

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL - 1 2010

John Wiegand V.P. Research and Development Canberra Corporation 3610 Holland-Sylvania Rd. Toledo, OH 43615

Subject:

Sanitizer/Virucidal Husky 803 S/V Disinfectant

EPA Reg. No. 8155-12

Application Dated: May 19, 2010 Receipt Date: June 03, 2010

Dear John Wiegand

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9. is acceptable.

# **Proposed Notification**

Revise Storage and Disposal Directions Per PR Notice 2007-4

# Comments

Based on a review of the material submitted, the following comments apply:
This application for notification to Storage and Disposal section per PR Notice 2007-4 is acceptable. A copy has been placed in our records for future reference.

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

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch1 Antimicrobial

Division (7510)

CONCURRENCES								
YMBOL			*******			:		
RIRNAME N								
PATE				*********	************		h ******	************
APPOILL PLA ABOV								

EPA Form 1320-1A (1/90)

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SEPA Environment		Registration Amendment Other			OPP Identifier Number			
Application for Pesticide - Section I								
1. Company/Product Number 8155-12		2. EPA Product Manager Velma Noble			3. Proposed Classification			
4. Company/Product (Name)		PM#			- 🗸	None Restricted		
Sanitizer/Virucidal Husky 803 S/V Disinf	ectant	31						
5. Name and Address of Applicant <i>(Include ZIP)</i> Canberra Corporation 3610 Holland-Sylvania Rd. Toledo, OH 43615  Check if this is a new address	Code)	6. Expedited Reveiw. 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						
Amendment - Explain below.  Resubmission in response to Agency lett  Notification - Explain below.	er dated	Final printed labels in repsonse to Agency letter dated "Me Too" Application.  Other - Explain below.						
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, 156.146, 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.								
Material This Product Will Be Packaged In:		ection - III						
Child-Resistant Packaging Unit Packaging	w	Water Soluble Packaging 2. Type			of Container			
Yes Yes		Yes			Metal			
✓ No ✓ No		√ No			✓ Plastic Glass			
* Certification must Unit Packaging we be submitted		"Yes" No. per ockage wgt containe	r	7	Paper Other (S	pecify)		
3. Location of Net Contents Information	4. Size(s) Retail Co	. Size(s) Retail Container			5. Location of Label Directions			
Label Container	Various - 0	Various - One gallon, 5 & 55			On label			
6. Manner in Which Label is Affixed to Product	Lithograph Paper glued Stenciled	Lithograph Other Silkscreen			reened ( ( )			
	S	ection - IV		(	( (. ( (.	•		
1. Contact Point (Complete items directly below	y for identification of	individual to be contacted,	if nec	cessary, to prec	နေန မျာ	application.)		
Name John Wiegand	i	Title V.P. Research and Development			Telephone No. (Include Area Code)			
I certify that the statements I have made I acknowledge that any knowlinglly false both under applicable law.		ttachments thereto are tru		urate and comp		6. Date Application Received (Stamped)		
2. Signature		3. Title  V.P. Research and Development						
4. Typed Name	5. Da	5. Date						
John Wiegand		May 19, 2010						



May 19, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard 2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Ms. Velma Noble, PM31, Regulatory Management Branch 1, Antimicrobial Division (7510C)

Re: Notification of Label Change for EPA Reg. 8155-12 to comply with PR Notice 2007-4

Dear Ms. Noble:

Attached please find Notification of label change for EPA Reg. No. 8155-12 Sanitizer/Virucidal Husky 803 S/V Disinfectant. The purpose of this Notification is to comply with the amended CFR §156.140 defined in PR-2007-4.

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.

