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

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	15th May.2018 –25th 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

Attachment 1: Test for skin sensitization (Murine local lymph node assay，LLNA)

SUMMARY

Murine Local Lymph Node Assay（LLNA）of the test article, ELASTOSIL®LR 3038/50 K1 CN, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices part 10: Tests for irritation and skin sensitization; ISO10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The extract of the test article was contacted on ears of mice for three consecutive days. At 48h after the last treatment, inject inter-peritoneally BrdU into mice. And then measured the extent of lymphocyte proliferation in the lymph node cells by ELISA. Finally the Stimulation Index（SI）were determined.

Under the conditions of this study, SI of the test group was 1.1 for the DMSO extract and 1.2 for the SC extract. It could be concluded that the extract of the test article had no evidence of causing sensitization in the mice.

MATERIALS

The test article was 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
Extraction Vehicle:	①SC; ②DMSO
Test Article Preparation:	According the requirement of the sponsor，the test article was sterilized by ethylene oxide two weeks before testing. Based on the ISO 10993-12:2012, the ratio of 1.25 cm^2:1 ml (Surface area of the test article to volume of extraction vehicle), 21 cm^2 of the test article were covered with 16.8 ml of extraction vehicle under aseptic conditions for preparing the SC and DMSO test extract at 37 ºC for 72 h. The extracts were used after extraction.
Reagent Control:	Two extraction vehicles without the test article was similarly prepared.

Positive Control:	2,4-Dinitrochlorobenzene (DNCB) was prepared at a 0.25% concentration in DMSO.
Condition of extract	The extract of the test article and controls were all clear and without any special treatments.

METHODS

Test System

Species:	Healthy mice of the BALB/c strain
Grade:	SPF
Source:	SHANGHAI JIESIJIE LAB ANIMAL CO., LTD
Sex:	Female
Body Weight Range:	17.0 g to 19.5 g
Age:	56d to 70d
Number of animals:	Twenty-five

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".
Food:	Diet was provided from Shanghai Pu Lu Teng Biological Technology Co., Ltd.
Water:	Pure Water
Housing:	Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment, and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No. of the test article and first treatment date.
Environmental:	The room temperature and humidity were monitored daily. The temperature range for the room was from 20 ℃ to 26 ℃. The room humidity range was from 50 % to 70 %. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Personnel:	Associates involved were appropriately qualified and trained.

Selection: Only healthy, unused animals were selected.

Experimental Procedure:

1. Treatment groups:

   Prior to dosing, the mice were identified and weighted. Twenty-five mice were divided into five groups. Five mice were used per group, with the test extracts group (SC and DMSO), the reagent control groups (SC and DMSO), and the positive control group. Each group was applied to the dorsal side of each ear of designated mice at a dose of 25μl per day for three consecutive days.

2. Experimental schedule:

   On Day 5, injected 5 mg BrdU inter-peritoneally. On Day 6, recorded the weight of each mice and any clinical observation. Approximately 24 hours（24h）after BrdU injection. Euthanized the mice. Excised the draining auricular lymph nodes from each mouse ear. Then preparation of cell suspensions.

3. Observation and record:

   Each day recorded the behaviour and body weight of the mice at Day 1 and Day 6. Both ears of each mouse were observed for erythema and scored.

4. Determination of cellular proliferation

   Briefly, 100μl of the LNC suspension was added to the wells of a flat-bottom microplate in triplicate. After fixation and denaturation of the LNC, anti- BrdU antibody was added to each well. Subsequently the anti- BrdU antibody was removed. Absorbance at 370 nm with a reference wavelength of 492nm was then measured. Measure the level of BrdU incorporation of lymphocyte proliferation in the lymph node cells by ELISA.

5. Calculation of results

   Results for each group were expressed as the SI. The SI was derived by dividing the mean BrdU labelling index for test group by the mean BrdU labelling index for the solvent group.

   A SI of 3 or more(≥3) shall be considered positive for designating a test article as a sensitizer.

Results

Clinical Observation:

All animals appeared clinically normal throughout the study. All the erythema grades of the SC and DMSO extract of the test articles were 0.

Stimulation Index（SI）:

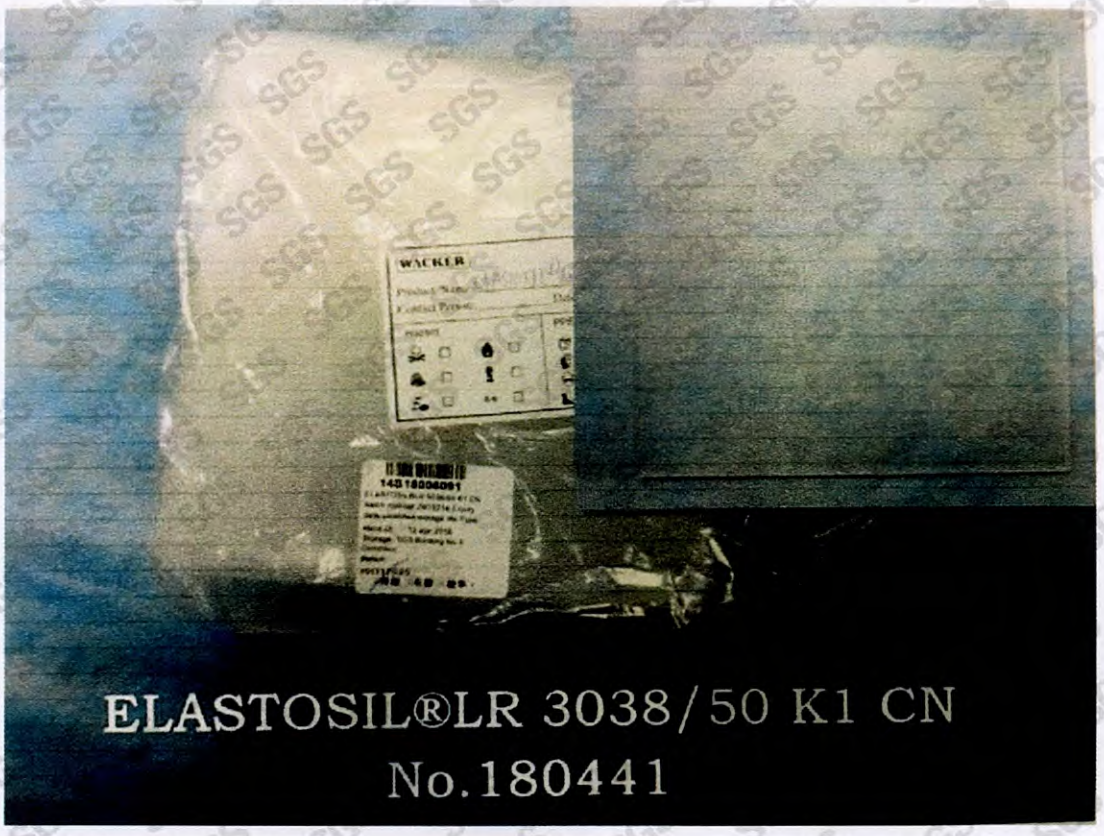
The result of SI was given below:

Group	SI
SC reagent control	1
DMSO reagent control	1
SC extract of test article	1.2
DMSO extract of test article	1.1
The positive control	3.3

CONCLUSION

Under the conditions of this study, the extract of the test article had no evidence of causing sensitization in the mice.

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 ***