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Test Report Number: SHAH01409693

Applicant: Ji'nan Zeng Chinese Traditional Medicine Science And Technology Co., Ltd
2-201, building 10, chunyuanli community
Shizhong District, Jinan, Shandong,
China

Date: Jan 07, 2022

Sample Description:

One group of submitted sample said to be :

Item Name	:	ZENGHERB(Armpit deodorant)
Item No.	:	20211010
Manufacture	:	Ji'nan Zeng Chinese Traditional Medicine Science And Technology Co., Ltd.
Sample Description	:	Brown Liquid

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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

Prepared And Checked By:
For Intertek Testing Services Ltd., Shanghai

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Cytotoxicity*

Test Method：Agar Diffusion Method

ISO 10993-5 (2009): Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity, section 8.4 (see note *1)

Remarks：*1 The original of this method comes from ISO 10993-5 (2009): Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity, section 8.4.

Appendix：

1. Test sample information:

Name of Sample:	ZENGHERB(Armpit deodorant)	Lot number:	/
Chemical Name:	/	Physical state:	Liquid
CAS number:	/	Color:	Brown
INCI name:	/	Purity:	/
Product name:	/	Storage conditions:	Room temperature
Relative molecular weight:	/	Stability:	Stable under storage conditions
Molecular formula:	/	Production Date:	/
Manufacturer:	/	Validity period:	/
Manufacturer Address:	/		

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

1.1 Test sample: Undiluted.

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2. Control group information:

2.1 Positive control（PC）：ZDEC polyurethane film (cut into 1.5cm*1.5cm size)

chemical name:	/
CAS number:	/
Physical state:	film
purity:	/
Lot number:	A-152K
Relative molecular weight:	/
Molecular formula:	/
manufacturer:	Hatano Research Institute
Validity period:	July 10, 2022

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

2.2 Negative control（NC）：High Density polyethylene film (cut into 1.5cm*1.5cm size)

chemical name:	/
CAS number:	/
Physical state:	/
purity:	/
Lot number:	C-141
Relative molecular weight:	/
Molecular formula:	/
manufacturer:	Hatano Research Institute
Validity period:	July 10, 2022

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

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3. Test acceptance criteria:

3.1 There is no significant difference in the test results of each parallel petri dish.
3.2 The negative control group showed the expected negative result.
3.3 The positive control group showed the expected positive result.

4. Test materials:

4.1 Cell line: L-929 cell (NCTC clone 929) (Source: Kunming Cell Bank, generation number: 25).
4.2 Culture medium: DMEM medium containing 10% fetal bovine serum (FBS) (FBS purchased from Gibco, Lot: 2275120)
4.3 Culture conditions: incubator temperature 37±1℃, 5% CO_2, humidity>90%
4.4 Agarose: Prepare agarose into a 3.2% agarose stock solution with ultrapure water, autoclave at 121℃ for 20 minutes for later use.
4.5 Neutral Red Staining Solution: Prepare neutral red with DMEM medium to a concentration of 0.01%, filter and sterilize with a 0.22μm syringe filter, and prepare it for immediate use.

5. Test procedure:

5.1 Steps:
5.1.1 The L929 cells were cultured routinely in 22 cm^2 culture dish, and when L929 cell approximately 80% confluence to monolayer, the culture medium was replaced by 1.5% (final concentration) agar /cultrure medium(culture medium : agar = 1:1)and solidified at room temperature.
5.1.2 0.01% neutral red vital stain was added gently on to the solidified agar surface for 15 min, then discard remainder dye liquor.
5.1.3 The test article was gently placed on the surface of the solidified agar, and the test object occupied about 1/10 of the area of the cell layer. The water-absorbing material needs to be pre-wetted with a medium to prevent dehydration of the agar. Positive and negative controls were prepared simultaneously.
5.1.4 Incubate the vessels using the same conditions for 24 h.
5.2 Evaluation criteria:
Examine the cells to determine cytotoxic effect before and after carefully removing the specimens from the agar. Examine the cells microscopically under convert microscopy and any change from normal morphology shall be recorded. A qualitative morphological grading of cytotoxicity is given in Table 1and Table 2.

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Table 1. Qualitative morphological grading of cytotoxicity of extracts Reactivity grades for agar and filter diffusion test and direct contact test

Grade	Reactivity	Conditions of cell 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 intra cytoplasmatic granules, no extensive cell lysis; not 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 completely 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	Fading zone limited to area under specimen
3	Moderate	Fading zone extending specimen size up to 1,0 cm
4	Severe	Fading zone extending farther than 1,0 cm beyond specimen

Score and determinant according to ISO 10993-5 (2009): Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity. The achievement of a numerical grade greater than 2, based on Tables 1 and 2 is considered a cytotoxic effect.

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To be continued

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6. Results:

The results of qualitative evaluation for cytotoxicity show as Table 3.

Table 3. The results of cytotoxicity test

Group	Morphology grade	Reactivity grade	Cells response grade (morphology / reactivity)
Test article	0	0	0/0
	0	0	0/0
	0	0	0/0
Negative control	0	0	0/0
	0	0	0/0
	0	0	0/0
Positive control	4	4	4/4
	4	4	4/4
	4	4	4/4

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 “ZENGHERB(Armpit deodorant)” has a score of 0/0 and has no potential cytotoxicity.

*Test Item is subcontracted on INTERTEK accreditation laboratory

Date Sample Received：Nov 29,2021
Testing Period：Nov 29,2021 To Jan 05, 2022

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End of report

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