

46781-6

1/28/2003

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JAN 28 2003

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Metrex  
1717 West Collins Avenue  
Orange, California 92867

Attn: Wendy Urtel  
Manager, Regulatory Affairs

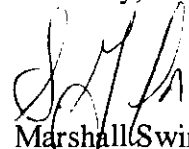
Subject: Cavicide  
EPA Reg. No. 46781-6  
Notification of Alternative Brand Name

This will acknowledge receipt of your notification to inform the Agency that the Effluent Discharge Labeling statement will remain on the 55 gallon containers of Cavicide, submitted under the provision of FIFRA Section 3(c)9. Based on a review of submitted material, the following comments apply.

This notification is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Solange Garvey at (703) 308-8911.

Sincerely,



Marshall Swindell  
Product Manger 33  
Regulatory Management Branch I  
Antimicrobial Division (7510C)

CONCURRENCES

| SYMBOL  |  |  |  |  |  |  |  |
|---------|--|--|--|--|--|--|--|
| SURNAME |  |  |  |  |  |  |  |
| DATE    |  |  |  |  |  |  |  |



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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

### Application for Pesticide - Section I

|   |  |  |
|---|--|--|
| 1. Company/Product Number<br>46781 / 46781-6  | 2. EPA Product Manager<br>M. Swindell  | 3. Proposed Classification<br><input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)<br>Metrex Research Corporation / Cavicide   | PM#<br>33  |  |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Metrex Research Corporation<br>1717 West Collins Avenue<br>Orange, CA 92867<br><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:<br>EPA Reg. No. _____<br>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.)  
 AS REQUESTED BY THE CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION, THIS NOTIFICATION IS INTENDED TO INFORM US EPA THAT THE EFFLUENT DISCHARGE LABELING STATEMENT REMAINS ON THE 55 GALLON CONTAINER OF CAVICIDE, EPA REG. NO. 46781-6, AS PER PR-NOTICE 95-1. The Effluent Discharge Labeling Statement has always been on the 55 gallon container of Cavicide. This notification is meant to satisfy California Department of Pesticide Regulation requirements of necessitating documentation that a notification be submitted to US EPA. See additional page.

### Section - III

|  |  |   |  |                      |   |
|--|--|---|--|----------------------|---|
| 1. Material This Product Will Be Packaged In:  |  |   |  | 2. Type of Container |   |
| Child-Resistant Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No  | Unit Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No | Water Soluble Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No | * Certification must be submitted  |                      | <input type="checkbox"/> Metal<br><input checked="" type="checkbox"/> Plastic<br><input type="checkbox"/> Glass<br><input type="checkbox"/> Paper<br><input type="checkbox"/> Other (Specify) _____ |
| 3. Location of Net Contents Information<br><input checked="" type="checkbox"/> Label <input type="checkbox"/> Container  |  | 4. Size(s) Retail Container<br>2, 8 and 24 oz; 1, 2.5 and 55 gallon                               | 5. Location of Label Directions<br><input checked="" type="checkbox"/> On Label<br><input type="checkbox"/> On Labeling accompanying product |                      |   |
| 6. Manner in Which Label is Affixed to Product<br><input checked="" type="checkbox"/> Lithograph<br><input type="checkbox"/> Paper glued<br><input type="checkbox"/> Stenciled |  | <input type="checkbox"/> Other _____  |  |                      |   |

### Section - IV

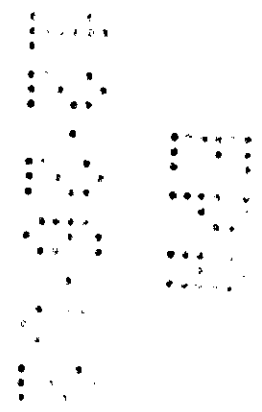
|  |   |  |
|--|---|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)  |   |  |
| Name<br>Wendy Urtel  | Title<br>Manager, Regulatory Affairs    | Telephone No. (Include Area Code)<br>714-516-7425    |
| <b>Certification</b><br>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. |   | 6. Date Application Received<br><br><b>(Stamper)</b> |
| 2. Signature<br>   | 3. Title<br>Manager, Regulatory Affairs |  |
| 4. Typed Name<br>Wendy Urtel   | 5. Date<br>12-18-02                     |  |

APPLICATION FOR PESTICIDE  
NOTIFICATION OF EFFLUENT DISCHARGE LABELING STATEMENT  
Product Name: Cavicide, EPA Reg. No. 46781-6

55 Gallon Label Only: The Effluent Discharge Labeling Statement is included on the 55 gallon container. Containers of less than 5 gallons do not have the Effluent Discharge Labeling Statement because of the exemption outlined in PR-Notice 95-1.

