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TOXIKON FINAL GLP REPORT: 09–5321–G2

RUBBER ARTICLES INTENDED FOR REPEATED USE

Test Article
LSR2050

Author
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Final Report Date
January 7, 2010

COMPLIANCE
21 CFR, Part 58
Good Laboratory Practice for Non–Clinical Laboratory Studies

MANAGEMENT OF THE STUDY

Performing Laboratory
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730

Sponsor
Momentive Performance Materials
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Waterford, NY 12188

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STUDY SUMMARY

The test article, LSR2050, when refluxed in purified water for 7 hours and subsequently refluxed in purified water for 2 hours, had a residue of 0.00 mg/in^2 and 0.00 mg/in^2 respectively.

The test article, LSR2050, when refluxed in hexane for 7 hours and subsequently refluxed in hexane for 2 hours, had a residue of 18.5 mg/in^2 and 3.28 mg/in^2 respectively.

Based on these results, LSR2050 meets the requirement for *Rubber Articles Intended for Repeated Use* 21 CFR 177.2600.

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Parts 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

INSPECTIONS	DATE OF INSPECTION	DATE REPORTED STUDY DIRECTOR	DATE REPORTED MANAGEMENT
WEIGHING FLASKS	12/11/09	12/11/09	12/11/09
RAW DATA	01/07/10	01/07/10	01/07/10
FINAL REPORT	01/07/10	01/07/10	01/07/10

Allison Lyons-Hook

Allison Lyons-Hook, B.A.
Quality Assurance

1/7/10
Date

STUDY DIRECTOR SIGNATURE AND VERIFICATION DATES

This study meets the technical requirements of the protocol. The study also meets the requirements of the Good Laboratory Practice Regulations, 21 CFR, Part 58, with the exemptions as stated in the Quality Assurance Statement.

Protocol Number:	PSW/PCHEM/001-09/000
Study Director:	Amtul Qamar, M.S.
Company:	Toxikon Corporation
Signature:	Amtul Qamar
Date:	1-7-10
Study Supervisor:	Amtul Qamar, M.S.

VERIFICATION DATES:
The Study Initiation Date is the date the protocol is signed by the Study Director.

Test Article Receipt:	11/18/09
Project Log Date:	12/02/09
Study Initiation Date:	12/07/09
Technical Initiation:	12/08/09
Technical Completion:	12/11/09

1.0 PURPOSE

The purpose of this study was to analyze the test article according to 21 CFR 177.2600, *Rubber Articles Intended for Repeated Use*.

2.0 REFERENCES

The study was conducted based upon the following references:

2.1 21 CFR 177.2600, *Rubber Articles Intended for Repeated Use*, Federal Register, Title 21, Chapter 1, 2009.

2.2 ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

3.0 COMPLIANCE

The study conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Non-Clinical Laboratory Studies.

4.0 IDENTIFICATION OF TEST AND CONTROL ARTICLES

The Sponsor supplied the following information on a test requisition form or other correspondence, wherever applicable (excluding confidential or trade secret information). The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

4.1 Test Article:

Test Article Name: LSR2050
CAS/Code #: Not Supplied by Sponsor (N/S)
Lot/Batch #: 09B094 (WTFD)
Physical State: N/S
Color: N/S
Expiration Date: N/S
Density: N/S
Stability: N/S
Solubility: N/S
pH: N/S
Storage Conditions: Room Temperature (N/S)
Safety Precautions: Standard Toxikon Laboratory Safety Precautions
Comment: LSR2050 (WTFD), press cure for 10 min @175 C; post cure 4 hrs at 200C

4.2 Control Articles (Toxikon Supplied):

4.2.1 Control Article Name: Purified Water
Toxikon QC #: 528120809
Physical State: Liquid
Color: Colorless
Stability: Stable at Room Temperature
Storage Conditions: Room Temperature
Safety Precautions: Standard Laboratory Safety Precautions

4.2.2 Control Article Name: Hexane
Toxikon QC #: CSC0906003OE
Physical State: Liquid
Color: Colorless
Stability: Stable at Room Temperature
Storage Conditions: Room Temperature
Safety Precautions: Standard Laboratory Safety Precaution

5.0 IDENTIFICATION OF TEST SYTEM

The test systems were recommended in the 21 CFR 177.2600 guidelines.

6.0 JUSTIFICATION OF TEST SYSTEM

The test article was analyzed through extraction mediums compatible with the test system. The extraction mediums were Purified Water and Hexane.

7.0 EXPERIMENTAL DESIGN

7.1 Experimental Design:
The analytical procedures for the analysis of the test article according to 21 CFR 177.2600 were performed by Toxikon Corporation.

