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Essex Testing Clinic, Inc.



FINAL REPORT

CLINICAL SAFETY EVALUATION

REPEATED INSULT PATCH TEST

New Drying Lotion
Reference # 10018 Revision 6

Sponsor

D'ARCY
1100 SW 12th Avenue
Pompano Beach, FL 33069

Sponsor Representative

Washington Washbrum

Clinical Testing Facility

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

Sponsor Code: D31
ETC Panel No.: 04137
ETC Entry No.: 10636

Date of Final Report

6-4-04

SIGNATURE PAGE

CLINICAL SAFETY EVALUATION

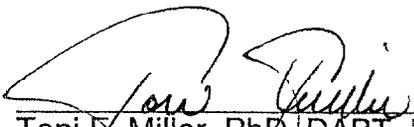
REPEATED INSULT PATCH TEST

New Drying Lotion
Reference # 10018 Revision 6



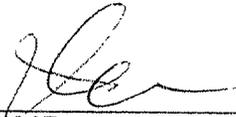
Tracey Troilo, BA
Study Director

6/2/2004
Date



Toni F. Miller, PhD, DABT, BCFE
Scientific Director
Principal Investigator

2 June 2004
Date



John A. Erienne, MD
Board-Certified Dermatologist
Medical Investigator

6/4/04
Date

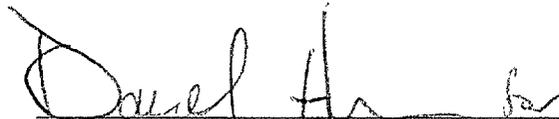
QUALITY ASSURANCE STATEMENT

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in CFR Title 21, Parts 50, 56 and 312 and/or the Declaration of Helsinki, as appropriate.

For purposes of this clinical study:

- Informed Consent was obtained.
- Informed Consent was not obtained.
- An IRB review was not required.
- An IRB review was conducted and approval to conduct the proposed clinical research was granted.

This study report has been reviewed to assure that it correctly describes the methods of testing and that the reported results accurately reflect the data obtained during the clinical study (ETC Panel No.: 04137; ETC Entry No.: 10636).



Sherri L. Sayles, MS
Manager, Quality Assurance

6-4-24

Date

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TABLE 1 - INDIVIDUAL SCORES

CLINICAL SAFETY EVALUATION
REPEATED INSULT PATCH TEST

New Drying Lotion
Reference # 10018 Revision 6

1.0 OBJECTIVE

The objective of this study was to determine the irritation and/or sensitization potential of the test article after repeated application under semi-occlusive patch test conditions to the skin of human subjects (non-exclusive panel).

2.0 SPONSOR

D'ARCY
1100 SW 12th Avenue
Pompano Beach, FL 33069

2.1 Sponsor Representative

Washington Washbrum

3.0 CLINICAL TESTING FACILITY

The study was conducted by:

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

4.0 CLINICAL INVESTIGATORS

Study Director: Tracey Troilo, BA
Principal Investigator: Toni F. Miller, PhD, DABT, BCFE
Medical Investigator: John A. Erianne, MD, Board-Certified Dermatologist

5.0 STUDY DATES

Study initiation: April 14, 2004

Final evaluation: May 20, 2004

Essex Testing Clinic, Inc. _____

6.0 ETHICS

6.1 Ethical Conduct of the Study

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures.

6.2 Subject Information and Consent

This study was conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study. A copy of the Informed Consent was provided to each subject.

7.0 TEST MATERIAL

The test article used in this study was provided by:

D'ARCY
1100 SW 12th Avenue
Pompano Beach, FL 33069

It was received on April 5, 2004 and identified as follows:

<u>ETC Entry No.</u>	<u>Test Article I.D.</u>	<u>Physical Description</u>
10636	New Drying Lotion Reference # 10018 Revision 6	Pink Liquid*

*The test article was not shaken. A spatula was dipped into the heavy sediment at the bottom of the jar. This sediment was applied to the patch. The test article was volatilized at least 30 minutes, but less than 90 minutes on the patch prior to application on the skin.

8.0 TEST SUBJECTS

A total of 55 subjects, 12 males and 43 females ranging in age from 18 to 69 years, were empaneled for this test.

The subjects chosen were dependable and able to read and understand instructions. The subjects did not exhibit any physical or dermatological condition that would have precluded application of the test article or determination of potential effects of the test article.

