

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

### **INTRACUTANEOUS TOXICITY – T13 (CURRENT USP)**

Test Article: Comb-18

Extracting Conditions:

A 30.6 cm<sub>2</sub> 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 0.8µm filter disc.

Procedure: Two healthy New Zealand White rabbits free of significant dermal blemishes were use as test animals for each extract or pair of extracts. Animals were housed individually, fed daily, and allowed water ad libitum. Prior to injection, the hair was closely clipped from the back and flanks of each rabbit. Exactly 0.2 ml of the test article extract was injected intracutaneously into five separate sites on the right side of the back of each animal while 0.2 ml of the control solution was injected into five separate sites on the left side. Injection sites were examined 24,48, and 72 hours after injection for erythema and edema. The average tissue reaction to the extract of the test article was compared with the control. The requirements of the test were met if no significant differences were noted.

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IMG Completed \_\_\_\_\_ Tech \_\_\_\_\_ Approved \_\_\_\_\_  
TII013-800

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Lab No. 95T 0321400

**INTRACUTANEOUS TOXICITY – T13  
(CURRENT USP)**

**Scoring Key**

ER = Erythema  
0 = No Erythema  
1 = Very Slight (barely perceptible)  
2 = Well-defined (pink)  
definite raising)  
3 = Moderate to Severe (red)  
4 = Severe (beet redness) to slight  
eschar formation (injuries in depth)

ED = Edema  
0 = No Edema  
1 = Very Slight (barely perceptible)  
2 = Slight (edges of area well-defined by  
definite raising)  
3 = Moderate (raised about 1 mm)  
4 = Severe (raised more than 1 mm, may  
extend beyond the area of exposure)

Extract	Rabbit No.	Site	24 hours		48 hours		72 hours	
			ER	ED	ER	ED	ER	ED
Sodium Chloride(SC)	85539	Test	0	0	0	0	0	0
	85541	Control	0	0	0	0	0	0
		Test	0	0	0	0	0	0
		Control	0	0	0	0	0	0
Cottonseed Oil (CSO)	85539	Test	2	1	2	1	1	1
	85541	Control	2	1	2	1	2	1
		Test	2	1	2	1	1	1
		Control	2	1	2	1	2	1

Average Test (-) Average Control	Difference	Passes	Fails
SC = 0.0 – 0.0	0.0	X	
CSO = 1.3 – 1.5	0.0	X	

Comments: The release paper was removed from one side. The ration of the test article to vehicle was adjusted due to the absorbent nature of the sample.

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