IRB/TSS PRECAUTIONARY LABEL REVIEW

IN 4/10/87 OUT 7/22/87

ACTION CODE: 161

REVIEWER: Donna Williams

PRODUCT MGR. NO. 17

Record Number(s)
191,828

FILE OR REG NO. 2724-UNR

PRODUCT NAME ZOECON RF-299 RTU CARPET PUMP SPRAY

COMPANY NAME & ADDRESS Zoecon Industries, Division of Zoecon Corp. 12200 Denton Dr., Dallas, TX 75234

SUBMISSION PURPOSE New product registration

CHEMICAL & FORMULATION Ready to Use Non-Aersol Spray (0.007% Methoprene and 0.25% Permethrin ai; 99.743 % inert ingredients).

PRODUCT USES Applied to carpets, rugs, upholstery and pet bedding to control fleas.

COMMENTS AND RECOMMENDATIONS:

1. All studies submitted are acceptable and the product was assigned the following categories:

	TOX CAT	CORE CLASS	MRID#
ACUTE ORAL LD 50	IV	MINIMUM	40106001
ACUTE DERMAL LD50	III	MINIMUM	40106002
EYE IRRITATION	III	MINIMUM	40106003
SKIN IRRITATION	IV	MINIMUM	40106004
DERMAL SENSITIZATION	Non-Sensitizer	MINIMUM	40106005

2. Acute Inhalation study conducted on Zoecon RF-252 Aerosol, EPA Reg No. 2724-322 is applicable to support this data requirement. Placing this product in TOX CAT IV for acute inhalation.

3. Labeling is partially acceptable, "Practical Treatment Statement" (heading) needs to be positioned above individual statements.

FILE OR REG NO. 2724-UNR

TEST ARTICLE: RTU 206-106-1 [0.13% permethrin & 0.18% hydroprene]

TEST FACTILITY & Mideco, Inc.

ADDRESS 520 Wakara Way

Salt Lake City, UT 84108

STUDY SUMMARIES:

1. ACUTE ORAL LD_{50} (LIMIT TEST) EPA MRID NO. 40106001
STUDY NO. 58551 ; STUDY INITIATED 5-20-85
Conforms with Health Assessment Guidelines (81-1) Y/N YES
Deviations from guidelines NONE

Level(s) Tested 5M & 5F SD rats: 5100 mg/kg undiluted, oral gavage.
Significant Toxic Signs Unremarkable.

Significant Necropsy Findings Unremarkable.

LD_{50}= (Males) > 5100 mg/kg 0% Mortality
(Females) > 5100 mg/kg 0% Mortality
(Combined) > 5100 mg/kg 0% Mortaltiy
Core Classification MINIMUM (If Supplementary list deficiencies)

Product Toxicity Category for this route of exposure IV

2. ACUTE DERMAL LD_{50} (LIMIT TEST) EPA MRID NO. 40106002
STUDY NO. 58552 ; STUDY INITIATED 5/31/85
Conforms with Health Assessment Guidelines (81-2) Y/N YES
Deviations from guidelines NONE
Level(s) Tested 5M & 5F NZ White rabbits: 2.1 g/kg undiluted. Clipped intact skin. 24-hour occulded exposure.
Significant Toxic Signs One mortality (female), diarrhea, well-defined to moderate erythema and slight edema.
Significant Necropsy Findings Kidney and lung discoloration. Expired animal; ocular and nasal discharge.

LD_{50}= (Males) > 2.1 g/kg 0% Mortality
(Females) > 2.1 g/kg 10% Mortality
(Combined) > 2.1 g/kg
Core Classification MINIMUM (If Supplementary list deficiencies)

Product Toxicity Category for this route of exposure III

FILE OR REG NO. 2724-UNR

3. PRIMARY EYE IRRITATION EPA MRID NO. 40106003
STUDY NO. 58554 ; STUDY INITIATED 5-20-85
Conforms with Health Assessment Guidelines (81-4) Y/N YES
Deviations from guidelines NONE

Level(s) Tested 9 NZ White rabbits: 0.1 ml undiluted corneal surface (appilcation). 3 washed 60 sec post-application. 6 no wash.
Ocular Findings [list number of animals elicting response and period of duration]
corneal opacity: 1/6 (unwashed) at 72-hrs, clearing by day-10.
iristis: none exhibited
conjunctivae: 6/6 (unwashed) & 3/3(washed) at 24-hrs. 1/6 (unwashed) at day-7, clearing by day-10.
Core Classification MINIMUM (If Supplementary list deficiencies)

Product Toxicity Category for this route of exposure III

4. PRIMARY DERMAL IRRITATION EPA MRID NO. 40106004
STUDY NO. 58553 ; STUDY INITIATED 5-21-85
Conforms with Health Assessment Guidelines (81-5) Y/N YES
Deviations from guidelines NONE

Level(s) Tested 6 NZ White rabbits: 0.5 mls undiluted. Clipped intact skin. 4-hour occluded, 4 test sites.
Dermal Findings [list number of animals elicting response and period of duration]
erythema 6/6 well-defined at 24 & 72-hrs. 6/6 very slight at 24 & 72-hrs.
edema none exhibited.
PDIS 1.46
Core Classification MINIMUM (If Supplementary list deficiencies)

Product Toxicity Category for this route of exposure IV

5. DERMAL SENSITIZATION EPA MRID NO. 40106005
STUDY NO. 58555 ; STUDY INITIATED 6-04-85
Test Method Used Buehler Test
Deviations from accepted test method None.

Concentration Tested 10M Hartely guinea pigs: undiluted. Clipped intact skin. 3, 6-hour repeat applications (same site).
Postive Control 0.2% DNCB in 80% ethanol/water.
Induction Findings/ Mean Score no dermal irritation elicted.
Challenge Findings/ Mean Score no dermal irritation elicted.
Product Classification Non-Sensitizer
Core Classification MINIMUM