



Attn.: John Goeffert
Simply Slick LLC
2949 Venture Drive
Suite 170
Janesville, WI. 53546
Phone: 608-563-5559

Fax:

EMSL Case N 361301329
Sample(s) Received 8/27/2013
Date of Analysis 9/9/2013
Date Printed 9/9/2013
Reported I J.Newton
E-mail: jgoeffert@simplyslick.com

- Laboratory Report -

Project: Condom Compatibility Test

Conclusions:

- Simply Slick Personal Lubricant was found to be compatible with one brand of polyurethane and one brand of polyisoprene prophylactics (less than 10% change of the mean values for all the tensile and air burst parameters between the sample and the control).

Procurement of Samples and Analytical Overview:

The material for analysis arrived at EMSL Analytical (Cinnaminson, NJ) on 8/27/2013. The package arrived in satisfactory condition with no evidence of damage to the contents. The data reported herein has been obtained using the following equipment and methodologies.

Methods & Equipment: ASTM D7661 – STM for Determining Compatibility of Personal Lubricants w Natural Rubber Latex Condoms

Definitions:


Baseline: Condoms tested in their “as-received” condition for the purposes of establishing a baseline for subsequent analysis.

Control: Condoms exposed to heat with out lubricant.

Positive Control: Condoms exposed to 40⁰C for 1 hour with mineral oil.

Sample: Condoms exposed to 40⁰C for 1 hour with sample lubricant.

Analyzed by:



John Newton
Senior Materials Scientist

9 September 2013

Date

Reviewed/Approved by :



Eugenia Mirica, Ph.D.
Laboratory Manager

9 September 2013

Date



EMSL Analytical, Inc.

200North, Route 130, Cinnaminson, NJ. 08077
Phone: (800) 220-3675

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Background:

Simply Slick Personal Lubricating Lotion was submitted to determine if the use of the personal lubricant resulted in detrimental effects to condoms in accordance with ASTM D7661. Condoms used during this study include Trojan Supra, polyurethane, lot# CZ3077C5 and Lifestyles Skyn, polyisoprene, lot# 1211120622.

Sample Preparation & Analysis:

Preparation and analysis of the samples was performed in accordance with ASTM D7661. This test method measures the change in tensile and airburst properties, specifically force at break, percent elongation at break, airburst pressure, and airburst volume, of various types of condoms and condom rings after 60 min of immersion in a liquid or gel lubricant. Condoms (up to the open end) and rings cut from condoms are immersed in personal lubricant, heated to body temperature, cleaned of excess lubricant, and tested for both tensile and airburst properties. Those properties are then compared to control condoms and rings that are subjected to the same procedures without adding lubricant. For comparison purposes, baseline testing is also performed on condoms directly from their packages. A final group exposed to mineral oil is also included to validate the laboratory's test technique.

The test parameters used during this study are as follows;

- Baseline: Tested in their as-received condition, no heat or lubricant applied
- Control: Exposure to 40⁰C for 1 hour, no lubricant applied
- Mineral Oil (Positive Control): Exposure to 40⁰C for 1 hour and mineral oil applied
- Sample: Exposure to 40⁰C for 1 hour and Conceive Plus personal lubricant applied

Method Limitations:

The testing performed is intended to determine the effects of the documented personal lubricant on the supplied condoms. The data reported herein does not represent testing on all prophylactic material or when used in conjunction with other lubricants, lotions, contraceptives or products.



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Results & Discussion:

Table 1: Mean values obtained during analysis on 20 condoms of each variety.