Section II - Additional Page

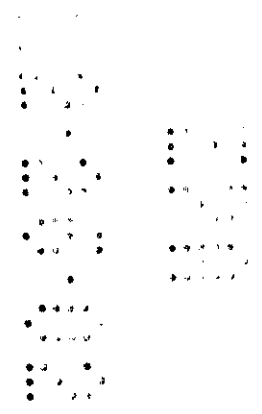
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any 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.





**EFFECTIVE AGAINST:**

- Mycobacterium tuberculosis var: bovis (BCG)\*\*
- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Trichophyton mentagrophytes
- Methicillin Resistant Staphylococcus aureus (MRSA)
- Vancomycin Resistant Enterococcus faecalis (VRE)
- Hepatitis B Virus (HBV)\*
- Poliovirus Types 1 and 2\*
- Adenovirus Type 8\*
- Herpes simplex virus Types 1 and 2\*
- Human Immunodeficiency Virus (HIV-1)\*
- Canine parvovirus\*



**DIRECTIONS FOR USE:**

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

**DESCRIPTION:**

Cavicide is a multi-purpose disinfectant/decontaminant cleaner for use on inanimate surfaces. It is useful in hospital operating rooms, emergency departments, isolation areas, neonatal units, ophthalmic and optometric facilities, eye surgical centers, dental operatories, surgical suites, animal care facilities, beauty salons, salon settings, manicure salons, skin care salons, barber shops, bathrooms, tanning salons, out-patient surgical centers, daycare centers, schools, ambulances, police and fire vehicles, prisoner detention facilities, jails, prisons, morgues, cadaver processing areas, funeral homes, patient care areas, laboratories, non-food contact surfaces in food preparation areas, storage areas, health club facilities, and other critical care areas where environmental control of cross contamination is important. Safe for cleaning/decontamination of delicate medical/ dental/ surgical/ optical/ salon/ barber/ veterinary/ environmental/ equipment/ implements and instrumentation. Cavicide will effectively clean and disinfect, when used as directed, such items as: infant incubators and bassinets, infant care cribs and warmers, infant/child care equipment surfaces, oxygen hoods, anesthesia machines and respiratory therapy equipment surfaces, operating room tables and lights, laboratory equipment and surfaces, physical therapy (PT) equipment surfaces, neck brace appliances and cervical collars, drained whirlpool tank surfaces, stretchers, spine back boards, ambulance equipment surfaces, slit lamps, external lenses for vision correction\*\*\*, countertops, exterior toilet surfaces, sinks, refrigerator units, floors, walls, handrails, door knobs, bed railings, bathing units, bathtubs, shower stalls, cabinets, shampoo bowls, manicure tables, chairs, workstations, nail/ hair care implements, tanning beds, hair dryers, telephones, diaper changing stations, baby cribs, hair clippers, shears, razors, hair cutting implements, clipper blades, salon surfaces, scissors, combs, brushes, manicure implements, washable nail files, hair rollers, animal cages, veterinary care surfaces, dental operator surfaces, dental countertops, dental chairs, unit stools, light lens covers, curing lights, and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), weight lifting surfaces, non-porous vinyl, stainless steel, painted surfaces, Plexiglas®, glass, and other hard non-porous surfaces.

\*\*\*Not for use on contact lenses.

**APPLICATIONS:**

**SURFACES:** (Where appropriate, follow Universal Precautions.)

**For PRECLEANING instruments, equipment and surfaces prior to disinfection:**

- Apply Cavicide directly to surface. Allow to remain wet for 30 seconds. Wipe surface using a paper or cloth towel. Discard towel.

**For DISINFECTING non-critical instruments and equipment surfaces:**

- Apply Cavicide directly to precleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain wet for 3 minutes at room temperature (69°F/20°C). \*\*For Tuberculocidal Activity: allow 5 minutes at room temperature. \*For inactivation of Poliovirus Types 1 and 2: allow 10 minutes at room temperature. For inactivation of Adenovirus Type 8: allow 20 minutes at room temperature. Wipe surface using a paper or cloth towel, or allow to air dry. Discard towel.

