

11694-98

09-02-2010



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP - 2 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Melissa Schnake
Illinois Tool Works, Inc.
P.O. Box 340
Olathe, KS 66051

Subject: Medaphene Plus Disinfectant Deodorant
EPA Reg. No. 11694-98
Application Dated: July 29, 2010
Receipt Date: August 5, 2010

Dear Ms. Schnake:

This letter acknowledges receipt of the following submission submitted in connection with registration under the provisions of PR Notice 98-10 and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification

- Revised Storage and Disposal Section per PR Notice 2007-4
- Revision of mandatory language

General Comments

Based on a review of the material submitted, your notification to update the container disposal statements per PR Notice 2007-4 and incorporate mandatory labeling is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by email at Campbell-mcfarlane.jacqueline@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission the submission to facilitate processing.

Sincerely,

Jacqueline McFarlane
Product Manager (34)
Regulatory Management Branch II
Microbiologicals Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11694-98	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Illinois Tool Works, Inc.	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Illinois Tool Works, Inc., D/B/A ITW Dymon P.O. Box 340 Olathe, KS 66051 <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: <input checked="" type="checkbox"/> EPA Reg. No. _____ 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.)

Changes per PR Notice 2007-4. Also minor update to language for HIV Personal Protection and Disposal of Infectious Materials (noted on Cover Letter)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <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 Melissa Schnake	Title Sr. Regulatory Specialist	Telephone No. (Include Area Code) 913-489-3111
Certification 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 (Stamped)
2. Signature 	3. Title Sr. Regulatory Specialist	
4. Typed Name Melissa Schnake	5. Date 29 July 2010	



July 29, 2010

U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504 P)
1200 Pennsylvania Ave. NW
Washington DC 20460-0001

Dear Sir or Madam:

Enclosed please find all the documents and paperwork necessary for a Notification to the current registration of EPA #11694-98 Medaphene Plus Disinfectant Deodorant.

I have included our Application and our Master label for your approval. See Certification Statement below.

In addition to the required changes per PR Notice 2007-4, I also changed the word "or" to "and" under PERSONAL PROTECTION in the SPECIAL INSTRUCTIONS FOR HIV-1. One other minor change was the word "should" was changed to "must" under DISPOSAL OF INFECTIOUS MATERIALS in the same section.

Please contact me should you have any questions.

Regards,

Melissa Schnake
Sr. Regulatory Specialist
mschnake@dymon.com

Encl.

Notification of label change per PR Notice 2007-4. This notification is consistent with the provisions of PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling (besides those outlined above) or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, 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.



Attention: This is an EPA product. Subregistration forms must be signed and sent to ITW Dymon Regulatory Dept. before product will be produced.

MASTER LABEL
All word(s), phrases, or symbols in { } and **bolded** are OPTIONAL

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, Methicillin-Resistant Staphylococcus Aureus (MRSA), Trichophyton mentagrophytes, Pseudomonas aeruginosa, Streptococcus pyogenes, HIV-1 (associated with AIDS), Human Coronavirus (HCoV), 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 • tele-phones • waste cans and laundry hampers • 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 and 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 must be auto-claved and disposed of according to local regulations for infectious waste disposal.

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.

(Product Name)

Disinfectant-Deodorant

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

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

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)

†Controls Mildew growth on fabric for 14 days and on hard surfaces for 21 days.
*Virucidal against Influenza A₂/Hong Kong, Human Coronavirus (HCoV), 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 XXXXXX

07/29/10 mks
chgd Disposal & other
small stuff
01/05/10 mks
added H1N1 & nfs in CA
05/05/06 mks
Add HCoV
03/29/04
347XXMV1
KRH

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

(DIRECTIONS FOR USE (con't.))

**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.

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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or discard in trash.
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.

NOTE: Not for sale or use in California.

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

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)
(company address)**

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

NOTIFICATION
Date Reviewed: 8/2/10
Reviewed By: [Signature]

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