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# Test Report

**Date: 17th Jan. 2019**

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

**Client address: 3rd Building WACKER CHEMICALS, 1535 HONGMEI ROAD, XUHUI DISTRICT, SHANGHAI**

**Assignment ID: 14A1806516**

**Sample No.: 14S18025747-02**

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

| | |
|---|---|
| Product Name | ELASTOSIL® LR 3038/40 K1 CN |
| Quantity Received | 1 bag |
| Batch Number | 3038/40K1:ZR13590 |
| Expiry Date | unlimited storage life |
| Type of Material | Synthetic Elastomer |
| Sample Receiving Condition | Room temperature |
| Sample Receiving Date | 29th Oct.2018 |
| Testing Period | 29th Nov. 2018–30th Nov. 2018 |

Test Requested, Test Method and Test Results:

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

***The above sample was submitted and identified by the client.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

Racy Li
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
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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 3038/40 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 78%. 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 3038/40 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 1.25 $cm^2$:1 ml (Surface area of the test sample to volume of extraction vehicle), 15 $cm^2$ of the test |

articles were covered with 12 ml 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 $1\times10^4$ 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





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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 | 0.821±0.024 | 102 |
| 100% of the test extract | 0.630±0.015 | 78 |
| 75% of the test extract | 0.662±0.021 | 82 |
| 50% of the test extract | 0.712±0.018 | 88 |
| 25% of the test extract | 0.732±0.034 | 91 |
| 100% of the positive control | 0.037±0.004 | 5 |
| The blank (row 2) | 0.816±0.034 | / |
| The blank (row 11) | 0.797±0.044 | / |

Note: n=6

The mean value of optical density of the blank was 0.806±0.039; 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 78%. 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 ***