Sample 1: Simply Slick Personal Lubricant F132601

Condom Type	Exposure	Break Force (N)	Elongation (%)	Burst Pressure (kPa)	Burst Volume (L)
Trojan Supra – Polyurethane (Lubricated), Lot # CZ3077C5	Baseline	29.8	745	5.3	29.0
	Control	28.2	745	5.1	29.5
	Mineral Oil	6.5	278	3.4	7.4
	Sample 12	27.6	743	5.1	28.0
Lifestyles Skyn – Polyisoprene (Lubricated), Lot # 1211120622	Baseline	33.3	729	5.2	26.7
	Control	32.2	728	5.2	26.4
	Mineral Oil	28.3	720	4.4	25.1
	Sample 12	33.0	723	5.2	25.7

Table 2: Percent change of the mean values for all the tensile and air burst parameters between the sample and the control.

Sample 1: Simply Slick Personal Lubricant F132601

Condom Type	Break Force % change	Elongation % change	Burst Pressure % change	Burst Volume % change
Trojan Supra – Polyurethane (Lubricated), Lot # CZ3077C5	-2.0	-0.3	-0.7	-5.2
Lifestyles Skyn – Polyisoprene (Lubricated), Lot # 1211120622	2.3	-0.6	-0.7	-2.4



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Per information provided by FDA representative, the criteria for assessing condom compatibility are:

- If the mean decrease between the test (conditioned and exposed to subject lubricant) and control (conditioned, but not exposed to lubricant) condoms for a specific condom type for all the airburst and tensile parameters evaluated is 10% or less, the subject lubricant is considered compatible with that condom type.
- If the mean decrease between the test and control condoms for a specific condom type for any of the airburst and tensile parameters evaluated is 20% or greater, the subject lubricant is considered not compatible with that condom type.
- If the mean decrease between the test and control condoms for a specific condom type for any of the airburst and tensile parameters evaluated is between 10% and 20%, the sponsor should provide a justification for that result.



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Analysis Date Break Force (N)

Condom Trojan Supra, Polyurethane, CZ3077C5
Lubricant Simply Slick Personal Lubricant, F132601

Run #	Baseline	Control	Mineral C	Lubricant	
1	31.0	28.9	5.0	26.0	
2	29.7	27.4	5.1	28.1	
3	28.3	29.2	6.9	27.4	
4	29.6	29.8	7.0	27.7	
5	30.6	29.9	7.3	27.9	
6	29.2	28.4	5.7	29.0	
7	32.3	26.8	5.6	27.5	
8	28.7	29.7	5.5	27.7	
9	29.4	26.4	6.6	27.4	
10	28.6	27.7	7.1	28.4	
11	32.7	27.4	6.0	26.8	
12	28.2	26.8	6.7	27.8	
13	29.0	26.6	6.4	27.3	
14	28.7	29.7	8.4	27.2	
15	32.8	29.2	6.5	27.1	
16	29.0	27.6	7.9	27.3	
17	27.1	28.9	6.3	28.8	
18	32.9	27.0	8.4	27.1	
19	28.2	29.1	6.2	28.1	
20	29.9	26.9	6.0	27.3	
Mean	29.8	28.2	6.5	27.6	
SD	1.71	1.22	0.97	0.68	
%RSD	5.75	4.35	14.87	2.48	
% Difference	N/A	N/A	-76.8	-2.0	= Value from Control



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Analysis Date: Elongation (%)

Condom: Trojan Supra, Polyurethane, CZ3077C5
 Lubricant: Simply Slick Personal Lubricant, F132601

Run #	Baseline	Control	Mineral Oil	Lubricant	
1	740	746	285	742	
2	749	743	276	745	
3	747	744	272	742	
4	749	738	277	741	
5	744	747	291	744	
6	741	747	273	741	
7	750	743	287	742	
8	748	747	264	744	
9	749	748	276	745	
10	748	743	283	745	
11	749	743	271	740	
12	741	743	291	745	
13	743	746	267	744	
14	741	742	285	742	
15	750	743	289	743	
16	748	744	265	741	
17	740	749	287	742	
18	746	746	275	741	
19	740	746	286	742	
20	748	749	266	743	
Mean	745.5	744.8	278.3	742.6	
SD	3.70	2.74	9.05	1.46	
%RSD	0.50	0.37	3.25	0.20	
% Difference	N/A	N/A	-62.6	-0.3	= Value from Control



