Test Report Number: SHAH01612011

Applicant: Guangzhou Great Healthcare co.,Ltd
206, Building 3, No. 6, Jiapin Third Street, Shatou street, Panyu District, Guangzhou

Date: Oct 20, 2023

Sample Description:

One group of submitted sample said to be :

Item Name	:	HERBAL ARMPIT DEODORANT CREAM
Batch No.	:	HD2309
MFG	:	SEP-2023
Manufacturer	:	Guangzhou Great Healthcare co.,Ltd
Test Type	:	Entrusted Test

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Tests Conducted:

As requested by the applicant, for details refer to attached page(s).

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To be continued

Authorized By:
For Intertek Testing Services Ltd., Shanghai

Shiny Ning
Manager

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1. Test sample information:

Name of Sample:	HERBAL ARMPIT DEODORANT CREAM	Lot number:	BATCH NO:HD2309 MFG:SEP-2023
Chemical Name:	/	Physical state:	Liquid
CAS number:	/	Color:	Brown
INCI name:	/	Purity:	/
Product name:	/	Storage conditions:	Room temperature
Relative molecular weight:	/	Stability:	/
Molecular formula:	/	Production Date:	/
Manufacturer:	/	Validity period:	/
Manufacturer Address:	/		

Note: "/" means this item is not applicable.

1.1 Test sample: Cut the filter paper into a size of 1.5cm*1.5cm, moisten the filter paper with the sample and place it on the surface of the agar layer for exposure.

2. Control group information:

2.1 Positive control：ZDEC Polyurethane film (Cut to 1.5cm*1.5cm size)

Chemical Name:	/
CAS No.:	/
INCI name:	/
Physical state:	Film
Purity:	/
Lot number:	A-223K
Relative molecular weight:	/
Molecular formula:	/
Manufacturer:	Hatano Research Institute
Valid period:	30th December, 2023

Note: "/" means this item is not applicable.

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2.2 Negative control：High Density Polyethylene Film (Cut to 1.5cm*1.5cm size)

Chemical Name:	/
CAS No.:	/
INCI name:	/
Physical state:	Film
Purity:	/
Lot number:	C-221
Relative molecular weight:	/
Molecular formula:	/
Manufacturer:	Hatano Research Institute
Valid period:	10th November, 2023

Note: "/" means this item is not applicable

3. Test acceptance criteria:

3.1 There was no significant difference in the detection results of each parallel culture dish.

3.2 The negative control group exhibited the expected negative results.

3.3 The positive control group exhibited the expected positive results.

4. Material:

4.1 Cell lines: L-929 cell (NCTC clone 929). Source: Kunming Cell Bank. Generation:29

4.2 Culture medium: DMEM with 10% fetal bovine serum (FBS, from Gibco, Lot: 2500251P).

4.3 Test condition: Incubate at 37±1℃ and >90% humidity in air with 5% CO_2 (volume fraction).

4.4 Agarose：The agarose was prepared into a 3.2% agarose stock solution with ultrapure water, and autoclaved at 121 ℃ for 20 min for use.

4.5 Neutral red dye：Neutral red was prepared with DMEM medium to a concentration of 0.01%, sterilized by filtration with a 0.22 μm syringe filter, and prepared for immediate use.

5. Test procedure:

5.1 Steps

5.1.1 Routinely culture L929 cells in a 22 cm^2 sterile petri dish. When the cells are 80% confluent and close to forming a monolayer, replace them with agar/medium containing a final concentration of 1.5% (agar:medium = 1:1) to distribute Homogeneous and solidifies at room temperature.

5.1.2 Add neutral red dye solution with a final concentration of 0.01% to stain the cells, and discard the dye solution after 30 min.

5.1.3 Gently place the test substance on the surface of the solidified agar, and the test substance occupies about 1/10 of the area of the cell layer. The absorbent material needs to be pre-wetted with the medium to prevent dehydration of the agar, while preparing positive and negative controls.

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5.1.4 Return to the incubator for a further 24 hours.

5.2 Judgment criteria：

Observations were made before and after removal of the samples, and cell morphological changes were observed and recorded under an inverted microscope. Abnormal cell morphology included general morphological changes, vacuolation, detachment, lysis, and loss of membrane integrity. According to Table 1, qualitative observation and classification of cell morphology were carried out. According to Table 2, the results of the reaction area were judged.

Table 1. Qualitative morphological grading of cytotoxicity of extracts

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; mot more than 50 % growth inhibition observable.
3	Moderate	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completly destroyed,but more than 50% growth inhibition observable.
4	Severe	Nearly complete or complete destruction of the cell layers.

Table 2. Reactivity grades for agar and filter diffusion test and direct contact test

Grade	Reactivity	Description of reactivity zone
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under specimen
3	Moderate	Zone extending specimen size up to 1,0 cm
4	Severe	Zone extending farther than 1,0 cm beyond specimen

The basis of this judgment is added according to *the ISO 10993-5 (2009): Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity.* If the score according to Table 1 and Table 2 is > 2, it is considered to have cytotoxic effect.

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6. Results:

In this experiment, the evaluation results of cell morphology and fading under the action of the samples are shown in Table 3.

Table 3. In vitro cytotoxicity assay results

Group	Cytotoxic Morphological Grading	Response range classification	Cellular Response Grading (Morphological Analysis/Fading Reaction)
Testing Sample	2	1	2/1
	2	1	2/1
	2	1	2/1
Negative Control	0	0	0/0
	0	0	0/0
	0	0	0/0
Positive Control	4	3	4/3
	4	3	4/3
	4	3	4/3

7. Conclusion:

According to *the ISO 10993-5 (2009): Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity*, under the conditions of this test, for this batch of test article "HERBAL ARMPIT DEODORANT CREAM" provided by the sponsor scored 2/1 and has no cytotoxicity.

Test Item is subcontracted on INTERTEK accreditation laboratory

Date Sample Received：Sep 26, 2023

Testing Period：Sep 26, 2023 To Oct 13, 2023

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To be continued

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End of report

The statements of conformity reported have considered the decision rule agreed, namely that Intertek have taken account of measurement uncertainty as calculated by Intertek, and applied according to ILAC-G8/09:2019 (Non-binary acceptance based on guard band w = U) except designation from the customer, regulation or test specification. This decision rule only applies to the numeric test results.

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