

74245-5

10-31-2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

October 31, 2006

Bob MacDonald
Agent for MRLB International, Inc.
c/o SRC Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: DentaPure Model DP40 Microbiological Water Purification Cartridge
EPA Registration No. 74245-5
Application Date: October 3, 2006
Receipt Date: October 6, 2006

Dear Mr. MacDonald:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Addition of precautionary text

General Comments

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

The notification application is acceptable and a copy has been placed 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 Y. Henson
Product Reviewer (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES							
MBOL	7510P	7510P					
RNAME	Wanda Y. Henson	Henson					
DATE	10/21/06	10/31/06					



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 74245-5	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DentaPure Model DP40 Microbiological Water Purification Cartridge	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) MRLB International, Inc. 2450 College Way Fergus Falls, MN 56537 <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 text additions through PR Notice 98-10.
 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 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.

Please forward any questions to the attention of Bob MacDonald at Scientific & Regulatory Consultants, Inc. (by e-mail) at bmacdonald@sroconsultants.com or (by fax) (260) 244-6273.

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 <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* 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		4. Size(s) Retail Container		5. Location of Label Directions	
<input type="checkbox"/> Label <input type="checkbox"/> Container				<input type="checkbox"/> On label	
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 Bob MacDonald	Title Agent for MRLB International, Inc.	Telephone No. (Include Area Code) (260) 244-6270
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<p align="center">Certification</p> <p>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.</p>	6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for MRLB International, Inc.
4. Typed Name Bob MacDonald	5. Date 10/13/04

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SRC

Scientific & Regulatory

Consultants, Inc.

October 3, 2006

Ms. Emily Mitchell, PM 32
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: NOTIFICATION
DentaPure Model DP40 Microbiological Water Purification Cartridge
EPA Reg. No.: 74245-5

Dear Emily,

On behalf of our client, MRLB International, Inc., enclosed is a notification to official update their precautionary sections CAUTION statement (below). *As you may recall we previously discussed and corresponded with you on this item, (e-mails attached).* We are resubmitting this notification per the recent response from Wanda Henson dated 09/28/06 requesting a complete label for this notification.

As you will recall we had questions from the State of New York in regards to our CAUTION statement in conjunction with your September 8, 2005 Notice of Pesticide Registration.

Our client has followed and incorporated the specific text outlined in Item 2 (d) for their proposed label. However it was also felt that it was an oversight that the text "In the event of a rupture of the cartridge and exposure to the iodinated resin" was not addressed.

Since this material (resin) is contained in the cartridge and would normally not come in contact with the user it would seem suitable to have this statement with the precautionary text. (We have bolded the "rupture" text inclusion below and additionally circled this area on one of the two label copies enclosed).

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.

With this text the user is still required to wear protection and to wash after handling even if the cartridge does not rupture but its inclusion also clearly points out that the "rupture" of the cartridge and thereby potential contact is of primary concern.

Thank you for your assistance on this matter. If you have any questions please contact me at (260) 244-6270 or by e-mail at bmacdonald@srconsultants.com.

Sincerely



Bob MacDonald
Agent for MRLB International Inc.



INSTRUCTIONS FOR USE

DentaPure® Model DP40 Microbiological Water Purification Cartridge
For Use As A Microbiological Dental Unit Water Purifier

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

*bound to strong base anion exchange resin

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 cartridge contains 4.0 cc iodinated resin (3.6 grams iodine). USEPA registered.

EPA REG. NO. 74245-5 EPA EST. NO. 74245-MN-001

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.

USES: 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 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.

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.

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.

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

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

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. 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 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.

IMPORTANT: 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.

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 or e-mail us at dentapure@dentapure.com. DentaPure® is a Registered Trademark of MRLB International Inc.