7.2 Reagents:

Purified Water	Toxikon Supplier
n-Hexane	J.T. Baker

7.3 Instrumentation and Conditions:
Mettler AT261 Balance – Accurate to 0.01 mg

7.4 Preparation/Extraction of Test and Control Materials:

7.4.1 Extraction in Purified Water (water):
Each sample had a surface area of 16.53 square inches.

A known surface area of the test article was extracted in refluxing water for 7 hours. The water was then evaporated to dryness, and the resulting residue weighed.

The test article was then extracted a second time in refluxing water for an additional 2 hours. The water was evaporated to dryness, and the resulting residue weighed.

A blank, water, was prepared in the same manner as the test article extract.

7.4.2 Extraction in n–Hexane:
Each sample had a surface area of 16.53 square inches.

A known surface area of the test article was extracted in refluxing n–hexane for 7 hours. The n–hexane was then evaporated to dryness, and the resulting residue weighed.

The test article was then extracted a second time in refluxing n–hexane for an additional 2 hours. The n–hexane was evaporated to dryness, and the resulting residue weighed.

A blank, n–Hexane, was prepared in the same manner as the test article extract.

7.5 Calculations:

$$\text{Residue (mg/in}^2\text{)} = \frac{\text{Total Weight of Test Article Residue (mg)} - \text{Blank (mg)}}{\text{Total Surface Area of Test Article (in}^2\text{)}}$$

8.0 EVALUATION CRITERIA

8.1 The weight of the residue for the first (7 hour) extraction of the test article in water shall not exceed 20 mg/in^2.

8.2 The weight of the residue for the second (2 hour) extraction of the test article in water shall not exceed 1 mg/in^2.

8.3 The weight of the residue for the first (7 hour) extraction of the test article in n–hexane shall not exceed 175 mg/in^2.

8.4 The weight of the residue for the second (2 hour) extraction of the test article in n–hexane shall not exceed 4 mg/in^2.

8.5 The study and its design employed methodology to minimize uncertainty of measurement and control of bias for data collection and analysis.

9.0 RESULTS

The test article, LSR2050, does meet the requirements set forth in 21 CFR 177.2600. Results can be found in Table 1.

10.0 CONCLUSION

The test article, LSR2050, when refluxed in purified water for 7 hours and subsequently refluxed in purified water for 2 hours, had a residue of 0.00 mg/in^2 and 0.00 mg/in^2 respectively.

The test article, LSR2050, when refluxed in hexane for 7 hours and subsequently refluxed in hexane for 2 hours, had a residue of 18.5 mg/in^2 and 3.28 mg/in^2 respectively.

Based on these results, LSR2050 meets the requirement for *Rubber Articles Intended for Repeated Use* 21 CFR 177.2600.

11.0 RECORDS

11.1 Original raw data are archived at Toxikon Corporation.

11.2 A copy of the final report and any report amendments is archived at Toxikon Corporation.

11.3 The original final report, and a copy of any protocol amendments or deviations, is forwarded to the Sponsor.

11.4 All unused test article shall be disposed of by Toxikon.

12.0 CONFIDENTIALITY AGREEMENT

Statements of confidentiality were not agreed upon prior to study initiation.

13.0 PROTOCOL AMENDMENT

One of the references listed in Section 2.0 of the protocol has been updated. The protocol has been amended to reflect this change. The following is the updated reference.

21 CFR 177.2600, *Rubber Articles Intended for Repeated Use*, Federal Register, Title 21, Chapter 1, 2009.

TABLE 1
Results

Purified Water			
Reflux Time	**Results**	**Evaluation Criteria**	**Meets Criteria**
First Extraction (7 Hours)	0.00 mg/in²	≤ 20 mg/in² for 7 hours	Yes
Second Extraction (2 Hours)	0.00 mg/in²	≤ 1 mg/in² for 2 hours	Yes

Hexane			
Reflux Time	**Results**	**Evaluation Criteria**	**Meets Criteria**
First Extraction (7 Hours)	18.5 mg/in²	≤ 175 mg/in² for 7 hours	Yes
Second Extraction (2 Hours)	3.28 mg/in²	≤ 4 mg/in² for 2 hours	Yes

APPENDIX I
Software Systems

Software	Use
Adobe Acrobat 8 Professional	Document preparation
DocuKnowledge 3.0	Lotus Domino-based document management system used for SOPs
Lotus Domino Rel. 5	Client-server application for sponsor, sample, test codes, and quotation management application databases
MS Office 2007 Small Business Suite	Business software (suite includes Word, Excel, PowerPoint, Outlook, Publisher, Office tools)
Rees CentronSQL System 2.0	Environmental monitoring and metrology system