

## 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<br>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

20-02853-N1

  
Véronique Taelemans

Date

17 Sep 2020

## TEST RESULT CERTIFICATE

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

|                          |                                      |                              |                                                                                                                                        |
|--------------------------|--------------------------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| <b>Test Article</b>      | multiFlon® GMP ePTFE Sheet Gasketing | <b>Ratio</b>                 | 0.1 g/ mL                                                                                                                              |
| <b>Lot/Batch #</b>       | 510201902                            | <b>Vehicles</b>              | USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG) |
| <b>Study</b>             | Class VI Test – USP                  |                              |                                                                                                                                        |
| <b>Sterility</b>         | Not Sterile                          |                              |                                                                                                                                        |
| <b>Storage Condition</b> | Room Temperature                     |                              |                                                                                                                                        |
| <b>Physical State</b>    | Solid                                | <b>Extraction Conditions</b> | 121 ± 2 °C for 1 hour ± 4 minutes                                                                                                      |
| <b>Comments</b>          | 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:

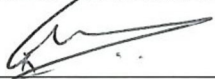
The extraction conditions were performed as stated above. Per Sponsor request, the test article was extracted beyond its absorptive capacity of 1.4 mL of NaCl and EtOH and 3.8 mL of CSO and PEG per 2.0 g of test article. A total of 4 units of test article were used for testing. The test article extracts 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.

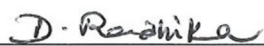
### RESULTS AND CONCLUSION:

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:

  
Gaurav Chavan, M.S.  
Quality Assurance

  
Radhika Devalaraja, Ph.D.  
Study Director

## TEST RESULT REPORT: 20-B11087-N1

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

|                              |                                               |                               |                                                  |
|------------------------------|-----------------------------------------------|-------------------------------|--------------------------------------------------|
| <b>Method:</b>               | <b>Qualitative MEM-elution: Dye Exclusion</b> |                               |                                                  |
| <b>Test Article:</b>         | multiFlon® GMP<br>ePTFE Sheet Gasketing       | <b>Extraction Conditions:</b> | Shaking incubation at<br>37±1°C for 24 ± 2 hours |
| <b>Lot:</b>                  | 510201902                                     | <b>Extraction Ratio:</b>      | 0.1 g/mL + preswell                              |
| <b>Sterilisation Method:</b> | Steam Sterilisation                           | <b>Extraction Vehicle:</b>    | 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 Koudien Witpas  
 Johan Neys  
 Quality Assurance

18 AUG 2020

The test results on the enclosed report are only referring to the tested articles. Partly reproduction of this report can only be allowed after written permission of Nelson Labs NV. Nelson Labs NV guarantees that all results are acquired by testing according to officially accepted scientific methodology.