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Test Report Date: 11th Jul. 2018

Client name: WACKER CHEMICALS (CHINA) CO., LTD

Client address: Bldg. 3, 1535 Hongmei Road Caohejing Hi-Tech Park Shanghai 200233, China

Assignment ID: 14A1802067

Sample No.: 14S18006091-02

Report on the submitted sample identified by the client as below:

Product Name ELASTOSIL®LR 3038/50 K1 CN

Quantity Received 1 bag

Batch number ZR13214

Expiry date unlimited storage life

Type of material Synthetic Elastomer

Sample Receiving Condition Room temperature

Sample Receiving Date 13th Apr.2018

Testing Period 17th May.2018 -18th May.2018

Test Requested, Test Method and Test Results:

Please refer to the following page(s), Attachment 1.

The test was carried out by SGS subcontractor certified ISO 17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS Sia Vone A验检测专用章 Sia Tong Life Science Quality Assurance Authorized Signature

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Attachment 1: Test for in vitro cytotoxicity (MTT cytotoxicity test)

SUMMARY

An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article: ELASTOSIL®LR 3038/50 K1 CN, based on the International Organization for Standardization ISO 10993-5:2009: Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity; ISO 10993-12:2012: Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.

Four concentrations (100%, 75%, 50%, and 25%) of the test article extracts, the blank, 100% of the negative control and the positive control were prepared using Minimum Essential Medium (MEM) supplemented with 10% fetal bovine serum. The semi-confluent monolayers of L-929 mouse fibroblast cells were incubated with the test extract, the blank and two controls in a 96-well microplate respectively at 37°C under the condition of 5% CO₂. After 24 h, the MTT colorimetric assay was employed and the plate was read on a microplate reader at 570 and 650nm. Then the viability of cells was calculated.

Under the conditions of this study, the viability of 100% extract of the test article was 84%. It can be considered that the test article extracts had not a cytotoxic potential.

MATERIALS

The test article provided by the sponsor was identified and handled as follows:

Test Article: ELASTOSIL®LR 3038/50 K1 CN

Sterilization Status: Non-sterile

Storage Conditions: Room temperature

Extract Vehicle: GIBCO's Minimum Essential Medium supplemented with L-glutamine

and 10% fetal bovine serum.

Test Extract Preparation: According the requirement of the sponsor, the test articles were

sterilized by ethylene oxide two weeks before the treatment.

Based on the ISO 10993-12:2012, the ratio of 1.25cm²:1 ml (Surface

area of the test sample to volume of extraction vehicle),24 cm² of the test articles were covered with 19.2ml extraction vehicle under aseptic

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conditions for preparing the test extract at 37 °C for 24 hours. The extract

was used immediately after extraction.

Blank Preparation: The extraction vehicle not containing the test sample, retained in a vessel

identical to that which holds the test article and subjected to conditions identical to those to which the test sample is subjected during its

extraction.

Negative Control Preparation: The ratio of 3 cm² high-density polyethylene: 1 ml (surface area of the

test article to volume of extraction vehicle) was used and extracted at

37°C for 24 hours.

Positive Control Preparation: The ratio of 6 cm² Polyurethane film containing 0.1% zinc

diethyldithiocarbamate (ZDEC): 1 ml (surface area of the test article to volume of extraction vehicle) was used and extracted at 37 °C for 24

hours.

Condition of Extracts: All the extracts of the test and controls were clear and without any

special treatments.

METHODS

Test System Management:

Mouse fibroblast cells (L-929, from the cell bank of Shanghai Institutes for Biological Sciences), were cultured in MEM with L-glutamine supplemented with 10% fetal bovine serum at 37 $^{\circ}$ C in a gaseous environment of 5% carbon dioxide (CO₂). A 96-well microplate method was employed for the MTT colorimetric assay. Each well was seeded 100 µL suspension of 1×10⁴ cells, and incubated at 37 $^{\circ}$ C in 5% CO₂ atmosphere for 24 hours prior to use.

Experimental Procedure:

After incubation, the growth medium was replaced with 100 μ L four concentrations (100%, 75%, 50%, and 25%) of the test extract, 100% of the negative control and the positive control, the blank (row 2 and 11) respectively. Six replicates were prepared for each group. The 96-well plate was incubated at 37 $^{\circ}$ C in 5% CO₂ for 24h.

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After 24 h treatment, the culture medium was removed carefully from the plates. 50μL of the MTT (Sigma, 1mg/mL) solution was then added to each test well and the plates were further incubated for 2 h at 37 °C in a 5% CO₂ atmosphere. Then the MTT solution was removed and 100μL isopropanol per well was added and shake for 10 min gently. The plate was read on a microplate reader at 570nm (reference wavelength 650nm). The viability of the cells was calculated according to the formula below:

Viab.%= $100 \times OD_{570e}/OD_{570b}$

Where

OD_{570e} is the mean value of the measured optical density of the extracts of the test sample;

OD_{570b} is the mean value of the measured optical density of the blanks.

A test meets acceptance criteria if the left and the right mean of the blanks do not differ by more than 15% from the mean of all blanks. If the viability of the test sample was reduced to <70% of the blank, it had a cytotoxic potential. The 50% extract of the test sample should have at least the same or a higher viability than the 100% extract; otherwise the test should be repeated.

RESULTS

Group	The optical density (570nm-650nm)	Viab.%
100% of the negative control	0.771±0.031	98
100% of the test extract	0.665±0.051	84
75% of the test extract	0.674±0.031	85
50% of the test extract	0.703±0.044	89
25% of the test extract	0.733±0.045	93
100% of the positive control	0.036±0.008	5 555
The blank (row 2)	0.790±0.024	the des the
The blank (row 11)	0.789±0.041	5 1 gg _ 1

Note: n=6

The mean value of optical density of the blank was 0.790±0.032; both the left (row 2) and the right (row 11) mean of the blanks were less than 15% from the mean of all blanks.

CONCLUSION

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PHOTOGRAPH OF THE TEST ARTICLE



Remark: Results and conclusions apply only to the test article tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***

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