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Essex Testing Clinic, Inc.



**FINAL REPORT**

**CLINICAL SAFETY EVALUATION**

**REPEATED INSULT PATCH TEST**

Drying Lotion FT 1003-023-001

Sponsor

**D'ARCY  
1100 SW 12<sup>th</sup> Avenue  
Pompano Beach, FL 33069**

Sponsor Representative

**Washington Washbrum  
R&D Lab Manager**

Clinical Testing Facility

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

**Sponsor Code: D31  
ETC Panel No.: 03282  
ETC Entry No.: 10231**

**Date of Final Report**

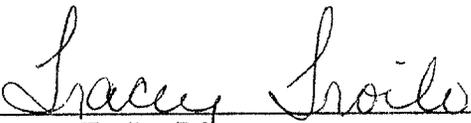
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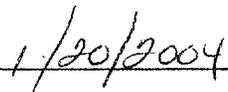
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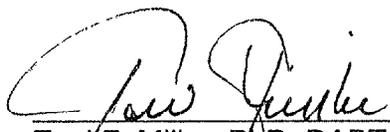
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**REPEATED INSULT PATCH TEST**

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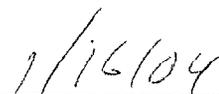
  
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Tracey Troilo, BA  
Study Director

  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Tony F. Miller, PhD, DABT, BCFE  
Scientific Director  
Principal Investigator

  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
John A. Erianne, MD  
Board-Certified Dermatologist  
Medical Investigator

  
\_\_\_\_\_  
Date

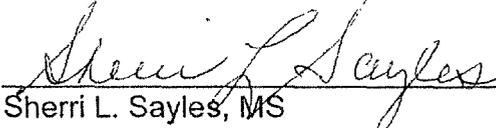
QUALITY ASSURANCE STATEMENT

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.: 03282; ETC Entry No.: 10231).

  
Sherri L. Sayles, MS  
Manager, Quality Assurance

20 Jan 2004  
Date

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## **CLINICAL SAFETY EVALUATION**

### **REPEATED INSULT PATCH TEST**

#### **Drying Lotion FT 1003-023-001**

#### **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.

#### **2.0 SPONSOR**

D'ARCY  
1100 SW 12<sup>th</sup> Avenue  
Pompano Beach, FL 33069

##### **2.1 Sponsor Representative**

Washington Washbrum  
R&D Lab Manager

#### **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. Erienne, MD, Board-Certified Dermatologist

#### **5.0 STUDY DATES**

Study initiation: November 24, 2003

Final evaluation: January 2, 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 12<sup>th</sup> Avenue  
Pompano Beach, FL 33069

It was received on November 19, 2003 and identified as follows:

<u>ETC Entry No.</u>	<u>Test Article I.D.</u>	<u>Physical Description</u>
10231	Drying Lotion FT 1003-023-001	Pink Bi-Level Liquid and Lotion*

\*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 to the skin.

## 8.0 TEST SUBJECTS

A total of 55 subjects, 8 males and 47 females ranging in age from 20 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.

## 10.0 RESULTS AND DISCUSSION

(See Table 1 for Individual Scores)

Forty-eight (48/55) subjects satisfactorily completed the test procedure on Test Article: Drying Lotion FT 1003-023-001. Seven (7/55) 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 on any subject at any time during the study.

## 11.0 CONCLUSIONS

Under the conditions of a repeated insult (semi-occlusive) patch test procedure, Test Article: Drying Lotion FT 1003-023-001 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: Drying Lotion FT 1003-023-001

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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	Discontinued					
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	Discontinued								
26	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0
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: Drying Lotion FT 1003-023-001**

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	0	0
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	Discontinued			
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	Discontinued									
40	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0
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	0	0	0	0	0
45	Discontinued										
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	Discontinued									
52	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	Discontinued	
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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