John Wiegand

V.P. Research and Development

# \*SANITIZER/VIRUCIDAL HUSKY 803 S/V DISINFECTANT

ANTIBACTERIAL, ANTI-MICROBIAL

ONE-STEP DISINFECTANT- SANITIZER-FUNGICIDE-VIRUCIDE\*-DEODORIZER

EFFECTIVE IN THE PRESENCE OF 5% SERUM CONTAMINATION

FOR HOSPITAL, INSTITUTIONAL AND INDUSTRIAL USE

FOR FARM, SCHOOL, DAIRY, RESTAURANT, FOOD HANDLING AND PROCESSING AREAS, BAR AND INSTITUTIONAL KITCHEN USE

FOR USE IN FEDERALLY INSPECTED MEAT AND POULTRY PLANTS

AN EFFECTIVE SANITIZER FOR FOOD CONTACT SURFACES

FORMULATED FOR VETERINARY PRACTICE/ANIMAL CARE/ANIMAL LABORATORY DISINFECTION

3rd SINK SANITIZER

#### **PICTOGRAM**

# **ACTIVE INGREDIENTS:**

Octyl decyl dimethyl ammonium chlorides	002.250%
Didecyl dimethyl ammonium chlorides	001.125%
Dioctyl dimethyl ammonium chlorides	001.125%
Alkyl (C14 50%, C12, 40%, C16 10%)	
dimethyl benzyl ammonium chlorides	003.000%
OTHER INGREDIENTS	092.500%
TOTAL	100.000%

# KEEP OUT OF REACH OF CHILDREN

# **DANGER**

#### 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 first 5 minutes, then continue rinsing eye. If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. 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.

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

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. See side panel for additional precautionary statements.

EPA REG. NO. 8155-12

EPA EST. NO. 8155-OH-1

**NET CONTENTS: ONE GALLON** 

MANUFACTURED BY: CANBERRA CORPORATION

**TOLEDO, OHIO 43615** 

#### BACK PANEL

(Note to reviewer: The following is considered optional marketing language.)

Contains no phosphorous.

Cleans Disinfects Deodorizes.

Disinfectant Deodorizer

When used as directed, this product will deodorize surfaces in restrooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and other places where bacterial growth can cause malodors.

This product will deliver non-acid disinfectant performance in an economical concentrate.

This product is an economical concentrate.

This product can be diluted for use with a mop and bucket, trigger sprayers, sponge or by soaking.

This product is formulated for use in daily maintenance programs to deliver effective disinfecting and malodor control.

This product will not leave grit or soap scum.

This product is a versatile disinfectant for Veterinary Practice, Animal Care, Animal Laboratory and Farm Premise applications.

This product deodorizes by killing microorganisms that cause offensive odors.

This product is a complete, chemically balanced disinfectant and sanitizer that provides clear use solutions even in the presence of hard water.

Cross-contamination is of major housekeeping concern. Cross-contamination is of major food safety concern. This product has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions and industry. This product is designed to help prevent cross-contamination that can lead to nosocomial infections.

Use this product:

- •as a disinfectant on hard non-porous surfaces
- •as a sanitizer on dishes, glassware and utensils.
- •as a sanitizer in bottling and beverage dispensing equipment.
- •as a sanitizer in sanitary filling of bottles and cans
- •in sanitizing bottles or cans in the final rinse application, and for external spraying of filler and closing machines.
- •as a sanitizer in beer fermentation and holding tanks.
- •as a Food-Grade Shell-Egg sanitizer, with best results achieved in water temperatures ranging from  $78^{\circ}F 110^{\circ}F$ . May be applied through automatic washing systems, immersion tanks, foaming apparatus and low pressure sprayers.
- •as a broad spectrum disinfectant in Ultrasonic baths (Ultrasonic cleaning units).
- •to disinfect salon/barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- •in federally inspected meat and poultry plants (as a sanitizer for all surfaces not always requiring a rinse).
- as a sanitizer for all surfaces not always requiring a rinse in official establishments operating under the Federal meat, poultry, shell egg grading and egg products inspection programs
- •to disinfect sinks and tubs.
- •in kitchens, bathrooms and other areas,
- •for (non-scratch) cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

Use in hospitals, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, bars, cafeterias, institutional kitchens, food preparation and storage areas, convenience stores, institutional facilities, public rest rooms, institutions, schools and colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, camp grounds, public facilities, food processing plants, egg processing plants, beverage plants, dairy facing, kennels, pet quarters, pet shops, zoos, animal laboratories, veterinary offices, transportation terminals, airports, lotes and motels, factories, business and office buildings, barber shops and salons, tanning salons and tattoo parlors, boats, cruise ships, recreational vehicles, buses, trains, subways, taxis, airplanes, cars and trucks

Use on washable hard nonporous surfaces: such as walls, floors, countertops, stovetops, sinks, appliances, refrigerators, dishes glassware, silverware, cutlery and other eating and cooking utensils, plastic and other nonporous cutting boards and chopping blocks, coolers, ice chests, refrigerated storage and display equipment, food bins, kitchen equipment, food processors, blenders, cabinets, tables, chairs, desks, telephones, door knobs, garbage cans, shower stalls, tubs and glazed tiles, whirlpool bathtubs, toilets bowls and other bathroom surfaces, kennel runs, cages, coils and drain pans and other hard nonporous surfaces of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, fiberglass, plastic, enameled surfaces, vinyl and plastic furniture.

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Use for farm premise sanitation: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, chutes, augers, silos and other facilities and

A concentrated one-step(Hospital) disinfectant that is effective against a broad spectrum of bacteria, is virucidal\*, fungicidal and eliminates odor causing bacteria when used as directed.

A hospital disinfectant at (1:164 dilution)(450ppm active)(3.5 oz. per 4.5 gallons of water); this product kills:

Bacteria: Psuedomonas aeruginosa

Staphylococcus aureus (Staph)

Salmonella choleraesuis

Viruses: \*Herpes Simplex Type 1

\*Herpes Simplex Type 2

\*Influenza A2/Hong Kong

Fungi: Trichophyton mentagrophytes (Athlete's Foot Fungus)

This product meets AOAC Use-Dilution Test Standards for hospital disinfectants.

This product meets AOAC Germicidal & Detergent standards for sanitizing previously cleaned food-contact surfaces.

This product is an effective sanitizer for use on food contact surfaces in 60 seconds.

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces, which could harbor hazardous microorganisms, minimizes the probability of contaminating food during preparation, storage or service. Effective cleaning will remove soil and prevent the accumulation of food residues, which may decompose or support the rapid development of food poisoning organisms or toxins. Application of effective sanitizing procedures reduces the number of those disease organisms which may be present on equipment and utensils after cleaning, and reduces the potential for the transfer, either directly through tableware such as glasses, cups and flatware or indirectly through food.

To prevent cross-contamination, kitchenware and food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized after each use and following any interruption of operation during which time contamination may have occurred.

Where equipment and utensils are used for preparation of foods on a continuous or production-line basis, utensils and food contact surfaces of equipment must be washed, rinsed with potable water and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

This product fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1999 Recommendations of the U.S. Public Health Services in waters up to 500 ppm of hardness calculated as CaCO3 when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

This product has been cleared by the FDA in 21CFR 178.1010 for use on food processing equipment, utensils and other food-contact articles at a concentration of 150-400 ppm active.

# NOTE TO REVIEWER - USE DIRECTION LANGUAGE IN ( ) IS CONSIDERED OPTIONAL.

Dilution:

Disinfection (1:164)

3.5 oz. per 4.5 gallons of water (450 ppm active quat)

Sanitizer (1:376)

2.0 oz. per 5.75 gallons of water (200 ppm active quat)

Sanitizer (1:496)

2.0 oz. per 7.75 gallons of water (150 ppm active quat)

#### **DIRECTION FOR USE**

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

# **DISINFECTION/VIRUCIDAL\* DIRECTIONS**

Add 3.5 oz of product per 4.5 gallons of water (0.78 oz. per gallon) (or equivalent dilution) to disinfect hard, nonporous

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

Apply use-solution with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray. Note: For spray applications, cover or remove all food products.

Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth, sponge or mop or allow to air dry. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled.

