



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 15, 2004

Kelly R. Hoskins
Supervisor, Regulatory Compliance
Illinois Tool Works, Inc
D/B/A ITW Dymon
805 East Old 56 Highway
Olathe, KS 66061

Subject: **Medaphene® Plus**
EPA Registration No. 11694-98
Application Dated August 29, 2003

Dear Ms. Hoskins:

The following amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with comment.

Proposed Label Amendment

Label revisions per PR Notice 2001-1 - 2001-6 and 1995-1

Label Comments

- 1. Delete the bracket [] from 100% in the ingredient statement.

General Comments

A stamped copy of the accepted labeling with comment is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Renae M. Whitaker

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

MASTER LABEL

All word(s), phrases, or symbols in { } and **bolded** are OPTIONAL
* Denotes Additional Brand Name

An effective disinfectant for hard surfaces for general hospital use, schools, medical, dental and business offices, sickrooms, nursing homes and ambulances. This product will control the following organisms: Salmonella choleraesuis, Staphylococcus aureus, Trichophyton mentagrophytes, Pseudomonas aeruginosa, Streptococcus pyogenes, HIV-1 (associated with AIDS) and tubercle bacilli.

GENERAL USES

Disinfecting: Bed springs and frames • bedside and office furniture • chart racks and equipment cabinets • countertops • door knobs • office machinery • sinks and mirrors • light fixtures and switches • supply, dressing and trash carts • telephones • waste cans and laundry hampers • wheel chairs and walkers • urinals.

Deodorizing: Odors from post-colostomy, post-ileostomy dressing and bags, malignant diseases, homes, kitchens, bathrooms, industrial plant processes, food processing and packaging plants, food stores, fecal matter, urine, burns, smoke, mildew and mold, decay, garlic, onions, food putrefaction, perspiration, tobacco, sickrooms, musty closets and fish.

DIRECTIONS FOR USE

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

For Pre-cleaning: Pre-clean surfaces with a suitable detergent prior to disinfecting.
For Disinfecting: Hold dispenser upright 6 to 8 inches from surface. Spray 2 to 3 seconds or until entire surface is wet. Allow to remain at least 10 minutes. Allow to air dry or remove with clean dry cloth.

For Mildew Control: Spray surface until moist. Do not use on polished wood furniture or rayon fabrics. Repeat application periodically to maintain control.

***KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1)(associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

For Commercial/Institutional Use Only

EPA Reg. No. 11694-98 (XXXX) EPA Est. No. 11694-KS-1 SDA-KS-774

Manufactured, Distributed, Sold in the USA by, for

ITW Dymon, Olathe, KS 66061

(For an MSDS, call XXX-XXX-XXXX or visit www.xxxxx.com and request document #XXXX)

Medaphene® Plus (*Country Garden) (*Mint) (*Spearmint) (*Lemon) (*Orange) Disinfectant-Deodorant

**Pseudomonacidal • Virucidal* • Mildewcidal†
Fungicidal • Staphylocidal • Tuberculocidal**

**Disinfects Herpes Simplex Virus Type 1 & 2
Influenza A₂ (Hong Kong) & HIV-1 (AIDS Virus)***

†Controls Mildew growth on fabric for 14 days and on hard surfaces for 21 days.
*Virucidal against Influenza A₂/Hong Kong, Herpes Simplex Type 1 and Herpes Simplex Type 2, on precleaned and inanimate hard surfaces. Kills HIV-1 (AIDS virus) on precleaned environmental surfaces/objects previously soiled with blood/body fluids.

ACTIVE INGREDIENTS:

o-phenylphenol 0.19%

ethyl alcohol 68.00%

OTHER INGREDIENTS: 31.81%

(100.00%)

(PRECAUCION AL CONSUMIDOR: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.)

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See (back, rear, side) panel for additional precautionary statements.

Net Contents XXXXXXX

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

MAR 15 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 11694-98

DIRECTIONS FOR USE (con't.)

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 or high level disinfection.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes eye damage. Do not get in eyes. Wear goggles or faceshield and rubber gloves when handling. Harmful or fatal if swallowed. Causes skin irritation. Do not get on skin or on clothing.
(NOTICE: This product contains chemicals known to the State of California to cause cancer.)

FIRST AID

IF IN 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 a poison control center or doctor for treatment advice. **IF SWALLOWED** - Call a poison control center or doctor immediately for treatment advice. 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** - 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. **IF ON SKIN OR CLOTHING** - 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

(ENVIRONMENTAL HAZARDS

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.) (Required on containers 5 gallons or larger.)

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat, sparks and open flame.

STORAGE AND DISPOSAL

STORAGE: Keep containers tightly sealed when not in use. Store container indoors and in a dry area. Keep from freezing. Use from original container only.

DISPOSAL: If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

(Buyer assumes all risk of use, storage or handling of this product not in strict accordance with directions given here-with.)

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PRN 2001-6
PRN 2001-1
PRN 1995-1

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