

TEST REPORT

No. of Report: CALT/BG2022A(I)1005-2

草本腋窝除臭霜

Name of Sample:

HERBAL

ARMPIT DEODORANT

CREAM

Item Tested:

Animal irritation test by skin exposure

(Single-exposure test)

Test Base:

Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23:2021. 7.2

Animal irritation test by skin exposure (Single-exposure test)

GUANGZHOU CHN-ALTERNATIVE BIOTECHNOLOGY Co.,Ltd.



TEST REPORT

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华代生物
CALT-BIO

Add.: Room 902 Room 704 Building B3, No.11 Kaiyuan Avenue, Huangpu District, Guangzhou, Guangdong Province, China

Tel: (020) 82510567 Fax: (020) 82510525

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Name of Sample	草本腋窝除臭霜 HERBAL ARMPIT DEODORANT CREAM		
Sample No.	2023A(I)1005	Test Type	Commission Test
Sample Source	Deliver from applicant	Contact	020-82510567
Sample Quantity	3 Bottles	Specification&Batch	/& HD2309
State and Characteristic	Yellow-brown Liquid	Received Date	26 th September, 2023
Detection Date	17 th October, 2023	Completion Date	20 th October, 2023
Applicant	Guangzhou Great Healthcare co.,Ltd		
Address	206, Building 3, No.6, Jiapin Third Street, Shatou Street, Panyu District, Guangzhou		
Test Address	Room 906 Building B3, No.11 Kaiyuan Avenue, Huangpu District, Guangzhou, Guangdong Province		
Item Tested	Animal irritation test by skin exposure (Single-exposure test)		
Method	Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23:2021. 7.2 Animal irritation test by skin exposure (Single-exposure test)		
Conclusion	Negligible		
Date for Reporting	22 nd October, 2023 (Official Seal)		

Remarks

Editor

Date

Verifier

Date

Approver

Date



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Appendix:

1. Basic sample information

Sample Name:	草本腋窝除臭霜	L/N:	
	HERBAL ARMPITDEO DORANT CREAM		HD2309
Chemical Name:	/	Physical state:	Liquid
CAS No.:	/	Colour:	Yellow-brown
INCI name:	/	Purity:	/
Product name:	/	Storage Conditions:	RT
Relative molecular weight:	/	Stability:	/
Molecular formula:	/	Production Date:	SEP-2023
Manufacture:	/	Valid period:	/
Manufacturer address:	/		

Note: "/" means this item is not applicable

1.1 Test article: The samples were extracted with 0.9% NaCl (polar extraction medium) and corn oil (non-polar extraction medium) at 0.2 g/mL in a water bath at (37±1) °C for (72±2) h to prepare an extract as the test article.

1.2 Sample photo:





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2. Control group information

Selfblank control

3. Laboratory animals and environment

3.1 General animal room: Laboratory animal use license number: SYXK (粤) 2023-0310.

3.2 Animal species: General New Zealand Rabbit, Animal certificate number: 44411600013385.

3.3 Animal source: Guangdong Medical Laboratory Animal Center (Sanshui Base): SCXK (粤) 2019-0035.

3.4 Environment: Temperature: 18-25°C, Relative humidity(%): 40-70%.

4. Test procedure

4.1 24h before the test, remove the hairs on both sides of the spine of the experimental animal without damaging the skin. The hair removal range is about 10cm×15cm, divided into 4 parts.

4.2 Apply 0.5 mL of the test substance extract to the two test parts, cover it with 2 layers of gauze (2.5cm×2.5cm), and use the other two parts as self-control. Then use a bandage (semi-closed or closed) to fix it. After the application time is at least 4 hours, mark the contact area with permanent ink, and remove the residual test substance with water or non-irritating solvent.

4.3 Result evaluation: In a single contact test, record the conditions of each contact position after removing the patch for (1±0.1)h, (24±2)h, (48±2)h and (72±2)h. If there is permanent damage, it is necessary to extend the observation time to evaluate the reversibility and irreversibility of this damage, but the extension period should not exceed 14 days.

Table 1. Primary or cumulative irritation index categories in arabbit

Mean score	Response category
0~0.4	Negligible
0.5~ 1.9	Slight
2.0~ 4.9	Moderate
5.0 ~8.0	Severe



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5. Result

5.1 Test results with 0.9% NaCl (polar extraction medium) as the control

Animal	Group		1h		24h		48h		72h	
			erythema	edema	erythema	edema	erythema	edema	erythema	edema
2b1 (♂) 2.3 Kg	Test article	upper left	0	0	0	0	0	0	0	0
		lower right	0	0	0	0	0	0	0	0
	Control	lower left	0	0	0	0	0	0	0	0
		upper right	0	0	0	0	0	0	0	0
2b2 (♀) 2.0 Kg	Test article	upper left	0	0	0	0	0	0	0	0
		lower right	0	0	0	0	0	0	0	0
	Control	lower left	0	0	0	0	0	0	0	0
		upper right	0	0	0	0	0	0	0	0
2b3 (♂) 2.1Kg	Test article	upper left	0	0	0	0	0	0	0	0
		lower right	0	0	0	0	0	0	0	0
	Control	lower left	0	0	0	0	0	0	0	0
		upper right	0	0	0	0	0	0	0	0
Primary irritation index			0							

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6. Conclusion

According to Biological evaluation of medical devices-Part 23: Tests for irritation ISO 10993-23:2021. 7.2 Animal irritation test by skin exposure (Single-exposure test), under this test condition, the TA "草本腋窝除臭霜 HERBAL ARMPIT DEODORANT CREAM" is predicted as Negligible.

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