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Analysis Date: Burst Pressure (psi)

Condom: Trojan Supra, Polyurethane, CZ3077C5
 Lubricant ID: Simply Slick Personal Lubricant, F132601

Run	Control				Mineral Oil			
	Baseline (psi)	Control (psi)	Mineral Oil (psi)	Lubricant (psi)	Baseline (kPa)	Control (kPa)	Mineral Oil (kPa)	Lubricant (kPa)
	0.7	0.8	0.5	0.8	4.8	5.5	3.4	5.5
	0.8	0.7	0.4	0.8	5.5	4.8	2.8	5.5
	0.8	0.8	0.5	0.7	5.5	5.5	3.4	4.8
	0.7	0.7	0.5	0.7	4.8	4.8	3.4	4.8
	0.8	0.8	0.4	0.7	5.5	5.5	2.8	4.8
	0.8	0.8	0.4	0.8	5.5	5.5	2.8	5.5
	0.8	0.8	0.5	0.7	5.5	5.5	3.4	4.8
	0.8	0.7	0.6	0.7	5.5	4.8	4.1	4.8
	0.7	0.7	0.5	0.8	4.8	4.8	3.4	5.5
	0.8	0.8	0.6	0.7	5.5	5.5	4.1	4.8
	0.8	0.8	0.5	0.8	5.5	5.5	3.4	5.5
	0.7	0.7	0.5	0.7	4.8	4.8	3.4	4.8
	0.8	0.7	0.5	0.8	5.5	4.8	3.4	5.5
	0.8	0.7	0.5	0.7	5.5	4.8	3.4	4.8
	0.8	0.8	0.5	0.8	5.5	5.5	3.4	5.5
	0.8	0.7	0.6	0.7	5.5	4.8	4.1	4.8
	0.7	0.8	0.6	0.7	4.8	5.5	4.1	4.8
	0.8	0.7	0.4	0.7	5.5	4.8	2.8	4.8
	0.7	0.7	0.4	0.7	4.8	4.8	2.8	4.8
	0.8	0.7	0.5	0.8	5.5	4.8	3.4	5.5
	Mean				5.3	5.1	3.4	5.1
	SD				0.32	0.35	0.47	0.35
	%RSD				6.11	6.85	13.87	6.79
	% Difference				N/A	N/A	-33.6	-0.7

$$kPa = (psi \times 6.894757)$$



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Analysis Date: Burst Volume (L)

Condom: Trojan Supra, Polyurethane, CZ3077C5
 Lubricant ID: Simply Slick Personal Lubricant, F132601

	Flow Rate (lpm) P <input type="text" value="25"/>				Flow Rate (lpm) P <input type="text" value="25"/>				Mean Flow Rate (lpm)	25
Run	Baseline (sec)	Control (sec)	Mineral Oil (sec)	Lubricant (sec)	Baseline (L)	Control (L)	Mineral Oil (L)	Lubricant (L)		
	74	69	18	69	30.8	28.8	7.7	28.8		
	68	75	20	66	28.5	31.0	8.3	27.5		
	69	70	18	68	28.9	29.1	7.4	28.3		
	70	68	19	65	29.0	28.5	7.8	27.3		
	68	70	19	65	28.1	29.3	7.8	27.2		
	71	74	17	68	29.4	30.8	7.1	28.3		
	66	68	17	67	27.5	28.2	6.9	27.8		
	72	74	15	66	30.1	30.7	6.4	27.3		
	67	75	18	69	28.0	31.0	7.5	28.8		
	67	72	15	65	27.8	30.2	6.4	27.3		
	69	69	19	69	28.8	28.9	8.0	28.7		
	68	67	17	67	28.3	27.7	7.2	28.0		
	72	72	19	68	30.0	30.0	7.9	28.3		
	73	69	18	70	30.3	28.8	7.4	29.1		
	72	72	20	67	30.1	30.0	8.3	27.8		
	72	74	18	69	29.8	31.0	7.4	28.6		
	67	70	17	65	27.9	29.3	7.1	27.2		
	70	72	19	69	29.3	30.2	7.9	28.8		
	70	72	16	66	29.3	30.0	6.5	27.5		
	67	66	19	67	27.8	27.5	7.7	27.7		
				Mean	29.0	29.5	7.4	28.0		
	$Vol(L) = Time(sec) \times \left(\frac{MFR}{60} \right)$				SD	0.97	1.10	0.57	0.65	
					%RSD	3.36	3.74	7.65	2.33	
	where: MFR = mean flow rate (lpm)				% Difference	N/A	N/A	-74.8	-5.2	



