

TEST RESULT REPORT: 20-B11657-N1

Project Number:	TE202426	Report Date:	21 Aug 2020
Sponsor:	Kraiburg TPE GmbH & Co. KG		
Contact Person:	<i>Eugen Andert</i>		
Address:	Friedrich-Schmidt-Strasse 2	Date Sample Arrival:	11 Aug 2020
City, State, Zip:	84478 Waldkraiburg	Technical Initiation:	17 Aug 2020
Country:	Germany	Technical Completion:	20 Aug 2020
PO Number:	4500116944		

Method:	Quantitative MEM-elution: XTT		
Test Article:	TM4MEP	Extraction Conditions:	Shaking incubation at 37±1°C for 24 ± 2 hours
Lot:	1175199	Extraction Ratio:	1.25 cm ² /mL
Sterilisation Method:	Steam Sterilisation	Extraction Vehicle:	MEM-complete

REFERENCE: ISO 10993-5 (2009), 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 quadruplicate and the cultures are subsequently incubated for 2 days, at 37 ± 1°C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Subsequently XTT-reagent was added to the wells and the cultures incubated for another 3-5 hours. Biological reactivity was evaluated by a photo spectrometer at 450 nm wavelength.


RESULTS:


Test item	Viability	Criteria
Positive Control	4%	Cytotoxic: < 70%
Negative Control	108%	Non-Cytotoxic: ≥ 70%
Test Item	112%	Non-Cytotoxic: ≥ 70%

OPINION AND INTERPRETATION: Based on the evaluation criteria mentioned above, the test item is considered to be non cytotoxic.

RECORD STORAGE: All raw data generated in this study will be archived at Nelson Labs NV, according to SOP0392, current revision

AUTHORIZED PERSONNEL


Elien Wouters
Study Director


21 AUG 2020
for *Kaathie Witepas*
Johan Neys
Quality Assurance

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