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TOXIKON FINAL GLP REPORT: 10-2223-G2

RUBBER ARTICLES INTENDED FOR REPEATED USE

Test Article
LSR2650

Author
Amtul Qamar, M.S.

Final Report Date
May 28, 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
260 Hudson River Road
Waterford, NY 12188

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STUDY SUMMARY

The test article, LSR2650 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, LSR2650 when refluxed in hexane for 7 hours and subsequently refluxed in hexane for 2 hours, had a residue of 12.4 mg/in^2 and 0.583 mg/in^2 respectively.

Based on these results, LSR2650 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	05/17/10	05/17/10	05/17/10
RAW DATA	05/28/10	05/28/10	05/28/10
FINAL REPORT	05/28/10	05/28/10	05/28/10

Priti Patel, B.S.
Quality Assurance

5/28/10
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:	P10-1165-00A
Study Director:	Amtul Qamar, M.S.
Company:	Toxikon Corporation
Signature:	Amtul Qamar
Date:	5-28-10
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:	05/10/10
Project Log Date:	05/11/10
Study Initiation Date:	05/17/10
Technical Initiation:	05/17/10
Technical Completion:	05/17/10

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. Test and control articles (exclusive of extracts) that are mixed with carriers require verification of concentration, homogeneity, and stability. Samples of test and control article mixtures were returned to the Sponsor for characterization and verification, unless this work was specifically contracted to Toxikon by Sponsor under a separate analytical protocol, whichever is applicable.

4.1 Test Article:

Test Article Name: LSR2650
CAS/Code #: Not Supplied by Sponsor (N/S)
Lot/Batch #: Pt. ZM 6120 (B-Stufe)
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: N/S
Safety Precautions: Standard Toxikon Laboratory Safety Precautions (N/S)
Comment: Test Article Description: Press Cure: 10 min / 170 C; Post Cure: 4 hrs/ 200 C

4.2 Control Articles (Toxikon Supplied):

4.2.1 Control Article Name: Purified Water
Toxikon QC #: 528051710
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 #: CSC0911002OE
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	EMD

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 18 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 18 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, LSR2650 does meet the requirements set forth in 21 CFR 177.2600. Results are presented in Tables 1, 2, and 3.

10.0 CONCLUSION

The test article, LSR2650 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, LSR2650 when refluxed in hexane for 7 hours and subsequently refluxed in hexane for 2 hours, had a residue of 12.4 mg/in^2 and 0.583 mg/in^2 respectively.

Based on these results, LSR2650 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 used and unused test article shall be disposed of by Toxikon.

12.0 CONFIDENTIALITY AGREEMENT

Per corporate policy, confidentiality shall be maintained in general, and in specific accordance with any relevant agreement specifically executed between Toxikon and the Sponsor.

TABLE 1
Analysis: Residue Obtained by Reflux with Purified Water

Test Article: LSR2650

Lot/Batch No.: Pt. ZM 6120 (B-Stufe)

First Extraction with Purified Water for 7 hours

Sample	(g)		
	Tare	Wt. 1	Weight Difference
Test Article Extract	102.6685	102.6687	0.0002
Blank Extract	105.0376	105.0378	0.0002

Second Extraction with Purified Water for 2 hours

Sample	(g)		
	Tare	Wt. 1	Weight Difference
Test Article Extract	100.5936	100.5936	0.0000
Blank Extract	96.7283	96.7283	0.0000

Legend:
Tare = Weight of Flask
Wt. 1 = Weight of Flask + residue, post evaporation
Weight Difference = Wt. 1 – tare weight

Test Article Extract (Weight Difference) – Blank (Weight Difference) = Amount of Residue from First Extraction

0.0002 g – 0.0002 g = 0.00 g = 0.00 mg

Amount of Residue from 7 hour Extraction = 0.00 mg

Test Article Extract (Weight Difference) – Blank (Weight Difference) = Amount of Residue from Second Extraction

0.0000 g – 0.0000 g = 0.0000 g = 0.00 mg

Amount of Residue from 2 hour Extraction = 0.00 mg

TABLE 2
Analysis: Residue Obtained by Reflux with Hexane

Test Article: LSR2650

Lot/Batch No.: Pt. ZM 6120 (B-Stufe)

First Extraction with Hexane for 7 hours

Sample	(g)		
	Tare	Wt. 1	Weight Difference
Test Article Extract	105.1654	105.3893	0.2239
Blank Extract	98.8655	98.8657	0.0002

Second Extraction with Hexane for 2 hours

Sample	(g)		
	Tare	Wt. 1	Weight Difference
Test Article Extract	148.6105	148.6211	0.0106
Blank Extract	94.8256	94.8257	0.0001

Legend:
Tare = Weight of Flask
Wt. 1 = Weight of Flask + residue, post evaporation
Weight Difference = Wt. 1 – tare weight

Test Article Extract (Weight Difference) – Blank (Weight Difference) = Amount of Residue from First Extraction

0.2239 g – 0.0002 g = 0.2237 g = 223.7 mg

Amount of Residue from 7 hour Extraction = 224 mg

Test Article Extract (Weight Difference) – Blank (Weight Difference) = Amount of Residue from Second Extraction

0.0106 g – 0.0001 g = 0.0105 g = 10.5 mg

Amount of Residue from 2 hour Extraction = 10.5 mg

TABLE 3
Results

Test Article: LSR2650

Lot/Batch No.: Pt. ZM 6120 (B-Stufe)

Results of Purified Water Extract

Reflux Time	Purified Water				
	Surface Area	Amount of Residue	Results	Evaluation Criteria	Meets Criteria
First Extraction (7 hours)	18.0 in^2	0.00 mg	0.00 mg/in^2	$\leq$ 20 mg/in^2	Yes
Second Extraction (2 hours)	18.0 in^2	0.00 mg	0.00 mg/in^2	$\leq$ 1 mg/in^2	Yes

