



EST. 1975

Consumer Product Testing Co.

FINAL REPORT

CLIENT:

Chattem, Inc.
1715 West 38th Street
Chattanooga, Tennessee 37409

ATTENTION:

William J. Durkin
Manager,
Product Safety & Regulatory Affairs

TEST:

Repeated Insult Patch Test
Protocol No.: 1.01

TEST MATERIAL:

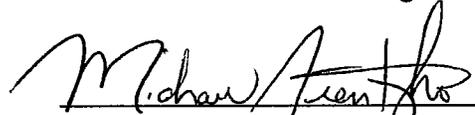
Study CSE 25-³⁹¹191 Non Hydrogel Type Patch Lot # E010

EXPERIMENT

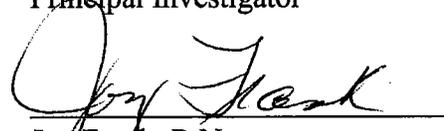
REFERENCE NUMBER:

C00-0602.01


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Consumer Product Testing Co.

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QUALITY ASSURANCE UNIT STATEMENT

Study No.: C00-0602.01

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of clinical laboratory studies. The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected at time intervals to assure the integrity of the study. The findings of such inspections are reported to management and the Study Director. All materials and data pertinent to this study will be stored or disposed of in accordance with current Standard Operating Procedures.

Date(s) of inspection:	June 16, 2000	July 31, 2000
	June 20, 2000	August 1, 2000
	June 28, 2000	August 7, 2000
	June 30, 2000	August 11, 2000

Senior personnel involved:

OnChi Cheung, B.S.	-	Quality Assurance Associate
Titilayo Bello, B.S.	-	Quality Assurance Associate


Kathleen Alworth, B.A.
Director of Quality Assurance

The representative signature of the Quality Assurance Unit signifies that this study has been performed in accordance with standard operating procedures and study protocol as well as government regulations regarding such procedures and protocols as outlined in the Federal Register (Vol. 46, No. 17 of Tuesday, January 27, 1981).

Objective: To determine by repetitive epidermal contact the potential of a test material to induce primary or cumulative irritation and/or allergic contact sensitization.

Participants: One hundred thirteen (113) qualified subjects, male and female, ranging in age from 18 to 79 years, were selected for this evaluation. One hundred two (102) subjects completed this study. The remaining subjects discontinued their participation for various reasons, none of which were related to the application of the test material.

Inclusion Criteria:

- a. Male and female subjects, age 16^a and over.
- b. Absence of any visible skin disease which might be confused with a skin reaction from the test material.
- c. Prohibition of use of topical or systemic steroids and/or antihistamines for at least seven days prior to study initiation.
- d. Completion of a Medical History form and the understanding and signing of an Informed Consent form.
- e. Considered reliable and capable of following directions.

Exclusion Criteria:

- a. Ill health.
- b. Under a doctor's care or taking medication(s) which could influence the outcome of the study.
- c. Females must not be pregnant or nursing.
- d. A history of adverse reactions to cosmetics or other personal care products.

Test Material: Study CSE 25-191 Non Hydrogel Type Patch Lot # E010

Study Schedule:	<u>Panel #</u>	<u>Initiation Date</u>	<u>Proposed Completion Date</u>	<u>Actual Completion Date</u>
	20000326	June 19, 2000	July 27, 2000	July 28, 2000
	20000334	June 21, 2000	July 27, 2000	August 3, 2000

^aWith parental or guardian consent

Methodology:

The upper back between the scapulae served as the treatment area. Prior to the initiation of this study, the test material was cut into approximately 1" x 1" pieces. This sample was then placed over the absorbent pad portion of an adhesive dressing*. When applied to the appropriate treatment site, this dressing formed a semi-occlusive patch.

Induction Phase:

Patches were applied three (3) times per week (e.g., Monday, Wednesday, and Friday) for a total of nine (9) applications. The site was marked to ensure the continuity of patch application. Following supervised removal and scoring of the first Induction patch, participants were instructed to remove all subsequent Induction patches at home, twenty-four hours after application. It was noted that due to a holiday weekend which occurred during the Induction Phase, subjects who required a makeup day experienced a delay between applications. The evaluation of this site was made again just prior to re-application. If a participant was unable to report for an assigned test day, one (1) makeup day was permitted. This day was added to the Induction period.

With the exception of the first supervised Induction Patch reading, if any test site exhibited a moderate (2-level) reaction during the Induction Phase, application was moved to an adjacent area. Applications are discontinued for the remainder of this test phase, if a moderate (2-level) reaction was observed on this new test site. Applications would also be discontinued if marked (3-level) or severe (4-level) reactivity was noted.

