

87117-1

11/18/2010

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

EPA Reg. Number: 87117-1  
Date of Issuance: NOV 18 2010

Term of Issuance: Conditional

Name of Pesticide Product: MicroClear

NOTICE OF PESTICIDE:  
  x   Registration  
       Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Rowpar Pharmaceuticals, Inc.  
c/o Wagner Regulatory Associates  
P.O. Box 640  
Hockessin, DE 19707

**FILE COPY**

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 (OPP Decision No. D-422429) is registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration 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 re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
  - a. Revise the "EPA File Symbol to read, "EPA Reg. No. 87117-1".

Signature of Approving Official:  
  
Wanda Y. Henson  
Acting Product Manager Team-32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Date: NOV 18 2010

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- b. The dental unit water line effluent has been updated to  $\leq 10$  CFU/ml to correlate with the supporting data.
- c. The routes of exposure in the "First Aid" statement must appear in the following order: If in eyes, If on skin or clothing, If swallowed and If inhaled.

3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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.

Sincerely,  
  
Wanda Y. Henson  
Acting Product Manager 32  
Regulatory Branch II  
Antimicrobials Division (7510P)

Enclosures: (Stamped Label)

# MicroCLEAR™

**ACCEPTED**  
with **COMMENTS**  
in EPA Letter Dated:

Cleans dental unit waterlines  
Dental waterline microbial contaminant control solution  
Kills odor causing bacteria  
Maintains dental unit water line effluent ≤ **10** CFU/ml

NOV 18 2010  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. **87117-1**

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

FIRST AID	
<b>If swallowed</b>	- 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.
<b>If in eyes</b>	-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 a poison control center or doctor for treatment advice.
<b>If inhaled</b>	- Move person to fresh air. -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. - Call a poison control center or doctor for treatment advice.
<b>If on skin or clothing</b>	- Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15 – 20 minutes. - Call a poison control center or doctor for treatment advice.
<b>For 24-hour emergency information on this product, call CHEMTREC 1-800-262-8200</b>	

### SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

**Active Ingredients:**  
 Chlorine dioxide.....0.1%  
**Other Ingredients**.....99.9%  
**Total 100.0%**

EPA Est. No. \_\_\_\_\_

EPA Reg. No. 87117-1

#### Manufactured by:

**Rowpar Pharmaceuticals, Inc.**  
16100 North Greenway-Hayden Loop F-400  
Scottsdale, Arizona 85260

Net Contents: \_\_\_\_\_

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# MicroCLEAR

Non-Staining  
Non-Corrosive  
pH Balanced

Does Not Affect Bond Strength  
Dental Unit Waterline Cleaner

Dental Waterline Microbial Contaminant Control Solution

Kills odor causing bacteria

Maintains dental unit water line effluent  $\leq 10$  CFU/ml

Use MicroCLEAR dental unit waterline cleaner to control water quality

Does not damage or harm lines or equipments even after long-term use

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

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## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Causes moderate eye irritation. Harmful if absorbed through skin or if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

### PHYSICAL OR CHEMICAL HAZARDS

Chlorine dioxide is a strong oxidizing agent. Contamination with other materials such as acids, chlorine, organic chemicals, etc. may cause a chemical reaction resulting in the evolution of gaseous chlorine dioxide and heat. Explosion and/or fire could result. Chlorine dioxide is a poisonous explosive gas. Keep all chemical and foreign materials away from this solution.

### DIRECTIONS FOR USE

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

#### Initial One-Time Treatment:

1. Empty and clean the self-contained bottle at the end of the day.
2. Fill the bottle with 100 ml (4 pumps) of MicroCLEAR™
3. Run each line for 30 seconds.
4. Leave MicroCLEAR™ in the lines overnight.
5. The next morning completely flush remaining solution through waterlines and remove the self-contained bottle.
6. Fill clean bottle with the daily use formula. Run this solution through the lines for 30 seconds.

#### Daily Use:

1. Prepare mixture by adding the required volume of concentrate (see table below) directly to the system's self-contained water bottle every time it needs to be refilled.
2. Fill the remainder of the bottle with water.

Volume of Bottle (ml)	Amount of MicroCLEAR™ (ml)	Amount of MicroCLEAR™ (oz.)	Number of Pumps
*750 (A-dec)	75	2.5	3
1000	100	3.5	4
*2000	200	7	8

\*Most common volumes on self-contained units.

NOTE: One full pump will dispense ¾ ounces (25 mL). Use a 1:10 dilution if the volume needed is not shown. For further information, call Rowpar Pharmaceuticals at (800) 643-3337.

### STORAGE AND DISPOSAL

**Pesticide Storage:** Store in a cool, dark area in original container. Do not contaminate water, food, or feed by storage or disposal. Do not store with easily oxidizable materials, acids, reducers, and combustible materials.  
**Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility. **Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Offer for recycling, if available.

### WARRANTY STATEMENT

The directions for use of this product are believed to be adequate and must be followed carefully, it is impossible to eliminate all risks inherently associated with the use of this product. To the extent consistent with applicable law, the products sold to you are furnished "as is" by Rowpar Pharmaceuticals, Inc. The manufacturer and the seller are subject only to the manufacturer's warranties, if any, which appear on the label of the product sold to you. Except as warranted by this label, Rowpar Pharmaceuticals, Inc. or the seller makes no warranties, guarantees, or representations of any kind to the buyer or the user, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold or use of the product, including, but not limited to, merchantability, fitness for a particular purpose or use, or eligibility of the product for any particular trade usage. To the extent consistent with applicable law, Buyer's or user's exclusive remedy, and Rowpar Pharmaceuticals, Inc. or the seller's total liability shall be limited to damages not exceeding the cost of the product. No agent or employee of Rowpar Pharmaceuticals, Inc., or the seller is authorized to amend the terms of this warranty disclaimer or the product's label or to make a presentation or recommendation different from or inconsistent with the label of this product.

To the extent consistent with applicable law, Rowpar Pharmaceuticals, Inc. or the seller shall not be liable for consequential, special, or indirect damages resulting from the use, handling, application, storage, or disposal of this product or for damages in the nature of penalties, and the buyer and the user waive any right that they may have to such damages.

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