

46781-7

09/04/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 04 2003

Wendy Urtel
Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92867

**Subject: Kleenaseptic
EPA Reg. No. 46781-7
Amendments Dated 6/24/03 (CSF review), and 6/25/03 (Label review)**

The two related amendments referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to revise the basic Confidential Statement of Formula (CSF), and to provide a revised label which changes the ingredients statement to match the changed CSF, and makes other minor changes, are acceptable.

The revised basic CSF dated 6/23/03 is acceptable and supercedes all prior basic CSF's for this product. Note that both amendments could have been combined into one amendment (CSF and label review) for ease of processing/reviewing.

A copy of the revised label stamped "Accepted" is attached.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,

Marshal Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

KLEENASEPTIC®

GERMICIDAL AND SURFACE CLEANSER FOR HARD, NON-POROUS, INANIMATE SURFACES

Bactericidal • Fungicidal • Tuberculocidal

Ready to Use • Spray-on Product

Contains Biodegradable Detergent

ACTIVE INGREDIENTS:

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride..... 0.26%
Isopropanol..... 14.84%

INERT INGREDIENTS..... 84.90%

TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals.
Caution. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. See side panel for additional precautionary statements.

PHYSICAL OR CHEMICAL HAZARDS: **Flammable.** Contents under pressure. Do not use or store near fire, sparks or flame. Exposure to temperatures above 130°F may cause bursting. Do not puncture or incinerate container.

EPA REG. NO. 46781-7 EPA EST. NO. 706-IL-1 REORDER NO.

NET WEIGHT: # lb.(# oz.)(# grams)

PACKED FOR:
Metrex Research Corporation
28210 Wick Road
Romulus, MI 48174

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP 04 2003

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

46781-7

EFFECTIVE ON HARD, NON-POROUS, INANIMATE SURFACES AGAINST:

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella choleraesuis
- Mycobacterium tuberculosis var: bovis
- Trichophyton mentagrophytes

DIRECTIONS FOR USE:

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

Kleenaseptic is useful in hospital operating rooms, neonatal units and other critical care areas where environmental control of cross contamination is important. Kleenaseptic will clean and disinfect when used as directed such items as: infant incubators and bassinets, respiratory therapy equipment surfaces 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.

SHAKE WELL BEFORE USING.

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.

Cleaning Instructions: Hold dispenser 6" to 8" from surface to be cleaned. Spray surface thoroughly and wipe clean using a clean cloth or paper towel. Repeat as needed until surface is visibly clean.

Disinfecting Instructions: Hold dispenser 6" to 8" from surface to be treated, spray pre-cleaned surface thoroughly wetting area and allow to remain on surface for at least 10 minutes at room temperature (69°F). Follow by wiping surface dry using a clean cloth or paper towel.

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FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • 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.
If swallowed	<ul style="list-style-type: none"> • Call a 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 a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
<p>In case of emergency call Metrex toll free, at 1-800-841-1428, Monday through Friday, between 6 a.m. and 4 p.m. Pacific Time. 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 and Container Disposal: Do not reuse empty container. Securely wrap original container in several layers of newspaper and discard in trash.

For product or technical information, contact Metrex at **1-800-841-1428** or visit our website at **www.metrex.com**.

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