

11694-98

1/4/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

JAN 4 2010

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**FILE COPY**

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

Subject: Notification Application per PR Notice 98-10  
**Medaphene Plus Disinfectant Deodorant**  
EPA Registration Number: 11694-98  
Application Date: December 2, 2009  
Receipt Date: December 8, 2009

Dear Ms. Schnake:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10.

**Proposed Notification:**

Addition of Influenza A virus (H1N1) label claim

**General Comment:**

Based on a review of the material submitted, the following comment applies:

The notification is acceptable.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at [garvie.heather@epa.gov](mailto:garvie.heather@epa.gov).

Sincerely,

A handwritten signature in cursive script, appearing to read "ShaRon Carlisle".

ShaRon Carlisle  
(Acting) Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

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**Application for Pesticide - Section I**

1. Company/Product Number 11694-98		2. EPA Product Manager 31 34 BP		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Medaphene Plus Disinfectant Deodorant		PM# Velma Noble			
5. Name and Address of Applicant (Include ZIP Code) Illinois Tool Works, Inc. 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.)

This Notification is for adding one label claim. We would like to add "Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)" claim to the current stamped accepted label. See Certification Statement.

**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
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
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 <i>Melissa Schnake</i>	3. Title Sr. Regulatory Specialist	
4. Typed Name Melissa Schnake	5. Date 12/02/2009	

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December 2, 2009

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

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.

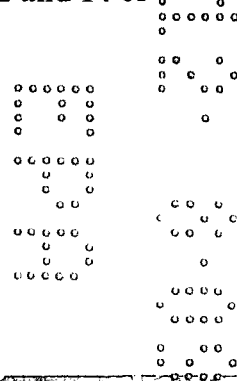
Please let me know if there is any further information required. Also, I would like to be informed via email as my submission is routed through the process.

Regards,

Melissa Schnake  
Sr. Regulatory Specialist  
mschnake@dymon.com

Encl.

**"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. Sec. 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."**



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 • telephones • 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 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.

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 A<sub>2</sub> (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 A<sub>2</sub>/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%
<b>OTHER INGREDIENTS:</b> .....	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 32 fl oz (1 qt) (946.4 mL)**

12/02/09 mks  
added H1N1 & nfs in CA  
mks 01/05/06

**(DIRECTIONS FOR USE (cont.))**

**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: 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.

**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.}

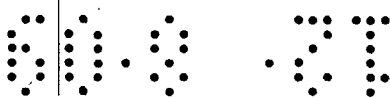
For Commercial/Institutional Use Only

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.xxxx.com and request document #xxxx}

**NOTIFICATION**  
Date Reviewed: 1/4/10  
Reviewed By: A. Garcia



Handwritten initials or mark.