

# *"Latex Friendly" Study for a Lotion Product*

*Final Test Report*

**# 65866**

***Study Sponsor:***

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***Study Investigator:***



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# ***Physical Testing Report***

## **# 65866**

**Objective :** To evaluate the “Latex Friendly” nature of a topical lotion, by **Physical** testing of Type 1 Latex gloves before and after treatment with test material, namely Derma Soothe Lotion, submitted by sponsor – PO # 51207.

**Received :** Six pairs of Kimberly-Clark Latex Gloves and one Gallon of Derma Soothe Lotion.

**Performed by:** Sandy Jones, Technician.

**Method :** ASTM D 412-98a(02)e1 for tensile properties of gloves – type 1 **before** immersion (untreated).  
ASTM D 471-99 for tensile properties of gloves – type 1 **after** immersion (treated).

Note: Type 1 gloves are medical and dentist standard gloves, Type 2 gloves are surgical.

### **Physical Properties (Type 1) : UNTREATED**

Die C dumbbells tested at 20 inches/min.

<b><u>UNTREATED</u></b>	<b><u>Results</u></b>	<b><u>Mean</u></b>	<b><u>Type 1 Specifications</u></b>
<b>Tensile Strength, MPa</b>	27.6	27.6	18 MPa min.
	29.6		
	24.0		
	30.0		
	25.4		
<b>Ultimate Elongation, %</b>	724	703	650% min.
	703		
	657		
	718		
	669		
<b>500% Modulus, MPa</b>	6.4	7.6	5.5 MPa max.
	7.7		
	7.6		
	7.4		
	7.6		

### **Physical Properties after fluid immersion (Type 1) : TREATED**

Die C dumbbell specimens were taken from gloves. The specimens immersed in lotion for 1 hr. @ 37°C. Specimens were removed from lotion and excess lotion was removed from test specimens. The gloves were tested.

<b><u>TREATED</u></b>	<b><u>Results</u></b>	<b><u>Mean</u></b>	<b><u>% Change</u></b>	<b><u>Interpretation</u></b>
<b>Tensile Strength, MPa</b>	15.5	18.2	-33.9	Greater than 18 MPa (minimum value)
	21.8			
	18.2			
	15.8			
	20.5			
<b>Ultimate Elongation, %</b>	622	704	0	No change
	792			
	662			
	732			
	704			
<b>500% Modulus, MPa</b>	5.5	4.7	-38.0	Less than 5.5 MPa (maximum value)
	2.7			
	5.1			
	3.2			
	4.7			

**Dimensions :**

A 1''x1'' specimen was taken from the glove, immersed in lotion for 1 hr. @ 37°C. Specimens were removed and excess lotion was removed, then the dimensions were taken immediately.

Note : No standard exists for length/width change.

	<u>Before</u>	<u>After</u>	<u>% Change</u>
<b>Length, inches</b>	1.0	1.029	+2.9
	1.0	1.023	+2.3
	1.0	1.025	+2.5
<b>Width, inches</b>	1.0	1.030	+3.0
	1.0	1.022	+2.2
	1.0	1.025	+2.5

**Discussion of Results -Physical Testing:**

The gloves provided by the sponsor for testing were Type 1 medical and dentist standard gloves. In this study, the test results for the untreated gloves were compared to that treated with Derma Soothe Lotion:

- Testing determined that the tensile strength of the gloves changed after the use of Derma Soothe Lotion, but remained within specifications of type 1 gloves.
- The gloves as received for testing, and after the immersion in the Derma Soothe Lotion met the Ultimate Elongation requirements of ASTM method for Type 1 gloves.
- The Modulus (stress @ 500% Elongation) of the untreated glove was above the maximum specification for this type (type 1) of gloves. After treatment (1 hour immersion @ 37°C in Derma Soothe Lotion) the gloves were found to be within the specifications of type 1 gloves, however they continued to have a maximum Modulus greater than the requirement of Type 2 gloves, suited for surgical use.
- The data indicated softening effect and a relative degradation of physical properties on the gloves. A further test to determine the degree of change of dimensions after the 1 hour @ 37°C immersion was carried out. The results showed an increase of approximately 2.6% in both length and width of the test specimen. This can be considered a minimal change.

NB: Hardness values were not possible/accurate for this type of thin film Latex.

# Analytical Testing Report

# 65866

**Objective :** To evaluate the “Latex Friendly” nature of a topical lotion, by **Analytical** testing of Type 1 Latex gloves before and after treatment with test material, namely Derma Soothe Lotion, submitted by sponsor– PO #51207.

**Received :** Six pairs of Kimberly-Clark Latex Gloves and one gallon of Derma Soothe Lotion.

**Performed by:** Ana Camelia Barbur, Senior Chemist.

## **Detection Method of Chemical Permeation: UV/VIS absorption spectrometry**

**Instrument:** Perkin Elmer UV/VIS Spectrometer Lambda 25

**Method:** ASTM F739-99a : Resistance to permeation by liquid through a latex film @ 37°C during two hours immersion.

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals which permeated through the specimens into the collection medium (distilled water). The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The characteristic wavelengths used in UV/VIS Absorption Spectrometry were 191 nm.