**INSTRUMENTS:** (Where appropriate, follow Universal Precautions.)

**For use as a precleaning immersion decontaminant solution:**

- Fill appropriate size container with a sufficient amount of Cavicide as to allow for complete submersion of instruments. Place instruments into Cavicide solution, cover and allow to soak for 10 minutes at room temperature (69°F/20°C). Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Change solution as needed when the solution becomes diluted or visibly soiled. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

**For use as a precleaning decontamination spray:**

- Place instruments into a suitable container. Spray Cavicide onto instruments so as to thoroughly drench all surfaces. Allow surface to remain wet for 30 seconds. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

**For use as an ultrasonic cleaning solution:**

- Thoroughly pre-rinse instruments under running water to remove visible gross debris. Using 1 ounce Cavicide per liter of water in ultrasonic unit, immerse instruments into mixed solution and activate ultrasonic unit for 5 minutes or longer if necessary. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Change solution as needed when the solution becomes diluted or visibly soiled. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

**For use as a manual cleaner:**

- Thoroughly pre-rinse instruments under running water to remove visible gross debris. Place pre-rinsed instruments into a solution of 1-ounce Cavicide per liter of water. Scrub instruments using a stiff bristle brush until visibly clean. (Instruments should be submerged as scrubbed.) Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Change solution as needed when the solution becomes diluted or visibly soiled. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

**For cleaning hair clippers, electric shears:**

While clipper/shear is running, hold it in the downward position and spray Cavicide directly onto the blades two or three times so as to thoroughly wet the blades. (Avoid spraying on the clipper case or dripping into the clipper housing.) Allow to remain wet for 3 minutes. Wipe dry with a clean, soft cloth. Lubricate as per clipper/shear manufacturer's instructions.

**For cleaning salon implements, shears and barber implements:**

• Spray implement/shear to thoroughly wet with Cavicide solution. Wipe away visible debris using a soft bristle brush or cloth. Immerse precleaned implement/shear into a container of Cavicide for 3 minutes. Remove implement/shear and wipe dry. No rinsing is necessary. Change solution as needed when the solution becomes diluted or visibly soiled.

**For disinfection of NON-CRITICAL, precleaned instruments:**

• Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and rough dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or an ultrasonic unit, immerse instruments into Cavicide solution for 3 minutes. \*\*For Tuberculocidal Activity, allow 5 minutes at room temperature (69°F/20°C). \*For inactivation of Poliovirus Types 1 and 2, allow 10 minutes at room temperature. For inactivation of Adenovirus Type 8, allow 20 minutes at room temperature. Remove and rinse instruments. Wipe dry prior to use. Change solution as needed when the solution becomes diluted or visibly soiled. **Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.**

This product is not to be used as a terminal sterilant/ high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.

CAVICIDE EFFECTIVELY KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS IN HEALTHCARE SETTINGS OR OTHER SETTINGS IN WHICH THERE IS AN EXPECTED LIKELIHOOD OF SOILING OF INANIMATE SURFACES/OBJECTS WITH BLOOD/BODY FLUIDS, AND IN WHICH THE SURFACES/OBJECTS CAN BE ASSOCIATED WITH THE POTENTIAL FOR TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUID:**

**Personal Protection:** Wear appropriate barrier protection such as protective gloves, gowns, masks or eye coverings.

**Cleaning Procedure:** Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection with Cavicide.

**Contact Time:** While the HIV-1 virus is inactivated in 2 minutes, use the recommended contact time for the disinfection of other organisms listed on this label.

**Infectious Materials Disposal:** Cleaning materials used that may contain blood or other bodily fluids should be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

| <b>FIRST AID</b>  |  |
|---|--|
| <b>If in eyes</b>   | <ul style="list-style-type: none"> <li>• 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.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>   |
| <b>If on skin or clothing</b>   | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>  |
| <b>If swallowed</b>   | <ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul> |
| <b>If inhaled</b>   | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>   |
| <p>For emergency information on product, call Metrex at 1-800-841-1428, Monday through Friday, between 6 a.m. and 4 p.m. Pacific Time.<br/>After 4 p.m., call Chemtrec 24-Hour Emergency Service at 1-800-424-9300.</p> |  |
| <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>   |  |

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Store in a cool place.

**Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of according to applicable Federal, State, or local procedures.

**Container Disposal:** Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or, if allowed by state and local authorities, by burning. If burned, keep out of smoke.

For product or technical information, contact Metrex at **800-841-1428** or visit our website at **www.metrex.com**.



**[The following statement is to be included only on labeling of containers greater than 5 gallons.]**

**Environmental Hazards:**

This pesticide 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.