Rest periods consisted of twenty-four hours following each Tuesday and Thursday removal, and forty-eight hours following each Saturday removal.

Challenge Phase:

Approximately two (2) weeks after the final Induction patch application, a Challenge patch was applied to a virgin test site adjacent to the original Induction patch site, following the same procedure described for Induction. The patch was removed and the site scored at the clinic twenty-four and seventy-two hours post-application.

Evaluation Key:

- 0 = No visible skin reaction
- + = Barely perceptible or spotty erythema
- 1 = Mild erythema covering most of the test site
- 2 = Moderate erythema, possible presence of mild edema
- 3 = Marked erythema, possible edema
- 4 = Severe erythema, possible edema, vesiculation, bullae and/or ulceration

Results:

The results of each participant are appended (Table 1).

Barely perceptible (+) to moderate (2-level) patch test irritant/cumulative irritant responses were observed on eleven (11/102) test panelists (Subject's #2, 22, 37 [discontinued], Panel #20000326; 9, 23, 25, 26, 28, 31, 50, 54, Panel #20000334) during the Induction and/or Challenge phases of the study. It was noted that Subject's #9 and 31 (Panel# 20000334) exhibited skin response patterns suggestive of a hyperirritability to one or more of the test product components. Based on the lack of any other observed dermal sequelae, neither of these response patterns was considered indicative of induced allergic contact sensitization.

Summary:

Under the conditions of a repeated insult (semi-occlusive) patch test, test material, Study CSE 25-191 Non Hydrogel Type Patch Lot # E010, was a patch test irritant/cumulative irritant to approximately 11% (11/102) of the test population. There was no evidence of induced allergic contact dermatitis.

Table 1
 Panel #20000326

Individual Results

Study CSE 25-191 Non Hydrogel Type Patch Lot # E010

Subject Number	24*hr	-----Induction Phase-----									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
1	0	0	-----DID NOT COMPLETE STUDY-----										
2	0	0	0	0	0	0	0	0	0	0	0	+	0
3	0	0	0	0	0	0	0	0	0	0	-----DNC-----		
4	0	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	-----DNC-----			
8	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0
22	+	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch
 DNC = Did not complete study

Table 1
 (continued)
 Panel #20000326

Individual Results

Study CSE 25-191 Non Hydrogel Type Patch Lot # E010

Subject Number	24*hr	-----Induction Phase-----									Virgin Challenge Site			
		1	2	3	4	5	6	7	8	9	24*hr	72 hr		
29	0	0	0	0	0	0	0	0	0	0	0	0	0	
30	0	0	0	0	0	0	0	0	0	0	0	0	0	
31	0	0	0	0	0	0	0	0	0	0	0	0	0	
32	0	0	0	0	0	0	0	0	0	0	0	0	0	
33	0	0	0	0	0	0	0	0	0	0	0	0	0	
34	0	0	0	0	0	0	0	0	0	0	0	0	0	
35	0	0	0	0	0	0	0	0	0	0	0	0	0	
36	0	0	0	0	0	0	0	0	0	0	0	0	0	
37	+	0	0	0	0	0	0	0	-----DNC-----					
38	0	0	0	0	0	0	0	0	0	0	0	0	0	
39	0	0	0	0	0	0	0	0	0	0	0	0	0	
40	0	0	0	0	0	0	0	0	0	0	0	0	0	
41	0	0	0	0	0	0	0	0	0	0	0	0	0	
42	0	0	0	0	0	0	0	0	0	0	0	0	0	
43	0	0	0	0	0	0	0	0	0	0	0	0	0	
44	0	0	0	0	0	0	0	0	0	0	0	0	0	
45	0	0	0	0	0	0	0	0	0	0	0	0	0	
46	0	0	0	0	0	0	0	0	0	0	0	0	0	
47	0	0	0	0	0	0	0	0	0	0	0	0	0	
48	0	0	0	0	0	0	0	0	0	0	0	0	0	
49	0	0	0	0	0	0	0	0	0	0	0	0	0	
50	0	0	0	0	0	0 ^m	0	0	0	0	0	0	0	
51	0	0	0	0	0	0	0	0	0	0	0	0	0	
52	0	0	0	-----DID NOT COMPLETE STUDY-----										
53	0	0	0	0	0	0	0	0	0	0	0	0	0	
54	0	0	-----DID NOT COMPLETE STUDY-----											
55	0	0	0	-----DID NOT COMPLETE STUDY-----										
56	0	0	0	0	0	0	0	0	0	0	0	0	0	