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Analysis Date Break Force (N)

Condom Lifestyles, Polyisoprene, 1211120622
Lubricant ID: Simply Slick Personal Lubricant, F132601

Run #	Baseline	Control	Mineral (Lubrican	
1	36.3	30.6	27.6	35.8	
2	32.6	34.6	30.6	34.1	
3	29.1	35.7	26.8	32.1	
4	30.0	33.8	26.7	29.8	
5	36.9	30.3	35.5	34.2	
6	32.6	31.2	22.3	33.6	
7	31.0	29.2	22.2	31.0	
8	36.3	36.9	25.1	34.2	
9	33.6	36.4	23.1	35.9	
10	34.9	29.1	27.6	34.4	
11	31.2	32.2	29.3	33.5	
12	33.2	31.4	32.8	30.7	
13	36.3	31.6	26.9	29.5	
14	33.7	32.2	35.2	29.1	
15	34.6	33.5	31.2	35.5	
16	35.1	29.9	26.8	30.5	
17	34.1	32.1	30.2	35.7	
18	30.0	30.3	32.8	34.5	
19	31.6	34.0	29.4	34.8	
20	32.0	29.4	23.2	30.3	
Mean	33.3	32.2	28.3	33.0	
SD	2.33	2.39	4.01	2.33	
%RSD	7.00	7.43	14.20	7.07	
% Difference	N/A	N/A	-12.3	2.3	= Value from Control



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Analysis Date Elongation (%)

Condom Lifestyles, Polyisoprene, 1211120622
Lubricant ID: Simply Slick Personal Lubricant, F132601

Run #	Baseline	Control	Mineral (Lubricant	
1	732	720	731	732	
2	713	723	732	725	
3	725	733	718	714	
4	729	716	729	731	
5	724	741	732	729	
6	741	711	717	715	
7	740	742	726	719	
8	742	730	717	712	
9	730	742	734	710	
10	728	741	713	727	
11	736	731	726	725	
12	724	745	734	723	
13	727	712	708	712	
14	733	724	703	718	
15	716	716	717	728	
16	731	718	705	720	
17	716	721	718	726	
18	730	743	710	724	
19	717	717	735	730	
20	738	730	706	741	
Mean	728.6	727.7	720.4	723.1	
SD	8.62	11.42	10.80	8.04	
%RSD	1.18	1.57	1.50	1.11	
% Difference	N/A	N/A	-1.0	-0.6	= Value from Control



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Analysis Date: Burst Pressure (psi)

Condom Lifestyles, Polyisoprene, 1211120622
 Lubricant Simply Slick Personal Lubricant, F132601

