SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Life Science Services Laboratory

T:021-61152161, 61155151 F:021-64951517
中国.上海.徐汇区宜山路 889 号 3 号楼 7 楼
7/F, the 3rd Building, Yishan Road , Xuhui District, Shanghai, China 200233

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 Tong.....

Sia Tong
Life Science Quality Assurance
Authorized Signature

Attention: To check the authenticity of testing/ Inspection report & certificate, please contact us at telephone: (86-755)8307 1443 or email: CN.Doccheck@sgs.com
3rd Building No.889 Yishan Road Xuhui District, Shanghai, China 200233 t(86-21)61152197 f(86-21)64951517 www.sgsgroup.com.cn
中国.上海.徐汇区宜山路 889 号 3 号楼 邮编：200233 t(86-21)61152197 f(86-21)64951517 e sgs.china@sgs.com
Member of SGS Group (SGS SA)

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% CO_2. 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 1.25cm^2:1 ml (Surface area of the test sample to volume of extraction vehicle),24 cm^2 of the test articles were covered with 19.2ml extraction vehicle under aseptic

conditions for preparing the test extract at 37 ℃ 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 cm^2 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 cm^2 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 ℃ 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 ℃ in a gaseous environment of 5% carbon dioxide (CO_2). A 96-well microplate method was employed for the MTT colorimetric assay. Each well was seeded 100 µL suspension of 1×10^4 cells, and incubated at 37 ℃ in 5% CO_2 atmosphere for 24 hours prior to use.

Experimental Procedure:

After incubation, the growth medium was replaced with 100 µL 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 ℃ in 5% CO_2 for 24h.

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 ℃ in a 5% CO_2 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
The blank (row 2)	0.790±0.024	/
The blank (row 11)	0.789±0.041	/

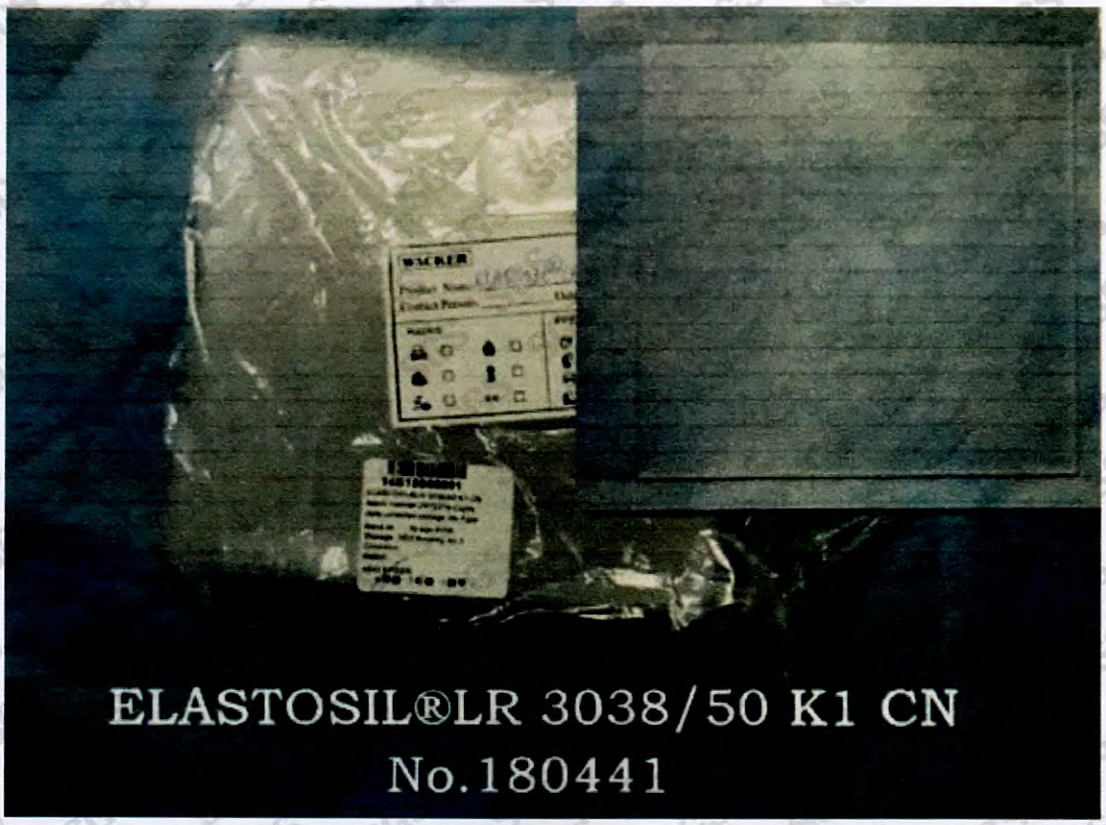
Note: n=6

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

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.

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 ***