

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: April 20, 1978

SUBJECT: Puritan #6790 - EPA File Symbol #541-EAL  
Caswell #507, 50, 658, 846, 887AA  
Shaughnessy #047501, 064101, 064103, 039107, 079020

FROM: William B. Greear *W. Greear*  
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Recommendations

Although the oral LD<sub>50</sub>, dermal LD<sub>50</sub>, eye and skin irritation studies were adequately performed, they were nevertheless performed with a 1:128 aq. dilution of Puritan #6790, rather than with the undiluted formulation and hence will not aid in support of registration of the formulation. The following studies should be submitted prior to registration:

1. Acute Oral LD<sub>50</sub> - formulation
2. Acute Dermal LD<sub>50</sub> - formulation
3. Primary Eye Irritation - formulation
4. Primary Skin Irritation - formulation
5. Teratology - on each of the following active ingredients
  - a. p-tert-amylphenol
  - b. o-phenylphenol
  - c. tetrasodium ethylene diamine tetraacetate
  - d. triethanolamine dodecylbenzenesulfonate

\*The data submitted have not exceeded any RPAR criteria

Review

1. Acute Toxicity and Irritation Studies on a 1:128 Aq. Dilution of Puritan #6790 - (Hill Top Testing Services, Inc., Report #77570-21, 8/14/77, Acc #232826)

- a. Acute Oral LD<sub>50</sub>

Fifty Sprague-Dawley derived albino rats, weighing 162-244g, were divided into 5 groups of 5 male and 5 female animals each and administered 0.464, 1.00, 2.15, 4.64 and 10.0 ml/kg of a

1:128 aq. dilution of Puritan #6790, by gavage. The animals were observed daily for mortality and signs of toxicity. At the end of the 14-day observation period the animals were weighed, sacrificed and necropsied.

### Results

LD<sub>50</sub> >10.0 ml/kg (no deaths occurred)

Toxic Signs: diarrhea

Necropsy: unremarkable

TOX Category: N/A

Classification: Core-Minimum Data

1) food consumption and body weight data were not determined daily.

### b. Acute Dermal LD<sub>50</sub>

21.5 ml/kg of a 1:128 aq. dilution of Puritan #6790 was applied to the clipped skin of the back of each of 4 male and 4 female New Zealand White rabbits, weighing 2216-2839 g. Four of the animals were further prepared by abrading the skin. The test material was allowed to remain in contact with the skin under an occlusive wrapping for a period of 24 hours. Following the 24 hour exposure period the wrappings were removed and any residual test material was removed. The animals were observed for 14 days. Gross necropsies were performed.

### Results

LD<sub>50</sub> >21.5 ml/kg (no deaths occurred)

Toxic Signs: diarrhea and emaciation in 2 rabbits; erythema

Necropsy: unremarkable

TOX Category: N/A

Classification: Core-Minimum Data

1) food consumption and body weight data were not determined daily.

### c. Primary Skin Irritation

0.5 ml of a 1:128 aq. dilution of Puritan #6790 was applied to an intact and an abraded area on the clipped skin of the back of each of 6 New Zealand White rabbits. The test material was allowed to remain in contact with the skin under an occlusive wrapping for a period of 24 hours; after which, the wrapping and any residual test material were removed. Irritation was scored at 24 and 72 hours.

Results

P.I. = 0/8

TOX Category: N/A

Classification: Core-Minimum Data

1) readings were not made on 2 intact and 2 abraded skin sites.

d. Primary Eye Irritation

0.1 ml of a 1:128 aq. dilution of Puritan #6790 was instilled into the right eye of each of 9 New Zealand White rabbits. Six rabbits received no further treatment. The treated eyes of the remaining 3 rabbits were irrigated after 30 secs with 200 ml of water. The ocular irritation was graded at 24 hours and daily thereafter for a total of 7 days.

Results

No irritation was observed.

TOX Category: N/A

Classification: Core-Guideline

WG/ccw

R/D Init: GEWhitmore 4/12/78

*✓ for GEW 4/25/78*