15136-10

10/7/2008



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

October 7, 2008

Kris J. Kontis, Ph.D. VP Regulatory Affairs Medical Chemical Corporation 19430 Van Ness Avenue Torrance, CA 90501

Subject: Med-Chem Germicidal Solution EPA Registration Number: 15136-10 Letter Dated: September 24, 2008 Receipt Date: September 24, 2008

Dear Dr. Kontis:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment

Revised label

General Comment

The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub. If you have any questions concerning electronic label submissions, a list of contacts is available at the following website: http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts.

A stamped copy of the label is enclosed for your record.

Other Comments

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at <u>heyward.adam@epamail.epa.gov</u> or Lisa McKelvin by telephone at (703) 308-7496 or by email at <u>mckelvin.lisa@epa.gov</u> during the hours of 8:00 am to 4:00 pm EST.

When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Lisa R. McKelm

Product Manager 34
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

MCC142A-09242008

ACTIVE INGREDIENTS:

ALKYL (40% C12, 50% C14, 10% C16) DIME	THYL
BENZYL AMMONIUM CHLORIDES	0.133%
SODIUM CARBONATE	0.416%
INERT INGREDIENTS	99.451%
Total	. 100.000%

CAUTION **KEEP OUT OF REACH OF** CHILDREN

Effective against:

Staphylococcus aureus, ATCC 6538 Pseudomonas aeruginosa, ATCC 15442 Salmonella choleraesuis, ATCC 10708 Trichophyton mentagrophytes, ATCC 9533

	MED-CHEM PINK	rusty instruments. Contaminated instruments and hypodermic needles should always be sterilized by autoclaving. For technical use of hospitals, medical, dental and veterinary professions only.	(NPIC Web site <u>www.npic.orst.edu</u>) STORAGE AND DISPOSAL: DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE DISPOSAL	-
	Germicidal Solution	PRECAUTIONARY STATEMENTS: HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS	CONTAINER DISPOSAL: This is not a re-fillable container. Do not re-use empty container (bottle, can, and bucket). Rinse container with	
	REVISED SEPTEMBER 2008 EPA Reg. No. 15136-10	CAUTION: Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid contamination of food.	water, then wrap container and put in trash. PESTICIDE STORAGE: Store in dry place at a temperature between 50°F and 120°F.	.
	EPA Est. No. 15136-CA-01 Catalog # 142A-1gl Net Contents: 1 Gallon	Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.	PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of	
	Manufactured By MCC Medical Chemical Corporation 19430 Van Ness Ave.	 IF SWALLOWED: Call a poison control center of doctor immediately for treatment advice Have person sip a glass of water if able to swallow 	Federal Law. If these wastes cannot be dispose of by use according to label instructions, contact your State Poison or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.	
Í	Torrance, CA 90501	FOR LABORATORY USE ONLY	NOT FOR THERAPEUTIC USE	ł

It is a violation of Federal Law to use this product in a manner

Clean instruments thoroughly and rinse. Submerge article in

solution for at least 10 minutes. May be used for disinfection of

metal, or glass instruments and apparatus including equipment

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 or in contact with the

bloodstream or normally sterile areas of the body, or (2)

contacts intact mucous membranes but which does not

ordinarily penetrate the blood barrier or otherwise enter

NOT FOR STERILIZATION of instruments contaminated

with spore-bearing pathogens, viral hepatitis, tuberculosis, or

and tubing. Do not use with soap or other cleaning agents.

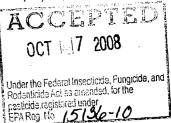
FOR DISINFECTION USE FULL STRENGTH:

First electronic version of this label; incorporates changes recommended in EPA letter August 28, 2008 (015136-00010.20080924.142A.pdf)

DIRECTIONS FOR USE:

inconsistent with its labeling.

normally sterile areas of the body.



Do not induce vomiting unless told to do so by a poison.

Rinse skin immediately with plenty of water for 15-20

Call a poison control center or doctor for treatment advice

Hold eye open and rinse slowly and gently with water for

Call a poison control center or doctor for treatment advice

Have the product container or label with you when calling a

National Pesticides Information Center (NPIC) at 1-800-858-

7378 seven days a week, 6:30 am to 4:30 pm Pacific Time

poison control center, doctor, or going for treatment. For

emergency information concerning this product, cat the

15-20 minutes. Remove contact lenses, if present, after the

· Do not give anything to an unconscious person

control center or doctor

Take off contaminated clothing

first 5 minutes, then continue rinsing

(NPIC Web site www.npic.orst.edu)

IF ON SKIN:

minutes

IF IN EYES: