

79755-5

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: 79755-5

Date of Issuance: OCT 21 2010

Term of Issuance:

Conditional

Name of Pesticide Product:

F10 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 I

CONCURRENCES

Table with columns for SYMBOL, SURNAME, and DATE, used for tracking approvals.

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b. As per the submitted and cited acute toxicity studies revise your Precautionary Statements to be in agreement with these studies as follows:

“Harmful if swallowed. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using 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 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.*

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

d. Revise the Directions for Use section of the label by deleting the reference to the application of this product via a foamer. It is not appropriate to apply a ready to use product via a foamer as the efficacy of the product may be compromised with the addition of foaming ingredients.

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.

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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 D372478
7510P:T. Lantz:10/21/2010:79755-5 reg notice

F10 VETERINARY DISINFECTANT (READY TO USE)

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 chloride0.0216%

Poly(hexamethylene biguanide) hydrochloride0.0016%

Other Ingredients.....99.9768%
Total.....100.0000%

EPA Registration No. 79755-5 EPA Establishment No. 79755.

Net Contents 1.06 quart

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

Distributed by:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS

Avoid contact with eyes or clothing. 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

CAUTION

First Aid

None required.

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 (ATCC 15442), Salmonella enterica (ATCC10708), and Staphylococcus aureus (ATCC 6538) on hard nonporous surfaces when used undiluted 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 F10 Veterinary Disinfectant (Ready to Use) 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. Use F10 Veterinary Disinfectant (Ready to Use) undiluted

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 1/4 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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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.

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