9.0 TEST PROCEDURE

The 9 Repeated Insult (semi-occlusive) Patch Test (9-RIPT) was conducted as follows:

9.1 Induction Phase

A sufficient amount of the test article (an amount to adequately cover the surface of the patch unit – approximately 0.1 g – 0.15 g) was placed onto a 2 cm x 2 cm square of Webril® cotton fabric affixed to Scanpor (Allerderm) semi-occlusive surgical tape. The patch was then applied to the back of each subject between the scapulae and waist, adjacent to the spinal mid-line. This procedure was performed by a trained technician/examiner and repeated every Monday, Wednesday and Friday until 9 applications of the test article had been made.

The subjects were instructed to remove the patch 24 hours after application. Twenty-four hour rest periods followed the Tuesday and Thursday removals and 48-hour rest periods followed each Saturday removal. Subjects returned to the Testing Facility and the site was scored by a trained examiner just prior to the next patch application.

If a subject developed a positive reaction of a level 2 erythema or greater during the Induction phase or if, at the discretion of the Study Director, the skin response warranted a change in site, the patch was applied to a previously unpatched, adjacent site for the next application. If a level 2 reaction or greater occurred at the new site, no further applications were made. However, any reactive subjects were subsequently Challenge patch tested.

9.2 Challenge Phase

After a rest period of approximately 2 weeks (no applications of the test article), the Challenge patch was applied to a previously unpatched (virgin) test site. The site was scored 24 and 72 hours after application. All subjects were instructed to report any delayed skin reactivity that occurred after the final Challenge patch reading. When warranted, selected test subjects were called back to the Clinic for additional examinations and scoring to determine possible increases or decreases in Challenge patch reactivity.

Dermal responses for both the Induction and Challenge phases of the study were scored according to the following 6-point scale:

- 0 = No evidence of any effect
- + = Barely perceptible (Minimal, faint, uniform or spotty erythema)
- 1 = Mild (Pink, uniform erythema covering most of the contact site)
- 2 = Moderate (Pink-red erythema uniform in the entire contact site)
- 3 = Marked (Bright red erythema with/without petechiae or papules)
- 4 = Severe (Deep red erythema with/without vesiculation or weeping)

All other observed dermal sequelae (eg, edema, dryness, hypo- or hyperpigmentation) were appropriately recorded on the data sheet and described as mild, moderate or severe.

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10.0 RESULTS AND DISCUSSION

(See Table 1 for Individual Scores)

Forty-seven (47/55) subjects satisfactorily completed the test procedure on Test Article: New Drying Lotion Reference # 10018 Revision 6. Eight (8/55) subjects discontinued for personal reasons unrelated to the conduct of the study. Discontinued panelist data are shown up to the point of discontinuation, but are not used in the Conclusions section of this final report.

There was no skin reactivity observed at any time during the course of the study.

11.0 CONCLUSIONS

Under the conditions of a repeated insult (semi-occlusive) patch test procedure, Test Article: New Drying Lotion Reference # 10018 Revision 6 was "Dermatologist-Tested" and did not induce skin irritation nor show any evidence of induced allergic contact dermatitis in human subjects.

TABLE 1
INDIVIDUAL SCORES
REPEATED INSULT PATCH TEST – SEMI-OCCLUSIVE
Test Article: New Drying Lotion Reference # 10018 Revision 6

Subj. No.	Induction Evaluation Number									Challenge Virgin Site	
	1	2	3	4	5	6	7	8	9	24hr	72hr
1	0	0	0	0	0	0	0	0	0	0	0
2	0	Discontinued								0	0
3	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0
17	0	Discontinued								0	0
18	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	Discontinued					0	0
20	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	Discontinued	
28	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0

Scale: 0 = No evidence of any effect
 + = Barely perceptible (Minimal, faint, uniform or spotty erythema)
 1 = Mild (Pink, uniform erythema covering most of the contact site)
 2 = Moderate (Pink-red erythema uniform in the entire contact site)
 3 = Marked (Bright red erythema with/without petechiae or papules)
 4 = Severe (Deep red erythema with/without vesiculation or weeping)

TABLE 1 (CONT'D)
INDIVIDUAL SCORES

REPEATED INSULT PATCH TEST – SEMI-OCCLUSIVE

Test Article: New Drying Lotion Reference # 10018 Revision 6

Subj. No.	Induction Evaluation Number									Challenge Virgin Site	
	1	2	3	4	5	6	7	8	9	24hr	72hr
31	0	0	0	0	0	0	0	0	0	Discontinued	
32	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0
40	0	Discontinued									
41	0	0	0	0	0	Discontinued					
42	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	Discontinued				
45	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0

Scale: 0 = No evidence of any effect
 + = Barely perceptible (Minimal, faint, uniform or spotty erythema)
 1 = Mild (Pink, uniform erythema covering most of the contact site)
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