



046781-00006-042299

Printed: 12:57:55 Friday, 21 May, 1999 # 41 / 2907

**Systems Integration Group, Inc.**

PM 33

46781-6  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

4-22-99

1 of 5

APR 22 1999

Metrex Reseach Corporation  
1717 West Collins Avenue  
Orange, CA 92867

Attention: Wendy A. Urtel  
Regulatory Affairs Specialist

Subject: Cavicide  
EPA Registration No. 46781-6  
Notification Dated March 19, 1999

This will acknowledge receipt of your notification to include the additional brand name "NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER", submitted under the provisions of FIFRA Section 3(c)9. Based on a review of the submitted material, the following comments apply.

The notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							





**EFFECTIVE AGAINST:** • Staphylococcus aureus • Pseudomonas aeruginosa • Salmonella choleraesuis • Mycobacterium tuberculosis var: bovis (BCG)\*\* • Methicilin Resistant Staphylococcus aureus (MRSA) • Vancomycin Resistant Enterococcus faecalis (VRE) • Trichophyton mentagrophytes • Herpes simplex virus types 1 and 2\* • Human Immunodeficiency Virus (HIV-1)\* • Poliovirus types 1 and 2\* • Coxsackievirus\*. (\*On inanimate surfaces.) (\*\*In 10 minutes at room temperature - 20°C.)

**DIRECTIONS FOR USE:**

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

**DESCRIPTION:** NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER is a multi-purpose, broad spectrum, ready to use, highly effective cleaner and disinfectant for use on the surfaces of inanimate objects. It is especially useful in hospital operating rooms, isolation areas, neonatal units, and other critical care areas where environmental control of cross contamination is important. NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER will effectively clean and disinfect, when used as directed, such items as: infant incubators and bassinets, anesthesia machines and respiratory therapy equipment surfaces, operating room tables and lights, and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), non-porous vinyl and upholstery, stainless steel, painted surfaces, Plexiglas®, glass, and other hard non-porous surfaces.

**APPLICATIONS:**

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

For disinfecting non-critical devices/medical equipment and surfaces:

• Apply NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER 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 10 minutes.) Follow by wiping surface using a clean paper or cloth towel; or rinse and either allow surface to air dry or wipe rinsed surface dry using a clean paper or cloth towel. Discard towel.

For precleaning medical equipment and other surfaces prior to disinfection:

• Apply directly to surface. Allow to remain wet for 30 seconds. Wipe surface clean using a paper or cloth towel or rinse surface and either wipe dry or allow to air dry. Discard dirty towel.

NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER 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 latex gloves, gowns, masks or eye coverings. • **Cleaning Procedure:** Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection with NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER. • **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.

# NOVAPLUS

## SURFACE DISINFECTANT DECONTAMINANT CLEANER

**BACTERICIDAL • VIRUCIDAL\* • FUNGICIDAL**

READY TO USE - CONTAINS 10% ALCOHOL

**ACTIVE INGREDIENTS:**

Diisobutylphenoxethoxyethyl dimethyl

isopropanol .....

**INERT INGREDIENTS:** .....

**TOTAL:** .....

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**PRECAUTIONARY STATEMENTS: HARMFUL TO HUMANS AND ANIMALS. MAY CAUSE EYE IRRITATION. AVOID DIRECT CONTACT WITH EYES WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES.**

EPA REG NO.: 46781-F  
EPA EST NO.: 46781-CO-1

Manufactured by

Reorder No: NP-1000

Net Content  
1 U.S. Gallon / 3.78 L  
Net Weight 8.22 L

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

For use as an immersion precleaning instrument decontaminant solution:

• Fill appropriate size container with a sufficient amount of undiluted NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER so as to allow for complete submersion of instruments. Place instruments into NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER solution, cover and allow to soak for 10 minutes. Remove and rinse. 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 an instrument preclean decontamination spray:

• Place instruments into a suitable container. Thoroughly spray NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER solution onto instruments so as to thoroughly drench all surfaces. Cover instruments and transport to appropriate cleaning area. 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 instrument ultrasonic cleaning solution:

• Thoroughly pre-rinse instruments under running water to remove visible gross debris. Using 1 ounce NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER per liter of water in ultrasonic unit, immerse instruments into mixed solution and activate unit for 5 minutes or longer if necessary. Remove instruments and rinse thoroughly. Change solution as needed. Follow with appropriate disinfection process. (Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)

For use as a manual instrument cleaner:

• Thoroughly pre-rinse dirty instruments under running tap water to remove visible gross debris. Place pre-rinsed instruments into a solution of 1 ounce NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER per liter of water. Scrub instruments using a stiff bristle brush until visibly clean. (Instruments should be submerged as scrubbed.) Rinse instruments thoroughly. Change solution as needed. Follow with appropriate disinfection process. (Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)

For disinfection of NON-CRITICAL, precleaned instruments:

• Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and then rough dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or ultrasonic unit, immerse instruments into undiluted NOVAPLUS SURFACE DISINFECTANT DECONTAMINANT CLEANER solution and allow to remain submerged for 3 minutes. For tuberculocidal activity, allow 10 minutes at room temperature (69°F/20°C). Remove and rinse or wipe dry prior to use. Change solution daily or more often as needed if 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.

**STORAGE AND DISPOSAL:**

**STORAGE:** Store in a cool place. **PESTICIDE DISPOSAL:** Dilute with water. Dispose of in ordinary sanitary sewer.

**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 information, please contact our technical service department at 1-800-841-1428 (TOLL FREE).

516S-1



OK  
WAVE  
3-16-99

516S