

421-435

12/20/2010

1/6

Chester Sempkowski
Kames Varley & Sons, LLC
1200 Switzer Ave
St. Louis, MO 63147

DEC 20 2010

SUBJECT: Mist-Away Cleaner Disinfectant
EPA Registration Number: 421-435
Application Dated: November 22, 2010
Receipt Date: December 01, 2010

Dear Mr. Sempkowski:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- Propose to change Storage and Disposal per PR Notice 2007-4.

Based on a review of the submitted information, this notification is acceptable. A copy has been inserted in your file for future reference.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Note to the jacket 421-435
Dec. 20, 2010

While reviewing a notification, I noticed that the following corrections need to be made at the next label amendment.

- In the Disinfection Section please change former name of microorganism *Salmonella choleraesuis* for **Salmonella enterica**.
- In Personal Protection Section change “Clean up *should* be done...” for “Clean up **must** be done...”

Emilia Oiguenblik

E. Oiguenblik

Team 31



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 421-435	2. EPA Product Manager Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Mist-Away Cleaner Disinfectant	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) James Varley & Sons, LLC 1200 Switzer Ave. St. Louis, MO 63147 <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 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 label change per PR Notice 2007-4. This notification is consistent with the guidance in 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 or the Confidential Statement of Formula for 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.

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 Chester Sempkowski	Title Technical Director	Telephone No. (Include Area Code) 773-284-6565
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>Chester Sempkowski</i>	3. Title Technical Director	
4. Typed Name Chester Sempkowski	5. Date 10/22/10	

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is not for use on medical device surfaces.

This cleaner-disinfectant is a proven "one step" disinfectant-cleaner-sanitizer-fungicide-mildewstat-virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination. Apply this cleaner-disinfectant undiluted. For heavily soiled areas, a preliminary cleaning is required. Use a fresh solution daily or when use solution becomes visibly dirty.

Disinfection: To disinfect hard, non-porous surfaces, treated surfaces must remain wet for 10 minutes. This cleaner-disinfectant is also virucidal and fungistatic. **For Schools, Industry and Medical Institutions Use:** The broad spectrum activity of this cleaner-disinfectant has been evaluated and found to be effective against the following organisms by the A.O.A.C. Use-Dilution Test: Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Streptococcus pyogenes, Salmonella choleraesuis, Klebsiella pneumoniae, Enterobacter aerogenes, Streptococcus faecalis, Shigella dysenteriae, Salmonella typhi, Brevibacterium ammoniagenes, Serratia marcescens.

A.O.A.C. Fungicidal Test: This cleaner-disinfectant is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus). For fungicidal activity in areas such as locker rooms, dressing rooms, shower and bathroom areas, and exercise facilities.

Mold & Mildew Control: This cleaner-disinfectant will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces (as indicated in general instructions above). Allow to dry on surface and repeat when mildew growth returns.

Sanitizing Non-Food Contact Surfaces (such as floors, walls, tables, etc.): This cleaner-disinfectant is an effective sanitizer against Staphylococcus aureus and Klebsiella Pneumoniae on hard porous and non-porous, environmental surfaces. Apply by mop, sponge, cloth, or as a coarse spray so as to thoroughly wet surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a clean cloth or sponge, or allow to air dry.

To Clean and/or Deodorize: Apply by mop, sponge, cloth, or as a coarse spray on hard non-porous surfaces. Wipe dry with a clean cloth or sponge, or allow to air dry.

***Virucidal Performance:** This cleaner-disinfectant was evaluated and found to be effective against the influenza A/Brazil Virus, Vaccinia and Herpes Simplex Type 1 and Type 2 and HIV-1 (AIDS virus) on hard, non-porous, inanimate environmental surfaces.

***KILLS HIV ON PRE-CLEANED, ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or 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 & DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS."

CONTACT TIME: Leave surface wet for 10 minutes.

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces/objects before application of this product.

PERSONAL PROTECTION: Clean up should always be done wearing protective latex gloves, gowns, masks and eye protection.

DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY HAZARDS TO HUMANS AND THE ENVIRONMENT KEEP OUT OF REACH OF CHILDREN

CAUTION

Causes moderate eye irritation. Avoid contact with eyes or skin and avoid contact with clothing. Do not inhale vapor or spray mist. Wash thoroughly with soap and water after handling. **ENVIRONMENTAL HAZARDS:** Do not discharge effluent containing this product into streams, rivers, lakes, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination Act (NPDES) permitting authority has been notified in writing prior to discharge. Do not discharge into ground water without previously notifying the local sewage treatment plant authority and the EPA.

FIRST AID

Have the product container or label with you when calling a poison control center or hospital. **If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. Have person sip a glass of water while being rinsed. If person is not breathing call 911 or ambulance. **If on skin:** Wash with soap and water. If irritation occurs, call a poison control center or doctor for treatment advice. Have person sip a glass of water while being treated. Do not give anything by mouth to someone who is unconscious or who cannot swallow. Do not induce vomiting unless directed to do so by a poison control center or doctor. Do not give anyone alcohol to drink. Do not give anyone milk or fatty foods to drink.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. **PESTICIDE STORAGE:** Keep product under locked storage, in original container. **PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Do not dispose of in septic tanks, surface water, or on the ground. Do not mix with other pesticides. Do not mix with food, feed, or animal feed. Do not mix with household waste. Do not mix with other pesticides. Do not mix with food, feed, or animal feed. Do not mix with household waste. Do not mix with other pesticides. Do not mix with food, feed, or animal feed. Do not mix with household waste.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse.

KEEP FROM CHILDREN

HAZARD RATING: 1 - Health, Moderate

.0260%
.0156%
.0104%
.0340%
99.9140%
00.0000%

190-IL-01

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
KEEP OUT OF REACH OF CHILDREN**

CAUTION

effective in water up
avily soiled areas, a

Causes moderate eye irritation. Avoid contact with eyes or skin and clothing. Harmful if inhaled or absorbed through skin. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

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rum activity of this
Use-Dilution Test:
raesuis, Klebsiella
i, Brevibacterium

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 of the EPA.

FIRST AID

is (the athlete's foot
ise facilities.

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

ors caused by them
peat when mildew

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. **If on skin:** 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 inhaled:** Move person to fresh air. If person is not breathing call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice. **If swallowed:** 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

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tal surfaces. Apply
60 seconds. Wipe

pe dry with a clean

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

12a A/Brazil Virus,
ental surfaces.

PESTICIDE STORAGE: Keep product under locked storage, inaccessible to children.

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ody fluids can be
IDS).

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or other toxic material is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

RESIDUES/OBJECTS

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available.

KEEP FROM FREEZING

es/objects before

HAZARD RATING: 1 - Health, 0 - Fire, 0 - Reactivity, 0 - Special

ye protection.
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