24* = Supervised removal of 1st Induction and Challenge Patch
 DNC = Did not complete study
 m = Additional makeup day granted at the discretion of the clinic supervisor

Table 1
 (continued)
 Panel #20000334

Individual Results

Study CSE 25-191 Non Hydrogel Type Patch Lot # E010

Subject Number	24*hr	-----Induction Phase-----									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
1	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	---	DNC--
3	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	2 ^A	2 ^X	-	-	-	2	2	2 ^{**}
10	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0
21	-----DID NOT COMPLETE STUDY-----												
22	0	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	+	0
24	0	0	0	0	0	0	0	0	0	0	0	0	0
25	+	0	0	0	0	0	0	0	0	0	0	0	0
26	+	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	1	0

24* = Supervised removal of 1st Induction and Challenge Patch
 A = Changed to adjacent site
 X = Patching discontinued
 ** = 96 follow-up evaluation

Table 1
 (continued)
 Panel #20000334

Individual Results

Study CSE 25-191 Non Hydrogel Type Patch Lot # E010

Subject Number	24*hr	-----Induction Phase-----									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
29	0	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0	0
31	+	+	2 ^A	2 ^X	-	-	-	-	-	-	0	+	0**
32	0	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	-----DID NOT COMPLETE STUDY-----										
44	0	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0
50	+	0	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0	0	0
52	0	-----DID NOT COMPLETE STUDY-----											
53	0	0	0	0	0	0	0	0	0	0	0	0	0
54	+	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0	0	0
57	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch
 A = Changed to adjacent site
 X = Patching discontinued
 ** = 96 follow-up evaluation

Table 2
Panel #20000326

Subject Data

Subject Number	Initials	Age	Sex
1	CS	40	M
2	DC	61	M
3	KW	66	F
4	RM	74	F
5	MS	68	F
6	DN	51	F
7	MB	31	F
8	ES	50	M
9	CV	63	F
10	JP	56	F
11	AB	43	F
12	AL	72	F
13	OU	73	F
14	WM	32	F
15	EG	56	F
16	KM	54	F
17	KS	53	F
18	DL	23	F
19	SC	51	M
20	DL	43	F
21	EW	53	F
22	DB	42	F
23	KL	22	F
24	MK	52	F
25	LD	67	F
26	MD	74	F
27	SM	24	F
28	MM	21	F

Table 2
(continued)
Panel #20000326

Subject Data

Subject Number	Initials	Age	Sex
29	JC	66	F
30	CT	32	F
31	LS	53	F
32	JB	50	F
33	RL	63	F
34	EL	67	M
35	JR	73	M
36	SR	68	F
37	TU	24	F
38	DB	51	F
39	EB	53	M
40	DL	56	M
41	LP	32	F
42	TL	52	F
43	SB	38	F
44	DS	69	F
45	HS	72	M
46	EG	36	M
47	SG	71	F
48	AS	18	F
49	MG	54	M
50	LH	35	F
51	DR	40	F
52	AF	47	F
53	PV	48	F
54	DW	18	M
55	JR	20	F
56	CD	31	F

Table 2
(continued)
Panel # 20000334

Subject Data

Subject Number	Initials	Age	Sex
1	CA	56	F
2	ED	33	F
3	CP	39	F
4	EK	78	F
5	CF	39	F
6	SV	47	F
7	LG	53	F
8	RG	56	M
9	EH	69	F
10	HH	73	M
11	AH	77	F
12	LR	49	F
13	CD	29	F
14	JT	70	F
15	LL	71	F
16	AL	73	M
17	MB	67	F
18	CS	38	F
19	MB	74	F
20	NV	53	F
21	KM	22	F
22	JD	51	F
23	JM	22	F
24	DH	25	M
25	LM	40	F
26	MP	43	F
27	AA	79	F
28	ID	76	F

Table 2
(continued)
Panel # 20000334

Subject Data

Subject Number	Initials	Age	Sex
29	DB	44	F
30	JP	72	F
31	MG	62	F
32	EP	76	F
33	SW	53	F
34	KD	46	F
35	TD	47	M
36	AH	34	F
37	MK	59	F
38	RC	24	F
39	WH	36	F
40	CM	39	F
41	LE	58	F
42	BW	58	F
43	AB	48	F
44	JC	62	M
45	RC	63	F
46	CF	36	F
47	MM	53	M
48	LM	42	F
49	LG	47	F
50	AP	37	F
51	AC	23	M
52	DS	64	M
53	RK	69	F
54	EC	76	F
55	RD	70	F
56	EH	71	F
57	SN	68	M