Results of Hexane Extract

Reflux Time	Hexane				
	Surface Area	Amount of Residue	Results	Evaluation Criteria	Meets Criteria
First Extraction (7 hours)	18.0 in^2	224 mg	12.4 mg/in^2	$\leq$ 175 mg/in^2	Yes
Second Extraction (2 hours)	18.0 in^2	10.5 mg	0.583 mg/in^2	$\leq$ 4 mg/in^2	Yes

$$\text{Results } (mg/in^2) = \frac{\text{Amount of Residue (mg)}}{\text{Surface Area } (in^2)}$$

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

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TOXIKON TEST PROTOCOL
FDA GLP GUIDELINES
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RUBBER ARTICLES INTENDED FOR REPEATED USE

TOXIKON PROTOCOL NUMBER: P10–1165–00A

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

MANAGEMENT OF THE STUDY

Performing Laboratory	Sponsor
Toxikon Corporation	Momentive Performance Materials
15 Wiggins Avenue	260 Hudson River Road
Bedford, MA 01730	Waterford, NY 12188

ORIGINAL

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PROTOCOL ACCEPTANCE

SHAHZAD ARSHAD
PRINT NAME

Sponsor's Representative Signature
Momentive Performance Materials
260 Hudson River Road
Waterford, NY 12188

5-10-10
Date

Lea Santa Anna
PRINT NAME

Lea Santa Anna
Quality Assurance Signature
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730

5/12/10
Date

AMTUL QAMAR
PRINT NAME

Amtul Qamar
Study Director Signature
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730

5-17-10
Date

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TABLE OF CONTENTS

1.0 PURPOSE

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

2.0 REFERENCES

The study will be 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 will conform 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 will supply the following information on a test requisition form or other correspondence, wherever applicable (excluding confidential or trade secret information). The Sponsor will be responsible for all test article characterization data as specified in the GLP regulations. Test and control articles (exclusive of extracts) that are mixed with carriers require verification of concentration, homogeneity, and stability. Samples of test and control article mixtures will be returned to the Sponsor for characterization and verification, unless this work was specifically contracted to Toxikon by Sponsor under a separate analytical protocol, whichever is applicable.

4.1 Test Article:

Test Article Name: To Be Determined (TBD)
CAS/Code #: TBD
Lot/Batch #: TBD
Physical State: TBD
Color: TBD
Expiration Date: TBD
Density: TBD
Stability: TBD
Solubility: TBD
pH: TBD
Storage Conditions: TBD
Safety Precautions: TBD

4.2 Control Article(s) (Toxikon Supplied, unless specified by the Sponsor):

4.2.1 Control Article Name: Purified Water
Toxikon QC #: To Be Determined (TBD)
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 #: To Be Determined (TBD)
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 are recommended in the 21 CFR 177.2600 guidelines.

6.0 JUSTIFICATION OF TEST SYSTEM

The test article will be analyzed through extraction mediums compatible with the test system. The extraction mediums will be 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 will be performed by Toxikon Corporation.

7.2 Reagents:

Purified Water	Toxikon Supplier
n–hexane	J.T. Baker (or equivalent)

7.3 Instrumentation and Conditions:
Mettler AT261 Balance – Accurate to 0.01 mg (or equivalent)

7.4 Preparation/Extraction of Test and Control Materials:

7.4.1 Extraction in Purified Water (water):
A known surface area of the test article will be extracted in refluxing water for 7 hours. The water will then be evaporated to dryness, and the resulting residue weighed. The weight of the residue shall not exceed 20 mg/in^2.

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The test article will then be extracted a second time in refluxing water for an additional 2 hours. The water will be evaporated to dryness, and the resulting residue weighed. The weight of the residue shall not exceed 1 mg/in^2.

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

7.4.2 Extraction in n–Hexane:
A known surface area of the test article will be extracted in refluxing n–hexane for 7 hours. The n–hexane will then be evaporated to dryness, and the resulting residue weighed. The weight of the residue shall not exceed 175 mg/in^2.

The test article will then be extracted a second time in refluxing n–hexane for an additional 2 hours. The n–hexane will be evaporated to dryness, and the resulting residue weighed. The weight of the residue shall not exceed 4 mg/in^2.

A blank, n–hexane, will be 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 will employ methodology to minimize uncertainty of measurement and control of bias for data collection and analysis.

9.0 RECORDS

9.1 Original raw data will be archived at Toxikon Corporation.

9.2 A copy of the final report and any report amendments will be archived at Toxikon Corporation.

9.3 The original final report, and a copy of any protocol amendments or deviations, will be forwarded to the Sponsor.

9.4 All unused test article will be handled as specified on the Test Requisition Form. If not indicated on the Test Requisition Form, all remaining test article will be discarded.

10.0 CONFIDENTIALITY AGREEMENT

Per corporate policy, confidentiality shall be maintained in general, and in specific accordance with any relevant agreement specifically executed between Toxikon and the Sponsor

11.0 PROTOCOL AMENDMENTS/DEVIATIONS

All changes to the approved procedure and the reason for the changes will be documented in writing, signed by the Study Director, dated, and maintained with the procedure. A Procedure Amendment/Deviation Report (PADR) will be generated as closely as possible to the time of the change. The document will be created and signed by the Study Director and sent to the Sponsor. Sponsor's signature will be required for amendments to indicate approval of the amendment. Acknowledgement of notification of deviations will either be with a signature or other form of documentation.

APPENDIX I
Software Systems

The following are the proposed software systems to be used during the conduct of this study. The actual systems used will be documented in the final report.

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