

US EPA ARCHIVE DOCUMENT



CASWELL FILE

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

AUG 7 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Cosmocil FB-EPA Symbol 10182-IL
CASWELL No. 676

TO: Arturo E. Castillo, PM #32
Disinfectant Branch
Registration Division (TS-767)

THRU: David L. Ritter, Acting Section Head
Review Section #1
Toxicology Branch/HED (TS-769)

FROM: Carlos A. Rodriguez
Review Section #1
Toxicology Branch/HED (TS-769)

DRJ 8/7/84
CAR 8/7/84
WJW 8/7/84

Registrant: ICI Americas, Inc.
Wilmington, DE 19897

Action Requested:

Registration as antimicrobial agent for treatment of fabrics.

Recommendation(s):

Toxicology Branch considers this chemical a human skin sensitizer and is concerned with the proposed use for treatment of fabrics that will come in contact with human skin. Therefore, Toxicology Branch recommends against the requested use in fabrics and requests the following information to demonstrate the safety of this new use:

1. Type of fabrics to be treated with this pesticide.
2. A leaching study to determine the leaching potential and amount of Cosmocil FB leached from the treated fabrics.

3. Revise the "Directions For Use" to provide the concentration of active ingredient necessary to calculate the quantity of Cosmocil FB to be applied to fabrics in terms of per cent or ppm.

A. Formulation of Cosmocil FB Antimicrobial Agent

Active Ingredient:

Poly (iminoimidocarbonyliminoimidocarbonyl iminohexamethylene hydrochloride)-----20.00%

Inert Ingredients:-----80.00%
100.00%

B. Uses:

Cosmocil FB is intended for use in impregnating fabrics to provide protection against bacterial attack.

C. Toxicity data in support of this action:

(Reviewer, W. Dykstra, June 15, 1978 and June 17, 1980 and Dykstra/Engler 10/12/82).

Acute oral LD₅₀ (rat) = 2747 (2131-3529) mg/kg (male)
 = 2504 (2025-2969) mg/kg (female)

Core Grade - Minimum.

Acute dermal LD₅₀ (rabbit) = > 2 ml/kg.

Core Grade - Minimum.

Primary dermal irritation (rabbit) PSI = 2.6 at 72 hours. Scabs were present 10 days post treatment.

Core Grade - Minimum.

Teratology (rabbit) - Not teratogenic at 160 mg/kg (highest level tested).

Core Grade - Minimum.

Teratology (mice) - Not teratogenic at 40 mg/kg (highest level tested).

Core Grade - Minimum.

Teratology (rat) - Not teratogenic at 2000 ppm (highest level tested.)

Core Grade - Minimum.

3-Generation reproduction study (rat) NOEL = 1300 ppm (highest level tested).

Core Grade - Minimum.

Mutagenic - salmonella reverse mutation (Ames) - negative for TA1535, 1537, 1538, TA100 and TA98 with and without metabolic activation.

Core Grade - Acceptable.

Mutagenic - mammalian cell transformation test - No mutagenic activity was observed.

Core Grade - Acceptable.

90-Day feeding study (dog) - NOEL = 5,500 ppm; LEL = 11,000 ppm (highest level tested); slight hemosiderosis in males; decrease in total body weight gain in females.

Core Grade - Minimum.

80-week dermal painting (mice)-non-oncogenic at 30 mg/day (highest level tested).

Core Grade - Minimum.

Life - time feeding study (mouse)-non-oncogenic at 1000 ppm (highest level tested).

Core Grade - Minimum.

124-Week feeding/oncogenic (rat) - non-oncogenic at 2,000 ppm (highest level tested).

Core Grade - Minimum.

26-Week oral (dog) - Dose related hepatotoxicity and nephrosis. Dose levels tested were 500, 1500 and 4,500 ppm. A NOEL was obtained at 500 ppm.

Core Grade - Minimum.

Sensitization Studies

1. Human Patch Test*

Vantocil IB (PHMB) 2% v/v resulted in skin sensitization when challenged by concentrations from 2% to as low as 0.1% v/v.

2. Magnusson and Kligman Study*

Vantocil IB (PHMB) 1% (w/v) aqueous solution resulted in skin sensitization in the guinea pig when challenged by a concentration of 20% (w/v).

3. Buehler Study*

Vantocil IB (PHMB) 10% (w/v) aqueous solution resulted in moderate skin sensitization to guinea pig when challenged by a 10% solution.

*Core Grade Classification - Core - Minimum Studies.

TS-769:RODRIGUEZ:s11:X73710:8/6/84

card 4