

79755-4

10/21/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 79755-4

Date of Issuance: OCT 21 2010

Term of Issuance:

Conditional

Name of Pesticide Product: F10CL Veterinary Disinfectant

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Health and Hygiene (PTY) LTD
P.O. Box 906, Florida Hills 1716
South Africa

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the EPA Registration Number to read, "EPA Reg. No. 79755-4".

Signature of Approving Official:

Velma Noble
Product Manager Team-31

Date:

OCT 21 2010

Regulatory Management Branch 1

CONCURRENCES

Table with columns for SYMBOL, SURNAME, DATE, and CONCURRENCES. Includes handwritten entries for 'Antimicrobials Division (7510P)', '7510P', and '10/21/10'.

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b. As per the submitted and cited acute toxicity studies, the signal word for this product is DANGER. Revise your label to include the signal word "DANGER." In addition, revise your Precautionary Statements to be in agreement with these studies as follows:

*"Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."*

c. Revise your First Aid statements to be in agreement with the acute toxicity studies by replacing the proposed language with the following statements:

*"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.*
- *Have person sip a glass of water if able to swallow.*
- *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.*

*Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.*

*Have product container or label with you when calling a Poison Control Center or doctor for treatment advice."*

d. Revise the first section of your directions for use to include the following clarification: *"Add 1 part F10CL to 49 parts water."*

e. Correct the directions for use to by indicating the correct ounces per gallon needed for the use solution. Revise to state **2.6 ounces per gallon of water**. Make this correction twice in the Directions for Use section.

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f. Revise the Container Handling section by correcting the Container Disposal statement to bring this label into agreement with PR Notice 2007-4. Revise to include the following language: "...Fill container ¼ full with water and recap. Shake for 10 seconds. *Drain for 10 seconds after flow begins to drip. Store rinsate for later disposal.* Repeat procedure two more times..."

General Comments

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosures: Stamped Label, DER D372434  
7510P:T. Lantz:10/21/2010:79755-4 reg notice

**F10CL VETERINARY DISINFECTANT**

For cleaning and disinfection of hard, non-porous surfaces, e.g. floors, walls, bathroom fixtures, equipment, utensils and instruments in veterinary practices, kennels, stables, catteries, aviaries and other animal housing facilities, made of stainless steel, vinyl, hard plastic, glass or chrome.

**Active Ingredients:**

Alkyl (50% C14, 40% C12, 10% C16)  
dimethyl benzyl ammonium chloride .....1.08%  
Poly(hexamethylene biguanide)..... 0.08%  
hydrochloride

Other Ingredients.....98.84%  
Total.....100.0%

EPA Registration No. 79755-4      EPA Establishment No. 79755.

Net Contents 0.68oz, 3.4oz, 6.8 oz, 1.06 quart, 1.3gal

Manufactured by: Health and Hygiene (Pty Ltd)  
P O Box 906, Florida Hills 1716,  
South Africa  
Tel +27 11 474-1668

Distributed by:

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT 21 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 79755-4

**PRECAUTIONARY STATEMENT**

**HAZARDS TO HUMAN AND DOMESTIC ANIMALS**  
*Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.*  
**KEEP OUT OF THE REACH OF CHILDREN**

**DANGER**

**First Aid**

Have product container or label with you when calling a Poison Control Center or doctor for treatment advice.  
If in eyes: Hold eye open and gently rinse with water for 15-20 minutes. Remove contact lens after the first 5 minutes, then continue rinsing

**Directions for Use**

It is a violation of federal law to use this product in a manner inconsistent with its labeling. This product is effective against *Pseudomonas aeruginosa* (ATCC15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538) on hard nonporous surfaces when used at 1:50 use solution for a contact time of 10 minutes.

Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.  
Empty all troughs, racks, automatic feeders, waterers, and other feeding and watering appliances.  
Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with use solution (2.6 oz per gallon of water) for a period of 10 minutes.  
Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used in removing litter and manure.  
Ventilate buildings, vehicles, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other feeding and watering appliances with soap or detergent, and rinse with water before reuse.

Clear away debris, clean and pre-rinse with water. Prepare a solution by mixing 1 part F10CL Veterinary Disinfectant with 49 parts of clean water (2.6 oz per gallon).  
Apply to surface as a wash, or through a foamer or spray device. Wet all surfaces thoroughly and leave for a contact time of at least 10 minutes. Reapply as necessary to ensure the surface remains wet for the entire 10 minute contact time. Leave to air dry.

Batch Number:

Expiry Date:

**Physical and Chemical Hazards**

Do not mix with soaps or anionic products

**Storage and Disposal**

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

**Pesticide Storage:**

Store tightly in closed container below 30°C in a locked area inaccessible to persons unfamiliar with its use.

**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 refill or reuse container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Drain for 10 seconds after flow begins to drip. Fill container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

**Spills and leakage**

Soak up on an inert material e.g. dry earth and dispose of in an approved site. Flush small amounts with copious amounts of water.

**Product information**

For information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378

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