Run	Control				Mineral Oil			
	Baseline (psi)	Control (psi)	Mineral Oil (psi)	Lubricant (psi)	Baseline (kPa)	Control (kPa)	Mineral Oil (kPa)	Lubricant (kPa)
	0.8	0.8	0.7	0.8	5.5	5.5	4.8	5.5
	0.8	0.7	0.6	0.8	5.5	4.8	4.1	5.5
	0.8	0.7	0.6	0.7	5.5	4.8	4.1	4.8
	0.7	0.7	0.6	0.7	4.8	4.8	4.1	4.8
	0.8	0.8	0.6	0.7	5.5	5.5	4.1	4.8
	0.8	0.7	0.6	0.7	5.5	4.8	4.1	4.8
	0.8	0.8	0.7	0.8	5.5	5.5	4.8	5.5
	0.7	0.7	0.7	0.8	4.8	4.8	4.8	5.5
	0.8	0.8	0.6	0.8	5.5	5.5	4.1	5.5
	0.7	0.8	0.6	0.7	4.8	5.5	4.1	4.8
	0.7	0.8	0.6	0.7	4.8	5.5	4.1	4.8
	0.7	0.8	0.7	0.8	4.8	5.5	4.8	5.5
	0.7	0.8	0.7	0.8	4.8	5.5	4.8	5.5
	0.8	0.7	0.6	0.8	5.5	4.8	4.1	5.5
	0.8	0.8	0.6	0.7	5.5	5.5	4.1	4.8
	0.8	0.7	0.7	0.8	5.5	4.8	4.8	5.5
	0.8	0.8	0.6	0.7	5.5	5.5	4.1	4.8
	0.7	0.7	0.7	0.7	4.8	4.8	4.8	4.8
	0.7	0.8	0.6	0.7	4.8	5.5	4.1	4.8
	0.8	0.7	0.6	0.8	5.5	4.8	4.1	5.5
				Mean	5.2	5.2	4.4	5.2
				SD	0.35	0.35	0.34	0.35
				%RSD	6.61	6.76	7.71	6.84
				% Difference	N/A	N/A	-15.9	-0.7

$$kPa = (psi \times 6.894757)$$



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Analysis Date: Burst Volume (L)

Condom: Lifestyles, Polyisoprene, 1211120622
 Lubricant ID: Simply Slick Personal Lubricant, F132601

Flow Rate (lpm) F 25 P 25 Mean Flow Rate (lpm) 25

Run	Control				Product			
	Baseline (sec)	Control (sec)	Mineral Oil (sec)	Lubricant (sec)	Baseline (L)	Control (L)	Mineral Oil (L)	Lubricant (L)
	63	65	60	62	26.2	27.1	24.9	25.9
	68	60	57	65	28.2	24.9	23.8	27.2
	60	64	60	58	25.1	26.5	25.0	24.2
	61	59	60	59	25.4	24.6	24.9	24.6
	68	58	58	58	28.2	24.3	24.0	24.2
	66	60	62	64	27.7	25.1	25.9	26.6
	62	65	57	58	26.0	27.2	23.8	24.3
	64	69	66	61	26.8	28.7	27.7	25.5
	69	64	56	68	28.5	26.5	23.2	28.3
	64	65	58	59	26.5	27.2	24.0	24.5
	60	60	60	60	25.2	25.2	24.8	25.1
	65	69	61	60	27.0	28.6	25.4	25.0
	61	59	63	64	25.2	24.8	26.2	26.6
	64	63	56	59	26.6	26.4	23.3	24.5
	68	63	64	68	28.5	26.3	26.8	28.5
	65	65	58	59	27.1	27.2	24.3	24.7
	59	65	60	69	24.7	27.3	24.8	28.5
	68	69	65	60	28.1	28.5	26.9	25.0
	61	62	66	61	25.2	25.8	27.5	25.4
	64	60	59	63	26.8	25.0	24.6	26.2
				Mean	26.7	26.4	25.1	25.7
				SD	1.27	1.37	1.33	1.45
				%RSD	4.75	5.21	5.32	5.63
				% Difference	N/A	N/A	-4.8	-2.4

$$Vol(L) = Time(sec) \times \left(\frac{MFR}{60} \right)$$



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EMSL Case N 361301329
Sample(s) Received 8/27/2013
Date of Analysis 9/9/2013
Date Printed 9/9/2013
Reported I J.Newton
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