Nelson Labs™
A Sotera Health company

Sponsor:
FluorTex GmbH
Wasserburger Str. 2
83543 Rott am Inn
Germany

NELSON LABS, EUROPE
Class VI Test - USP

Summary: Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

Test Article:	multiFlon® GMP ePTFE Sheet Gasketing
Assigned NLE Lab Number:	20-02853-N1
Testing Facility:	Toxikon Corporation
LOT Number:	510201902

Sample Preparation & Chain of Custody Statement: The biocompatibility test articles were received at Nelson Labs Europe and assigned a project number. The test articles were then shipped to the Nelson Laboratories, LLC Salt Lake City facility where they received an official assigned Nelson assigned Laboratory Number/s and tested.

If you have any questions, please feel free to call or email any of our Subcontracting personnel at 003216400484. Thank you for testing with Nelson Labs Europe.

Customer Support — Véronique Taelemans

17/9/2020
Date

TOXIKON
RIGHT. FROM THE START.SM

TEST RESULT CERTIFICATE

Sponsor	Nelson Laboratories, NV	**Technical Initiation**	8/13/2020
Address	Romeinsestraat 12 Leuven, Belgium B-3001	**Technical Completion**	9/4/2020
Contact	Cindy Claes / Marijke De Roo / Véronique Taelemans	**Report Date**	9/11/2020
P.O. Number	TE202367	**Final Non-GLP Report**	20-02853-N1

Test Article	multiFlon® GMP ePTFE Sheet Gasketing	**Ratio**	0.1 g/ mL
Lot/Batch #	510201902	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test – USP		
Sterility	Not Sterile		
Storage Condition	Room Temperature		
Physical State	Solid	**Extraction Conditions**	121 ± 2 °C for 1 hour ± 4 minutes
Comments	None		

REFERENCES:

The study was conducted based upon the following references:

United States Pharmacopeia 43, National Formulary 38, 2020. <88> Biological Reactivity Tests, *In Vivo*.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE:

The extraction conditions were performed as stated above. Per Sponsor request, the test article was extracted beyond its absorptive capacity of 1.4 mL of NaCl and EtOH and 3.8 mL of CSO and PEG per 2.0 g of test article. A total of 4 units of test article were used for testing. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS AND CONCLUSION:

None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, or edema in both test and control sites and no signs of clinical toxicity. In both the Systemic and Intracutaneous Tests, the controls were normal through 72 hours. One of the rabbits implanted with test article exhibited mild discoloration at one of the sites. All of the remaining implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI – 121°C

AUTHORIZED PERSONNEL:

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Quality Assurance

D. Radhika
Radhika Devalaraja, Ph.D.
Study Director

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ISO 17025 BELAC 363 - TEST

TEST RESULT REPORT: 20-B11087-N1

Project Number:	**TE202295**	**Report Date:**	**18 Aug 2020**
Sponsor:	**FluorTex GmbH**		
Contact Person:	*Detlef Reichl*		
Address:	Wasserburger Str. 2		
City, State, Zip:	83543 Rott am Inn	Date Sample Arrival:	24 Jul 2020
Country:	Germany	Technical Initiation:	11 Aug 2020
PO Number:	2629	Technical Completion:	14 Aug 2020

Method:	**Qualitative MEM-elution: Dye Exclusion**		
Test Article:	multiFlon® GMP ePTFE Sheet Gasketing	**Extraction Conditions:**	Shaking incubation at 37±1°C for 24 ± 2 hours
Lot:	510201902	**Extraction Ratio:**	0.1 g/mL + preswell
Sterilisation Method:	Steam Sterilisation	**Extraction Vehicle:**	MEM-complete

REFERENCE: ISO 10993-5 (2009), USP 43-NF 38 (2020) <87>, Nelson Labs SOP0228 (Rev 14)

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test item extract was determined. Positive (natural rubber) and negative (silicone) control articles were prepared to verify the proper functioning of the test system. The control articles were autoclaved prior to the preparation of the extracts and are extracted under the same conditions as the test item. Handling and extraction conditions of the test articles are described in the table above. The maintenance medium on the cell cultures is replaced by the extracts of the test item or control article in triplicate and the cultures are subsequently incubated for 2 days, at 37 ± 1°C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity was rated on the following scale: Grade 0 (No reactivity); Grade 1 (Slight reactivity), Grade 2 (Mild reactivity), Grade 3 (Moderate reactivity) and Grade 4 (Severe reactivity).

RESULTS AND EVALUATION:

Sample	Grade			Criteria	Evaluation
	Rep. 1	Rep. 2	Rep. 3		
Positive Control	4	4	4	> grade 2	Cytotoxic
Negative Control	0	0	0	grade 0	Not Cytotoxic
20-B11087-N1	0	0	0	< grade 3	Not-Cytotoxic

OPINION AND INTERPRETATION: Based on the evaluation criteria mentioned above, the test item is considered to be Not-Cytotoxic.

RECORD STORAGE: All raw data generated in this study will be archived at Nelson Labs NV, according to SOP 4.2.8, current revision

AUTHORIZED PERSONNEL

Elien Wouters
Study Director

for Johan Neys
Quality Assurance

18 AUG 2020