

IRB/TSS Precautionary Labeling Review 3-25-86

TO: PM-16

SUBJECT: 400-UEO

Hinder-H Rabbit and Deer Repellent  
Uniroyal Chemical  
Division of Uniroyal, Inc.  
74 Amity Road  
Bethany, CT 06525

In TSS: 11-29-86  
Record #: 163355  
Action: 161  
Accession #: 260535

Formulation: Spray concentrate.

Active Ingredients:

Ammonium soaps of higher fatty acids --- 15%  
Inert Ingredients - - - - - 85%

Background: This is an application for  
a new registration. [REDACTED]

[REDACTED] but is  
geared more towards home garden  
use. Registration has submitted dermal  
sensitization and dermal irritation studies  
to support both registrations.

subject product but is proposed to be used on home gardens. The acute oral, acute dermal, acute inhalation and primary eye irritation studies on 400-383 have been reviewed and approved previously and these studies will support registration of 400-383 and 400-11ED.

Submitted Data: Studies were done by:  
Environmental Health and Toxicology  
Chevron Environmental Health Center  
P.O. Box 1272  
Castro and Midway streets  
Richmond, CA 94802.

1. Dermal Sensitization: SOCAL 2082, date 1-6-84. 14M Hartley albino guinea pigs were induced with a series of ten 6-hour occluded dermal application of 0.4 ml of 10% solution in saline. This dilution factor was determined by pre-test screening and applications were spaced 2 days apart. Challenge with 0.3 ml was 2 weeks after the last induction application. A second challenge was given a week later.

→ 2

Slight to well defined erythema and slight edema was observed in 12 subjects after first challenge, and in 10 subjects after second challenge. Mean scores were higher than mean induction scores. Irritation after tenth induction was also higher than the rest of the applications. A positive control group of 10 subjects showed positive sensitization when induced and challenged with 0.1% ~~DNCB~~ DNCB.

Study classification: Core minimum data.  
Product classification: Mild sensitizer.

2. Primary Dermal Irritation: SOCAL 2081, date 10-13-83. Six NZ white rabbits received 4 hours occluded dermal exposure to 0.5 ml on 2 intact and 2 abraded sites per rabbit. Observations were made at 1, 24, 48, 72 hours and on days 7 and 14. Draize scoring <sup>system</sup> was used to record irritation. Slight to well-defined erythema and slight edema were observed. Edema cleared by 7 days and erythema cleared by 14 days.

PDIS = 2.

Study classification: Core minimum data

Product classification: Toxicity category III

Comments: 1. The dermal sensitization and the primary dermal irritation studies are acceptable, and acute toxicity profile for these 2 products (400-383 and 400-UEO) is now complete as follows:

Exposure Route	Toxicity Category
Acute Oral	IV
Acute Dermal	III
Primary Eye Irritation	II
Primary Dermal Irritation	III
Acute Inhalation	III
Dermal Sensitization	Mild Sensitizer

2. On the basis of ~~above~~ <sup>the</sup> toxicities given above, following changes should be made in precautionary labeling:

- Add "if inhaled" to "Harmful if swallowed". ~~Also~~
- Add "Avoid breathing spray mist."

3. Note to Team: The 400-383 label has a statement - "Retreatment may be necessary after heavy rainfall", which is missing from proposed label of subject product.

Rita Kumar  
IRB/TSS