

11694-98

8-12-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 12 2002

Kelly R. Hoskins
Regulatory Specialist
Illinois Tool Works, Inc.
D/B/A ITW Dymon
805 E Old 56 Hwy
Olathe, KS 66061

Subject: Notification per PR Notice 98-10
Medaphene Plus Disinfectant Spray (Bulk)
EPA Registration No. 11694-98
Application Dated: July 17, 2002
EPA Received Date: July 24, 2002

Dear Ms. Hoskins:

This letter acknowledges receipt of your notification, submitted in connection with registration under FIFRA 3(c)9 and PR Notice 98-10.

Proposed Notification

- Alternate Brand Name "Medaphene Plus Country Garden Disinfectant Spray"

General Comments

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

The application for notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions regarding this letter, please contact me at 703-308-6422.

Sincerely,



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

CONCURRENCES

SYMBOL	7510.C						
SURNAME	Heyward						
DATE	8-12-02						



Use read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

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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 Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Medaphene Plus Disinfectant Spray (Bulk)	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Illinois Tool Works, Inc. D/B/A ITW Dymon 805 E Old 56 Hwy Olathe, KS 66061 <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: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" 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.)
Notification of additional brand name. Adding "Medephene Plus Country Garden Disinfectant Spray". See attached 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
				<input type="checkbox"/> Other (Specify) _____	
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"/>	
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 Kelly R. Hoskins	Title Regulatory Specialist	Telephone No. (include Area Code) (913) 397-9889 ext. 224
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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 Regulatory Specialist	6. Date Application Received (Stamped)
4. Typed Name Kelly R. Hoskins	5. Date 17 July, 2002	

"Notification of Alternate Brand Name per PR Notice 98-10."

"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."

Released to Tabco
010730
JDP

NOTIFICATION
Date Reviewed: 8-12-02
Reviewed By: A. Peters

ITW Dymon

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

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 contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not or rarely 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 or high level disinfection.

Medaphene® Plus Country Garden 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 A/Hong Kong, Herpes Simplex Type 1 and Herpes Simplex Type 2, on pre-cleaned and inanimate hard surfaces. Kills HIV-1 (AIDS virus) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids.

ACTIVE INGREDIENTS:

o-phenylphenol 0.19%
ethyl alcohol 68.00%

OTHER INGREDIENTS: 31.81%

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**

STATEMENT OF PRACTICAL TREATMENT

If in EYES: Immediately flush with copious amounts of water, lifting eyelids to insure complete removal. Flush for 15 minutes minimum. Consult a physician. **If on SKIN:** Flush with water 15 minutes minimum. If irritation persists, consult a physician. **If SWALLOWED:** Immediately drink a large quantity of water. Contact a physician immediately.

See side panel for additional precautionary statements.

Net Contents 32 fl oz (1 qt) (946.4 mL)

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.

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.

PHYSICAL OR CHEMICAL HAZARDS

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

STORAGE & DISPOSAL

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

Pesticide Disposal: Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Do not reuse empty container. Rinse container thoroughly and discard in trash.
For Commercial/Industrial Use Only.
EPA Reg. No. 11694-98 EPA Est. No. 11694-KS-1
SDA-KS-774

Manufactured in the U.S.A. for

ITW Dymon

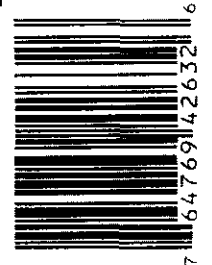
805 E. Old 56 Highway
Olathe, KS 66061
www.dymon.com

FEEDBACK 877-816-3204 **MSDS** www.dymon.com

PRODUCT/MSDS DOCUMENT # 42632

42632

010730



7/23/01
Igrna
DYMOM
CDYMON
P#42632
QuarkXPress4.11
FOLDER(S):
Macydymon
jansan
Labels
ITEM DYMOM
426 DYMOM
42632Dymom_L.qxd
COLORS:
Pms 293
Pms 186
Pms 347
CAP COLOR:
White
Vendor:
Tabco
LABEL TYPE:
Poly
STOCK:
Pressure Sensitive
BOX ART:
ITW Dymon
Box Printer-Black
INSTRUCTIONS:
None

P/H