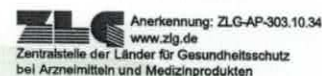


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Akkreditated Laboratory
DAkKS: D-PL-13207-01

Zwisler Laboratorium GmbH, Blarerstraße 56, 78462 Konstanz, Europe

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Herr Dominik Bugge (sponsor)
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GLP Good Laboratory Practice
Statement of GLP Compliance

Commentary to Report N° 1706.2709

The following remarks are not part of the study report. They may only be considered as additional information for the sponsor without responsibility. This commentary is valid without a signature.

Notice

In compliance with EN ISO 10993-5:2009 one specimen of the test item was tested in-vitro for cytotoxicity. Therefor L-929 cells were cultured as subconfluent monolayer (16th split of DSMZ culture: DSM ACC2, mouse connective tissue fibroblasts clone of strain L). After sterilisation (121°C, 20min, steam) an extract in culture medium with serum (37°C, 24h) was prepared of the specimen (49.0 cm², surface area/volume ratio of 3 cm²/ml). The culture medium (RPMI 1640, lot 1858636) was supplemented with 10% v/v fetal bovine serum (FBS, lot 1805395) and 100 U/ml penicillin and 100 µg/ml streptomycin (lot 1842943/1864845). All compounds were purchased from Life Technologies (Invitrogene) GmbH, Darmstadt. The extract was tested undiluted and diluted 1:2, 1:4 and 1:8 in cell culture medium, and was incubated with the cells for two days. Thereafter the degree of cell destruction was evaluated using microscopy and subsequent viability staining (MTT). The suitability of the test system was confirmed by positive and negative controls.

Sample-No.	Test Item	Quantitative Evaluation % viability (ISO)	Qualitative Evaluation reactivity grade (USP)
1706.2709	Clickline Zangeneinsatz, Art. No.: 33410C-S	88+/-1.9 %	1 (slight reactivity)

Microscopy/Qualitative Evaluation: Not more than 10 to 20 % of the cells were round and showed no discrete intracytoplasmic granules (corresponding to slight reactivity), only some cell lysis and empty areas were observed.

Quantitative Evaluation: A sample with a cell viability above 70% is considered to be NON CYTOTOXIC, but slightly reactive.

Qualitative: The extract resulted in cell reactivities that characterize the sample to comply with USP<87>.

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SUMMARY: The sample is considered to have NO CYTOTOXIC POTENTIAL.

Dr. Christian Draing, Study Director

Konstanz, 8/2/2017

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 Anerkennung: ZLG-AP-303.10.34
www.zlg.de
Zentralstelle der Länder für Gesundheitsschutz
bei Arzneimitteln und Medizinprodukten

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Report N° 1706.2709

Sampling and tests were performed according to specifications under 'specimen data' and 'methods' respectively. Particulars about best measurement capability and technical standards are available on request.

Results

Clickline Zangeneinsatz

Reactivity	grade 1/1/1/1/1	at 100% extract
Vitality	89/89/87/84/89/89%	at 100% extract
Vitality	mean 88 +/-1.9%	at 100% extract
Reactivity	grade 0/0/0/0/0	at 50% extract
Vitality	mean 90 +/-2.0%	at 50% extract
Vitality	91/88/90/90/88/93%	at 50% extract
Reactivity	grade 0/0/0/0/0	at 25% extract
Vitality	mean 93 +/-3.2%	at 25% extract
Vitality	89/97/94/90/94/94%	at 25% extract
Reactivity	grade 0/0/0/0/0	at 12.5% extract
Vitality	102/98/98/103/100/99	at 12.5% extract
	%	
Vitality	mean 100 +/-1.9%	at 12.5% extract

Negative Control (LDPE)

Reactivity	grade 0/0/0/0/0	at 100% extract
Vitality	97/94/99/94/98/102%	at 100% extract

Positive Control (ZDEC)

Reactivity	grade 4/4/4/4/4	at 100% extract
Vitality	1/1/3/1/1/1%	at 100% extract
Reactivity	grade 4/4/4/4/4	at 50% extract
Vitality	0/1/0/3/1/1%	at 50% extract
Reactivity	grade 4/4/4/4/4	at 25% extract
Vitality	3/2/2/2/2/1%	at 25% extract

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Reactivity grade 0/0/0/0/0 at 12.5% extract
Vitality 98/90/92/91/91/102% at 12.5% extract

Positive Control for Diffuse Reaction

Reactivity grade 2/2/2/2/2 at 0.05% phenol
Vitality 67/61/61/59/65/65% at 0.05% phenol
Reactivity grade 4/4/4/4/4 at 0.225% phenol
Vitality 3/3/2/2/1/2% at 0.225% phenol

methods Cytotoxic Effect ISO 10993-5, USP<87>, ZLG cytotox-3e.doc, Vers. 13
Extraction ISO 10993-5, ZLG cytotox-3e.doc, Vers. 13

specimen data: number 1706.2709, receipt of specimen 22.06.2017, experimental starting date 27.06.2017, experimental completion date 30.06.2017, under the designation 'inactive medical device', Medizinprodukt, manufactured by add'n solutions GmbH & Co. KG, sampling was performed by sponsor, principal code 33410C-S, 1unit, delivery by DHL, temperature at delivery: 32°C,

The sign '<' means 'less than the quoted value', '>' means 'more than the quoted value'. Detected microorganisms are reported as '+ n.' and negative test results as 'n.n.' this means the microorganism was not found in the specified volume. Methods labeled with an 'A' are out of the accredited ambit; methods labeled with a 'U' were performed by a sub contractor. Test results exclusively refer to the specimen and not to the entire lot, bundle etc. This test report may only be copied or published as a complete document including the signature on the last page and all data of 1 specimen (number 1706.2709) with permission of the laboratory.

To improve our service we would like to ask you for a feedback. Are you happy with our service or how could we improve this service? Please feel free to send us your comments and recommendations. Thank you for your input and the continuing good cooperation


Dr. Christian Draing, Study Director

Konstanz, 8/2/2017

Explanation of the evaluation of test specimen (according to SOP Cytotox-3e, version 13)

Observations for cytotoxicity are evaluated using a reactivity scale from 0 to 4 based on USP <87> (a) and using a cytotoxicity scale based on ISO 10993-5 (b). Additionally an internal comment of the laboratory is added (c).

a) USP<87>: Microscopy/Qualitative Evaluation:

0	None reactivity	Discrete intracytoplasmatic granulas, no cell lysis is observed.
1	Slight	10% to 20% of the cells are round, loosely attached, and without intracytoplasmatic granulas. Some lysed cells are present.
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmatic granulas. No extensive cell lysis and empty areas between cells are observed.
3	Moderate	Not more than 70% of the cell monolayer contain rounded cells or are lysed.
4	Severe	Nearly complete destruction of cell monolayer.

b) ISO 10993-5: Quantitative Evaluation

Non cytotoxic	sample extract which results in a cell viability above 70%
Cytotoxic	sample extract which results in a cell viability below 70%

c) internal comment of the laboratory: Quantitative Evaluation

0	Non cytotoxic	sample extract which results in a cell viability above 90%
1	Slight reactivity, non cytotoxic	sample extract which results in a cell viability above 70%
2	Slight cytotoxic	sample extract which results in a cell viability between 50% - 70%
3	Cytotoxic	sample extract which results in a cell viability between 30% - 50%
4	Severe cytotoxic	sample extract which results in a cell viability below 30%