Rinse food contact surfaces such as countertops, tables, picnic tables, appliances and/or stove tops with potable water orior to reuse. Do not use on glasses, dishes or utensils. For heavily soiled areas, a preliminary cleaning is recommended.

This product is not for use on medical device surfaces.

#### **FUNGICIDAL DIRECTIONS**

This product is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker room, dressing rooms, shower and bath areas, exercise facilities. Follow disinfection directions.

#### NON-ACID TOILET BOWL AND URINAL DISINFECTANT DIRECTIONS

Remove heavy soil prior to disinfection.

Add 0.78 oz. of product to the toilet bowl or urinal and mix. Brush thoroughly over exposed surfaces and under the rim with a cloth, sponge or bowl mop. Allow to stand for 10 minutes and flush.

# SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION DIRECTIONS:

Mix 3.5 oz. of product with 4.5 gallons of water (0.78 oz. per gallon) (or equivalent dilution) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled. Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to instruments.

# **ULTRASONIC BATH DISINFECTANT DIRECTIONS:**

Use product to disinfect hard, nonporous non-critical instruments/objects compatible with Ultrasonic cleaning units. Pour fresh solution of 3.5 oz. of product with 4.5 gallons of water (0.78 oz. per gallon) (or equivalent dilution) directly into bath chamber. Pre-clean soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to manufacturer's use directions. Remove objects and rinse with sterile water or allow to air dry. Prepare a fresh solution for each use.

#### WHIRLPOOL BATH DISINFECTANT DIRECTIONS:

After using whirlpool unit, drain and fill with a use solution of 3.5 oz. of product with 4.5 gallons of water (0.78 oz. per gallon) (or equivalent dilution) to just cover the intake valve. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair lift, and any related equipment with a clean swap, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the unit has been thoroughly disinfected, drain the solution from the unit and rinse disinfected surfaces with fresh water. Repeat for heavily soiled units.

#### TO SANITIZE FOOD CONTACT SURFACES:

Use 2 oz. of product per 5.75-7.75 gallons of water (0.25-0.34 oz. per gallon of water) (150-200 ppm active quat) (or equivalent dilution) for sanitizing of pre-cleaned hard nonporous food-contact surfaces.

Apply recommended use-dilution with a cloth, sponge, coarse sprayer or by immersion, thoroughly wetting surfaces. Treated surfaces must remain wet for one (1) minute. Allow to air dry. Do not rinse. (No Potable water rinse required.) For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface; rub with brush, sponge or cloth. Avoid breathing spray. Note: For sprayer applications, cover or remove all food products.

Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion. Prepare fresh solution for each use. For mechanical applications, use-solution may not be re-used for sanitizing but may be re-used for other purposes, such as cleaning.

Wipe dry with sponge, mop or cloth or allow to air dry. Prepare fresh solution daily or more often if solution becomes visibly diluted, cloudy or soiled.

# TO SANITIZE FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN POOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS:

For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard nonporous surfaces.

Prior to application, remove gross food particles and soil by pre-flush or pre-scrape, and when necessary, pre-soak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Apply a use solution of 2 oz. of product per 5.75-7.75 gallons of water (0.25-0.34 oz. per gallon of water) (150-200 ppm active quat) (or equivalent dilution) to the pre-cleaned hard surface, with a cloth, mop, sponge or sprayer, or by immersion, thoroughly wetting surfaces. Surfaces must remain wet for at least one (1) minute (60 seconds) followed by adequate draining and air drying. Do not rinse. (No Potable water rinse required.)

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(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has <u>any uses other than</u> Household and Residential)

#### STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for ten seconds after the flow begins to drip. Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(Note to reviewer: For Nonrefillable Containers, Container is over one gallon:)

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in areas inaccessible to children. Open dumping is prohibited.

**Pesticide Disposal**: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate 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.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Then offer for recycling if available or puncture and dispose in sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for ten seconds after the flow begins to drip. Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times.

#### FOR CONTAINERS 5 GALLONS AND OVER:

#### **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.

