

VARISEAL MANUFACTURING CORP
PO BOX 710
15547 MAIN MARKET ROAD
PARKMAN, OH 44080
ATTN: DEBASHISH CHAKRAVARTHY

Lab No 93T 11849 00
PO No 7444
ID NO. Not supplied

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**ACUTE SYSTEMIC TOXICITY – T 12
(CURRENT USP)**

Test Article: Comb -18

Extracting Conditions:

A 30.6 cm_ portion was covered with 80 ml of vehicle(s) and extracted at 50° C for 72 hour(s). Control solutions (extracts without test article) were prepared in a similar manner.

Condition of Extracts:

Test (s): SC cloudy with particulates, CSO clear with particulates.

Control (s): SC and CSO clear

SC and CSO tests clear upon filtering with _m filter disc.

Procedure:

Healthy, young albino mice ranging in body weight from 17 to 23 grams were used as test animals. The animals, identified by fur markings, were group housed in stock cages and offered food and water ad libitum.

Two groups, each consisting of five mice, were used for each extract. One group was injected with the extract of the test article, while the other group was injected with the control solution. After injection, the animals were observed immediately and at 4, 24, 48 and 72 hours. The initial and final body weights were recorded as well as mortalities and/or reactions. If, during the observation period, none of the animals treated with the test article extract showed a significantly greater reaction than the animals treated with the control solution, then the test article met the requirements of the test.

**ORIGINAL ON
FILE**

Completed

Tech

Approved

Test Article : Comb- 18

| | | Mortality | and | Body | Weight | Data | | |
|---|------------------|------------------------|------------------------|--------------------|------------------|------------------------|------------------------|--------------------|
| | | TEST | ARTICLE | | CONTROL | ARTICLE | | |
| Extract, Route And Dose | Animal Number | Weight (g) Day 0 | Weight (g) Day 3 | # Dead/ #Tested | Animal Number | Weight (g) Day 0 | Weight (g) Day 3 | # Dead/ #Tested |
| Sodium Chloride Injection (SC) (IV,50 ml/Kg) | 1 | 18 | 21 | 0/5 | 1 | 17 | 19 | 0/5 |
| | 2 | 17 | 19 | | 2 | 17 | 17 | |
| | 3 | 17 | 20 | | 3 | 17 | 13 | |
| | 4 | 17 | 19 | | 4 | 17 | 18 | |
| | 5 | 18 | 19 | | 5 | 17 | 17 | |
| Cottonseed Oil (CSO) (IP, 50 ml/Kg) | 1 | 18 | 19 | 0/5 | 1 | 17 | 21 | 0/5 |
| | 2 | 18 | 22 | | 2 | 17 | 19 | |
| | 3 | 17 | 20 | | 3 | 17 | 19 | |
| | 4 | 20 | 20 | | 4 | 17 | 19 | |
| | 5 | 18 | 21 | | 5 | 17 | 17 | |

Test Article: **PASSES**

Date Prepared: 9-21-93 Date Injected: 9-24-93 Date Terminated: 9-27-93

Comments: Release paper removed from two sides.

ORIGINAL (w/signatures) ON FILE

Completed

Tech

Approved