

Report To

E. I. DuPONT DeNEMOURS

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The Irritancy and Sensitization Potential
of paint components #6237 & #6238

Submitted By
Ivy Research Laboratories Inc.
Philadelphia., Pennsylvania 19101

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STUDY SYNOPSIS

OBJECTIVE:

To evaluate the hazard potential of an experimental enamel consisting of two parts, #6237 and #6238.

SUBJECTS:

Forty adult male subjects started the test. Twenty-nine completed the study and eleven subjects did not complete it due to unrelated reasons.

MATERIALS:

The experimental enamel was supplied by the Haskell Laboratories of the E. I. DuPont DeNemours & Company and was identified as follows:

Part - A - #6237

Part - B - #6238

METHOD:

The experimental enamel was applied to one inch skin sites on the volar forearms of all subjects for a total of fifteen applications on alternate days. Before each new application, the dried paint was removed by peeling. Two weeks after the last induction application, the paint was applied to a new skin site and evaluated twenty-four and forty-eight hours later.

RESULTS:

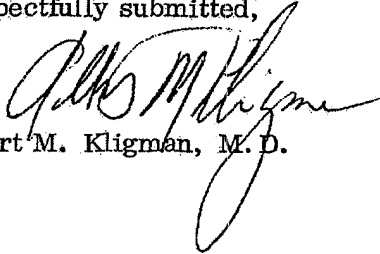
The results are recorded in the accompanying table.

No subject exhibited signs of contact allergy. During induction, some slight cases of irritation were noted usually slight erythema or mild glazing. Removing the paint each time may have contributed to this slight non-allergic inflammation. There were no reports of itching, burning, or other subjective symptoms associated with contact allergy.

CONCLUSIONS:

This two component experimental enamel did not induce any cases of contact sensitization. The contact sensitization capacity of this paint is very low and not likely to be a significant hazard in actual use.

Respectfully submitted,


Albert M. Kligman, M. D.

SUBJECT DATA

Subject No.	Initials	Age	Weight	Race
1	W. M.	21	165	N
2	N. S.	33	190	N
3	J. C.	44	220	N
4	A. M.	33	150	N
5	J. J.	25	137	W
6	W. M.	28	165	N
7	O. M.	30	176	N
8	C. J.	21	181	N
9	M. P.	43	140	N
10	F. L.	51	200	N
11	B. T.	27	165	N
12	W. R.	21	170	W
13	W. J.	31	181	N
14	J. McN.	28	160	N
15	J. M.	40	195	N
16	A. G.	37	167	N
17	W. B.	22	175	N
18	J. S.	26	200	N
19	R. A.	25	180	N
20	D. T.	48	186	N

SUBJECT DATA

Subject No.	Initials	Age	Weight	Race
21	R. P.	23	170	N
22	T. B.	27	185	N
23	W. B.	24	150	N
24	L. J.	34	190	N
25	C. L.	36	177	N
26	A. A.	40	170	N
27	J. W.	25	165	N
28	J. M.	30	180	N
29	R. G.	31	195	N
30	B. S.	29	165	N
31	P. W.	25	168	N
32	G. M.	21	210	N
33	R. G.	36	167	N
34	W. A.	44	158	N
35	S. V.	38	171	N
36	B. H.	23	165	N
37	C. E.	29	195	N
38	E. A.	40	200	N
39	R. B.	21	139	N
40	J. J.	26	163	N

KEY

INDUCTION

0	No Reaction
0+	Faint Erythema
1	Brisk erythema
2	Brisk erythema, peeling
3	Erosion
4	Ulceration

CHALLENGE

0	No Reaction
1	Erythema, Edema
2	Erythema, Edema, vesicles
3	Erythema, Edema, tired vesicles
4	Erythema, Edema, tired weeping vesicles

TABLE I
Induction Exposures

Subject No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1	0	0	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+	0+	0+	0+	0+
3	0	0	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+	0+	0+
5	0	0	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+	0+	0+
7	0	0	0	DISCHARGED											
8	0	0	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+	0+	0+
10	0	0	0	0	0	0+	0+	0+	0+	0+	0+	0+	0+	1	1
11	0	0	0	0	0	0	0	0+	0+	0+	0+	0+	0+	0+	0+
12	0	0	0	0	0	DISCHARGED									
13	0	0	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	0	0
15	0	DISCHARGED													
16	0	0	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+	0+	0+
18	0	0	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+	0+	0+
20	0	0	0	0	DISCHARGED										

TABLE I

Induction Exposures

Subject No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
21	0	0	0	0	0	0	0	0	0+	DISCHARGED					
22	0	0	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	0	0	0
24	0	0	0	0	0	0	0+	0+	0+	0+	0+	0+	0+	0+	0+
25	0	0	DISCHARGED												
26	0	0	0	0	0	0	0	0	0	0+	0+	0+	0+	0+	0+
27	0	0	0	DISCHARGED											
28	0	0	0	0	0	0	0	0+	0+	0+	0+	0+	0+	0+	0+
29	0	0	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+	0+	0+
31	0	0	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+	0+	0+
33	0	0	0	0	0	0	0+	0+	0+	0+	0+	0+	0+	0+	1
34	0	0	0	0	0	0+	0+	0+	DISCHARGED						
35	0	0	0	0	0	0	0	0+	0+	0+	0+	0+	0+	0+	0+
36	0	0	0	DISCHARGED											
37	0	0	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+	0+	0+
39	0	0	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+	0+	0+

TABLE II
Schedule of Challenges

Subject No.	24 Hours	48 Hours
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7		
8	0	0
9	0	0
10	0	0
11	0	0
12		
13	0	0
14	0	0
15		
16	0	0
17	0	0
18	0	0
19	0	0
20		

TABLE II

Schedule of Challenges

Subject No.	24 Hours	48 Hours
21		
22	0	0
23	0	0
24	0	0
25		
26	0	0
27		
28	0	0
29	0	0
30	DISCHARGED	
31	0	0
32	0	0
33	0	0
34		
35	0	0
36		
37	0	0
38	DISCHARGED	
39	0	0
40	0	0