Calculation: Average permeation rate for each sampling time interval (except time = 0) was calculated using the equation below:

$$P_i = \frac{(C_i - C_{i-1}) \times V_t}{(T_i - T_{i-1}) \times A}$$

Where:

$P_i$  = average permeation rate, ug/cm<sup>2</sup>/min. at time interval  $T_i - T_{i-1}$ .

$C_i$  = concentration of test chemical detected in collection medium, ug/l, at time  $T_i$

$V_t$  = volume of collection medium, l.

$I$  = an index number starting with  $i=1$  for the first sample.

$T_i$  = sample time, minutes.

$A$  = area of specimen in contact with the test chemical, cm<sup>2</sup>.

## **Table and Graphs:**

See page 6.

The headers used in the tables are clarified as follows:

$A_{\text{test}}$  = Optical absorbance of sampling liquid measured by UV/VIS spectrometer.

$P_i$  = average permeation rate, ug/cm<sup>2</sup>/min. at time interval  $T_i - T_{i-1}$ .

$C_i$  = concentration of test chemical detected in collection medium, ug/l, at time  $T_i$

Interval Permeation = The amount of the permeated chemical in ug/cm<sup>2</sup> through the specimen cross-section during each sampling interval.

**Permeation Test Results:**

TEST CHEMICAL	BREAKTHROUGH DETECTION TIME	PERMEATED MASS PER UNIT AREA AT BREAKTHROUGH	STEADY STATE PERMEATION RATE
	Minutes	(Avg.) ug/cm <sup>2</sup>	(Avg.) ug/cm <sup>2</sup> /min.
Derma Soothe Lotion	33	22.4	1.52

See following report for more details (file 65866 data. Pdf).

**Discussion of Results -Analytical Testing :**

- Analytical results were good, i.e. 33 minutes mean for breakthrough time which is a relatively long time for medical specialists.
- The gloves did not demonstrate any leakage due to lotion use. Slight swelling was observed, a normal occurrence comparable to that of exposure to water.

**FINAL CONCLUSION**

Given the experimental conditions and in view of the results obtained in the course of this study, we conclude that the test material Derma Soothe Lotion is «Latex Friendly» when used with Type 1 gloves (Medical and Dentist use).

Elisabeth Fiquet, M. Sc  
President, Supervisor of Clinical Studies



Signature

Date: Mont-Royal January 23<sup>rd</sup>, 2006

I the undersigned, Elisabeth Fiquet, declare that this study progressed under my supervision, in conformance with Good Laboratory Practices. The reported results truly reflect the data obtained during the study in a complete and exact manner.

DESCRIPTION OF PRODUCT EVALUATED			
01)Condition Before Test	New		
02)Manufacturer	Kimberly Clark		
03)Product Identification	Kimberly Clark Latex Glove		
04)Lot ID/Mft - Date	Lot D52 exp 04/07		
05)Nominal Thickness, mm	To be confirmed by Rosedale		
06)Material Type	Type 1 Latex		
07)Weight/Unit Area, g/m <sup>2</sup>	144.0		
CHALLENGE CHEMICAL			
08)Chemical Name	Derma Soothe Lotion		
09)CAS Number	N/A		
10)Concentration	As received from sponsor - No dilution		
11)Chemical Source	Rosedale Therapeutics LLC		
TEST METHOD			
12)Standard Test Method Used	ASTM F739-99a		
13)Dvn. From Standard Test Method	None		
14)Testing Laboratory	Evalulab Inc.		
15)Analytical Method	UV-VIS Spectrometry		
16)Temperature, Degree C	23.5		
17)Specimen Area Exposed, cm <sup>2</sup>	5.076		
18)Collection System	Closed Loop		
19)Collection Medium	Distilled Water		
20)Collection Medium Volume, liter	Cell # 1	Cell # 2	Cell # 3
	0.023	0.023	0.023
21)Collection Medium Flow Rate, ml/min	11		
22)Breakthrough Concent'n, ug/L	4927.0		
23)Detection Limit, ug/L	1000		
24)Test System Sensitivity Factor, ug/cm <sup>2</sup>	22.4		
25)Comments/Other conditions	Magnetic Stir Bar (in the Sampling Chamber) was used		
TEST RESULTS			
26) Date Tested	Specimen#1	Specimen#2	Specimen#3
	01-09-2006	01-09-2006	01-09-2006
27)Number of Specimen Tested	3		
28)Location Sampled From	Palm		
29)Breakthrough Detection Time (Duration of Test for No Permeation), min	Specimen#1	Specimen#2	Specimen#3 Mean
	30	30	40 33
30)Standardized Breakthrough Time, min	Specimen#1	Specimen#2	Specimen#3 Mean
	30	30	40 33
31)Steady State Permeation Rate, ug/cm <sup>2</sup> /min	Specimen#1	Specimen#2	Specimen#3 Mean
	1.31	1.87	1.38 1.52
32)Sample Thickness, mm	Specimen#1	Specimen#2	Specimen#3 Mean
	0.181	0.171	0.174 0.175
33)Selected Data Points	13		
34)Other Observation	Slight Swelling and No Degradation was observed		
35)Source of Data	UV-VIS Absorbance at 191 nm of wavelength		