



EMSL Analytical, Inc.

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

Attn.: *J.Goeffery*
Simply Slick LLC
2949 Venture Drive
Janesville, WI 53546

Phone: 608-563-5559

Fax:

EMSL Case No.: 361400525
Sample(s) Received: 3/14/2014
Date of Reporting: 6/30/2014 Rev.1
Date Printed: 6/30/2014
Reported By: M.Zacharkow

Email: jgoeffery@simplyslick.com

- Laboratory Report -

Project: Condom Compatibility Test

Conclusions:

- Simply Slick personal lubricant was found to be compatible with the male latex contraceptives documented herein.

Procurement of Samples and Analytical Overview:

The material for analysis arrived at EMSL Analytical (Cinnaminson, NJ) on 3/14/2014. 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 with 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 40°C for 1 hour with mineral oil.
Sample: Condoms exposed to 40°C for 1 hour with sample lubricant.

-07/27/2014: Revises report 361400525, issued 04/15/2014. The purpose of Rev1 is to include results for one additional brand of latex condom. Rev1 adds results for “Lifestyles” brand latex condoms, lot number 1312051822.

Analyzed by:

Michael Zacharkow
Laboratory Technician

15 April 2014

Date

Reviewed/Approved by :

John Newton
Senior Materials Scientist

30 June 2014

Date



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Background:

Simply Slick personal lubricant was submitted to determine if use of the product resulted in detrimental effects to condoms in accordance with ASTM D7661. Condoms used during this study include Atlas non-lubricated latex (Lot 13X1874), Trojan non-lubricated latex (Lot TT3026Z), and Lifestyles non-lubricated latex (Lot 1312051822).

Sample Preparation & Analysis:

Preparation and analysis of the samples was performed in accordance with ASTM D7661. No modifications were employed. 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 40°C for 1 hour, no lubricant applied
Mineral Oil (Positive Control): Exposure to 40°C for 1 hour, mineral oil applied
Sample: Exposure to 40°C for 1 hour, lubricant applied

Test Criteria:

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

- If the mean difference 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.

Method Limitations:

The testing performed is intended to determine the effects of the supplied lubricants 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:

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

Sample 1: 361400525-0001 **Simply Slick Personal Lubricant**

Condom Type	Exposure	Break Force (N)	Elongation (%)	Burst Pressure (kPa)	Burst Volume (L)
Trojan	Baseline	38.5	742	2.014	35.41
Latex	Control	36.1	745	1.914	34.29
(non-Lubricated)	Mineral Oil	2.4	179	0.941	7.89
Lot# TT3026Z	Sample	35.5	759	1.771	34.86
Atlas	Baseline	60.0	815	1.991	36.66
Latex	Control	57.9	819	2.024	36.33
(non-Lubricated)	Mineral Oil	2.2	170	0.777	7.43
Lot# 13X1874	Sample	55.2	854	1.881	36.40
Lifestyles	Baseline	46.1	768	2.080	40.67
Latex	Control	44.6	756	2.070	40.00
(non-Lubricated)	Mineral Oil	1.7	134	1.000	22.27
Lot#1312051822	Sample	49.3	789	1.980	39.60

Comments: None

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

Sample 1: 361400525-0001 Simply Slick Personal Lubricant

Condom Type	Break Force (%) Change	Elongation (%) Change	Burst Pressure (%) Change	Burst Volume (%) Change
Trojan Latex (non-Lubricated) Lot# TT3026Z	-1.7	1.9	-7.5	1.7
Atlas Latex (non-Lubricated) Lot# 13X1874	-4.7	4.3	-7.1	0.2
Lifestyles Latex (non-Lubricated) Lot#1312051822	10.5	4.4	-4.3	-1.0



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Important Terms, Conditions, and Limitations:

Sample Retention: Samples analyzed by EMSL will be retained for 60 days after analysis date. Storage beyond this period is available for a fee with written request prior to the initial 30 day period. Samples containing hazardous/toxic substances which require special handling may be returned to the client immediately. EMSL reserves the right to charge a sample disposal or return shipping fee.

Change Orders and Cancellation: All changes in the scope of work or turnaround time requested by the client after sample acceptance must be made in writing and confirmed in writing by EMSL. If requested changes result in a change in cost the client must accept payment responsibility. In the event work is cancelled by a client, EMSL will complete work in progress and invoice for work completed to the point of cancellation notice. EMSL is not responsible for holding times that are exceeded due to such changes.

Warranty: EMSL warrants to its clients that all services provided hereunder shall be performed in accordance with established and recognized analytical testing procedures and with reasonable care in accordance with applicable federal, state and local laws. The foregoing express warranty is exclusive and is given in lieu of all other warranties, expressed or implied. EMSL disclaims any other warranties, express or implied, including a warranty of fitness for particular purpose and warranty of merchantability.

Limits of Liability: In no event shall EMSL be liable for indirect, special, consequential, or incidental damages, including, but not limited to, damages for loss of profit or goodwill regardless of the negligence (either sole or concurrent) of EMSL and whether EMSL has been informed of the possibility of such damages, arising out of or in connection with EMSL's services thereunder or the delivery, use, reliance upon or interpretation of test results by client or any third party. We accept no legal responsibility for the purposes for which the client uses the test results. EMSL will not be held responsible for the improper selection of sampling devices even if we supply the device to the user. The user of the sampling device has the sole responsibility to select the proper sampler and sampling conditions to insure that a valid sample is taken for analysis. Any resampling performed will be at the sole discretion of EMSL, the cost of which shall be limited to the reasonable value of the original sample delivery group (SDG) samples. In no event shall EMSL be liable to a client or any third party, whether based upon theories of tort, contract or any other legal or equitable theory, in excess of the amount paid to EMSL by client thereunder.

The data and other information contained in this report, as well as any accompanying documents, represent only the samples analyzed. They are reported upon the condition that they are not to be reproduced wholly or in part for advertising or other purposes without the written approval from the laboratory.