sentence from the "Hazards To Humans And Domestic Animals" section.
4. Revise the first sentence in **Environmental Hazards** section to read "This product is toxic to fish and aquatic organisms."
5. The word "or" should be inserted between [Prior to] **or** [Before] under the use directions for the cartridge being used in conjunction with the water bottle.

General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

Sincerely,

Emily H. Mitchell
Product Manager – Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)



INSTRUCTIONS FOR USE
DentaPure Model DP40 Microbiological Water Purification Cartridge
[DENTAPURE®]
[For Use As A Microbiological Dental Unit Water Purifier]
[Microbiological Water Purification Cartridge]

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.

Active Ingredient: Iodine*.....46%
Other Ingredients.....54%
Total.....100%

*bound to strong base anion exchange resin

KEEP OUT OF REACH OF CHILDREN
CAUTION

[In the event of a rupture of the cartridge and exposure to the iodinated resin:]

FIRST AID:

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.

[SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS]

EPA Registration No: 74245-5 EPA Establishment No: 74245-MN-001
MRLB International, Inc. / DentaPure®
2450 College Way, Fergus Falls, MN 56537
Telephone #: 800-972-3543 US PATENT # 5,370,534

NET CONTENTS: Microbiological Dental Unit Water Purifier.

Table with 6 columns: Unit Size, DP365, DP90, DP40, DP1, Water Wise. Row 1: Iodinated Resin, 38.0 cc, 12.1 cc, 4.0 cc, 2.5 cc, 2.5 cc.

ACCEPTED with COMMENTS
EPA Letter Dated:
APR 24 2007

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

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

CAUTION:

In the event of a rupture of the cartridge and exposure to the iodinated resin 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. Safety and effectiveness in children under the age of two has not been established.

ENVIRONMENTAL HAZARDS: 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 discharge 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.

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

DIRECTIONS FOR USE

[General Instructions and Information]

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.

[General Precautions]

USES: [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.

[IMPORTANT]

Use [DentaPure®] cartridge on dental unit waterlines only. Use [DentaPure®] purified water for dental procedures only, not for general consumption. 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.

DIRECTIONS FOR USE FOR DENTAPURE®

[[The][Your] DentaPure® cartridge is installed on the pick-up tube in your water bottle or on the waterline in the Dental Unit Junction box by a dental technician. The cartridge is held in place and retained by luer-loc fittings or compression fittings.] [Refer to your installation instructions for your model DentaPure.]

Once 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 cartridge. The flushes maintain the iodine levels necessary for bacteriological control.

[If the cartridge is used in conjunction with a bottle water system:] The bottle must be emptied each night and the empty bottle replaced on the manifold. [Prior to] [Before] 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.

Change the cartridge if the level of iodine output falls to less than 0.5 ppm. Use iodine sensitive test strips to verify performance. See the chart below for suggested change intervals. To change cartridge, follow installation instructions. Remove the used cartridge and install the new DentaPure® cartridge. Operate the dental instrument to check flow and verify that 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.

Suggested use table:

DentaPure® Unit Size	If Water Usage Records Are Kept	If Water Usage Records are NOT Kept
DP40	40 Liters	60 Calendar Days
DP90 & Water Wise	60 Liters	90 Calendar Days
DP365	240 Liters	365 Calendar Days
DP1	Use until filter clogs or 40 liters	

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.

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. [Initial dark discoloration of water is caused by release of activated carbon.] [Operate water until flow appears clear.]

[Manufactured by] MRLB International Inc.[/DentaPure®]
2450 College Way
Fergus Falls, MN 56537
[Telephone #: 800-972-3543]
[Phone:] 218-739-2222 or Fax: 218-736-3241

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

DentaPure[®]

DentaPure Model DP40 Microbiological Water Purification Cartridge
Dental Unit Water Purification Cartridge

Model Number	Iodinated Resin
DP365	38.0 cc
DP90	12.1 cc
DP40	4.0 cc
DP15	2.5 cc
Water Wise Purifier	6.0 cc

Net Contents: One Cartridge

Keep Out of Reach of Children

CAUTION

See accompanying instructions for use for directions, first aid and additional precautionary statements.

Active Ingredients

Iodine*	46%
Other Ingredients	54%
Total	100%

Bound to a strong base anion exchange resin

U.S. Patent #5,370,534

EPA Est. No. 74245-MN-001

EPA Reg. No. 74245-5

www.DentaPure.com

1-800-972-3543

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