Nelson Labs
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ISO 17025 BELAC 363 - TEST

TEST RESULT REPORT: 18-B9467-N1

Project Number:	TE182307	Report Date:	09 Oct 2018
Sponsor:	Baumer A/S		
Contact Person:	Patrick Sonnichsen		
Address:	Runetoften 19		
City, State, Zip:	8210 Aarhus	Date Sample Arrival:	27 Sep 2018
Country:	Denmark	Technical Initiation:	02 Oct 2018
Purchase Order:	4500889517	Technical Completion:	05 Oct 2018

Method:	**Qualitative MEM-Elution: Dye Exclusion**		
Test Article:	PEEK tip for level switch	**Extraction Conditions:**	Shaking incubation at 37 ± 1°C for 24 ± 2 hours
Lot:	N/A	**Extraction Ratio:**	3 cm²/mL
Additional Info:	The test article was autoclaved prior to extraction.	**Extraction Vehicle:**	MEM-Complete

REFERENCE: ISO 10993-5 (2009), USP 41-NF 36 (2018) <87>, Nelson Labs SOP 3.1.2.3 (Rev 12)

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.

SCORING: 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
Test item	0	0	0	< grade 3	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

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