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FOOD AND DRUG
Research **LABORATORIES, INC.**

60 Evergreen Place
East Orange, New Jersey 07018
(201) 677-9500

857 9525

FINAL REPORT

CLINICAL SAFETY EVALUATION OF SAMPLE: AVA ALOE VERA GEL-A

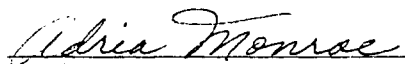
10 Repeated Insult Patch Test

52 Subjects

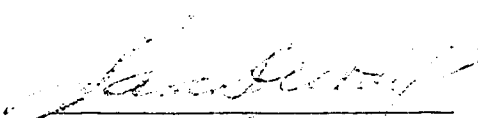
Submitted to:

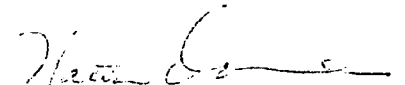
J. Christopher Van Wagoner
Q.C. Director
Aloe Vera of America
802 Easy Street
Garland, Texas 75042

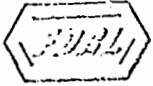
Panel No. 81-042
OE No. 2449


Adria Monroe, BS
Project Manager

December 9, 1981


Harold Schwartz, PhD
President


Nathan Dorman, MD
Dermatologist



CLINICAL SAFETY EVALUATION OF SAMPLE: AVA ALOE VERA GEL-A

PURPOSE

The purpose of the test was to determine the irritation and/or sensitization potential of the test product after repeated application under occlusion to the skin of human subjects.

EXPERIMENTAL DESIGN

Panel Selection

A total of 52 subjects, 5 male and 47 female, ranging in age from 18 to 60 years completed the test.

The subjects were informed of the nature of the test including possible adverse reactions. Written informed consent was obtained. Parental consent was obtained for minors.

Additionally, the subjects were dependable and were able to read and understand instructions. The subjects did not exhibit any physical or dermatological condition which would have precluded application of the test product.

Test Material

The test material used in this study was provided by Aloe Vera of America. It was received on September 18, 1981 and was as follows:

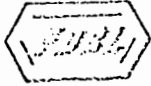
<u>Product</u>	<u>Description</u>
Ava Aloe Vera Gel-A	brownish-yellow liquid

Method

The 10 Repeated Insult Patch Test (10 RIPT) was conducted as follows:

Induction Phase:

The quantity of test material per test patch was approximately 0.2ml of the product. The test material was placed onto a 2 cm square of Webril^R (Kendall) non-woven cotton fabric affixed to 1" Dermicel (Johnson & Johnson) cloth tape. The patch was applied to the inner aspect of the arm or the back of each subject and covered with overlapping strips of Blenderm (3M) tape to form occlusion.



Method

Induction Phase: (cont'd)

The subjects removed the patch 24 hours after application. Twenty-four hour rest periods followed the Tuesday and Thursday removals and 48-hour rest periods followed the Saturday removal. The site was scored by a trained examiner just prior to the next patch application. This procedure was repeated until 10 applications of the test material had been made.

Responses were scored according to the following scale:

- 0 = no reaction
- ± = minimal erythema
- 1 = erythema
- 2 = erythema and edema
- 3 = erythema and moderate edema with papules
- 4 = erythema, marked edema, substantial vesiculation

Challenge Phase:

Ten to seventeen days after application of the last induction patch, the challenge patch was applied to the original contact site and to a fresh, adjacent site. The sites were scored at 24 and 48 hours after application. The panelists were asked to report to the laboratory any delayed reactions which might have occurred after the last reading of the challenge.

RESULTS AND CONCLUSIONS

A total of 52 subjects completed the test; 9 subjects discontinued for personal reasons and not because of adverse reactions to the test product, 2 subjects were discontinued due to violation of protocol -- data is shown up until discontinuation.

Sample: Ava Aloe Vera Gel-A (See Table)

Only slight transient reactions were observed during testing.

Under 10 RIPT experimental procedures, Sample: Ava Aloe Vera Gel-A did not induce irritation nor sensitization in human subjects.

TABLE

Sample: Ava Aloe Vera Gel-ARepeated Insult Patch Test - Individual Scores

No.	Initials	Age	Sex	Exposure Number										Challenge				
				1	2	3	4	5	6	7	8	9	10	Original		Virgin		
													24h	48h	24h	48h		
1	NC	50	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
2	MM	33	F	Discontinued										0	0	0	0	
3	LP	34	F	Discontinued														
4	MI	41	F	Discontinued														
5	JC	36	F	Discontinued														
6	WC	40	F	0	0	0	0	0	0	0	0	Discontinued						
7	MF	35	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
8	JS	35	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
9	MV	28	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
10	RJ	24	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
11	BW	31	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
12	LG	38	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
13	YG	29	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
14	NA	54	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
15	WW	32	M	0	0	0	0	0	0	0	0	Discontinued						
16	MW	19	F	Discontinued, violation of protocol														
17	BL	55	F	Discontinued, violation of protocol														
18	PS	24	F	0	Discontinued													
19	SL	34	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
20	RS	20	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
21	LW	27	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
22	DW	23	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
23	TZ	20	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
24	NK	58	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
25	WK	26	M	0	0	0	±	0	0	0	0	0	0	0	0	0	0	
26	PP	20	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
27	PP	26	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
28	LG	18	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
29	AMB	18	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
30	JC	43	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
31	JD	21	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
32	MA	30	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
33	MB	58	M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
34	BB	38	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
35	JC	39	F	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Scale: 0 = no reaction

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h = hours after application

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													24h	48h	24h	48h		
36	LJ	30	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
37	EP	30	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
38	JI	18	F	0	0	Discontinued												
39	EP	51	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
40	PMcC	18	F	0	0	Discontinued												
41	AO'R	60	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
42	BP	41	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
43	VP	57	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
44	JC	26	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
45	PB	35	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
46	DS	47	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
47	RH	18	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
48	MC	30	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
49	KB	20	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
50	PS	35	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
51	RM	19	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
52	LJN	47	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
53	LK	34	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
54	CMcG	21	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
55	ER	26	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
56	MM	23	F	0	0	0	0	0	0	0	0	1	0	0	0	0		
57	EB	31	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
58	ET	50	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
59	KB	18	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
60	AR	18	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
61	PS	47	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
62	DR	57	F	0	0	0	0	0	0	0	0	0	0	0	0	0		
63	CMcC	47	F	0	0	0	0	0	0	0	0	0	0	0	0	0		

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