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苏州大学
卫生与环境技术研究所
最终报告

报告编号: SDWH-M201801609-3

参照 ISO 10993-10:2010 方法进行

医疗卫生用非织造布

的皮肤致敏试验

豚鼠最大限度法

芝麻油浸提

委托单位

常州锦欣达纤维新材料有限公司

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目 录

检测报告说明

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二、检测报告涂改或无检验检测专用章无效。

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试验确认与签名

试验样品	
接样日期：	2018- 05-30
试验计划书编号：	SDWH- PROTOCOL- GLP-M201801609-3
试验计划书生效日期：	2018- 06-11
试验操作开始日期：	2018- 06-12
试验操作结束日期：	2018- 07-12
报告完成日期：	2018- 07-19

编制：唐亚楠　　　　2018-07-19 日期

审核：王巧雁　　　　2018-07-19 日期

试验负责人

签发：许军　　　　2018-07-23 日期

授权签字人

苏州大学卫生与环境技术研究所

质量控制声明

试验过程恪守美国食品药品监督局《非临床研究实验室的良好实验室规范》21 CFR 58 部分。

豁免执行的条款为：21 CFR 条款 58.105 和 58.113，样品鉴定和样品与载体的混合物的稳定性。

质量办公室负责监督试验过程，监督日期见下表，并报告试验负责人和 SDWH 管理层。

监督	监督日期	数据报告试验负责人	数据报告 SDWH 管理层
试验过程	2018-06-19	2018-06-19	2018-07-19
原始数据	2018-07-19	2018-07-19	2018-07-19
最终报告	2018-07-19	2018-07-19	2018-07-19

质量办公室：周杰 2018-07-19

QA 日期

1.0 摘　　要

试验样品采用豚鼠最大限度试验，评价其潜在的皮肤致敏反应，以芝麻油浸提样品。

将试验样品浸提液皮内注射 10 只豚鼠，包扎并试图诱发致敏，5 只对照动物使用溶剂同法操作。恢复期内，10 只受试豚鼠和 5 只对照豚鼠采用样品浸提液进行激发试验。

在本次试验条件下，试验样品浸提液在豚鼠皮肤未发现皮肤致敏反应，致敏阳性率为 0%。

2.0 目　　的

采用豚鼠最大限度试验，评价样品的皮肤致敏反应。该试验系统用豚鼠来检测表面接触引起的接触性致敏反应，并类推到人类，但试验结果并不代表样品真正的致敏危险性。

3.0 参考标准

医疗器械的生物学评价第 10 部分 刺激与皮肤致敏试验 ISO 10993-10:2010
医疗器械的生物学评价第 12 部分 样品制备和参照样品 ISO 10993-12:2012
医疗器械的生物学评价第 2 部分 动物保护要求 ISO 10993-2:2006

4.0 执行规范

美国食品药品监督局《非临床研究实验室的良好实验室规范》21 CFR 58 部分

ISO/IEC 17025:2005《检测和校准实验室能力的通用要求》CNAS-CL01 检测和校准实验室能力认可准则 (中国合格评定国家认可委员会 实验室认可证书 No.CNAS L2954)

检验检测机构资质认定评审准则 (中国国家认证认可监督管理委员会 资质认定 中国检验机构和实验室强制性批准 CMA 180015144061)

5.0 对照和试验样品确定

5.1 试验样品

样品名称：医疗卫生用非织造布
来样原始状态：未灭菌
CAS 编号：未提供
型号：未提供
规格：双 S 亲水无纺布
批号：JXD2018005
样品材料：无纺布
包装材质：未提供
性状：固体
颜色：白色
密度：未提供
稳定性：未提供
溶解度：未提供
保存条件：室温

试验样品信息是由样品委托单位提供。委托单位负责遵守 GLP 试验有关样品的相关规定。

5.2 对照样品

5.2.1 阴性对照

样品名称：芝麻油（SO）

制造商：吉安市绿源天然香料油提炼厂

规格：25kg

批号：20180523

性状：油状液体

颜色：淡黄色

保存条件：室温

5.2.2 阳性对照

样品名称：2,4-二硝基氯苯（DNCB）

制造商：Xiya Reagent^{R}

规格：100g

批号：W5656

诱导浓度：0.5%

激发浓度：0.1%

溶剂：芝麻油

配制日期：2018-06-19

性状：液体

颜色：浅黄色

保存条件：室温

6.0 试验系统鉴别

种属：哈特兰豚鼠（天竺鼠）

数量：15（试验组 10 只、对照组 5 只）

性别：雄性

试验初体重：300～500g

健康状况：健康未使用过的动物

饲养：豚鼠按组饲养在笼子内，做好标识编号、试验代号、试验开始日期等信息

动物鉴别：苦味酸染色

笼子：塑料笼子

适应期：在实验环境下 7 天

7.0 饲养和护理

动物来源：苏州高新区镇湖实验动物科技有限公司 SCXK（苏）2015-0007

垫料：玉米芯垫料,苏州双狮实验动物饲料科技有限公司

饲料：实验豚鼠全价颗粒饲料, 苏州高新区镇湖实验动物科技有限公司

水：自来水（符合GB 5749-2006卫生标准）

室温：18-26℃

相对湿度：30%-70%

光照:每天需要 12 小时光照，全光谱日光灯

人员：检测人员有相应检测资质

选择：选择健康未使用过的动物

食物、水、垫料中无干扰试验数据污染物存在

8.0 试验系统确认

白色豚鼠历史上曾用于致敏研究（Magnusson 和 Kligman，1970）。在该类试验研究中，豚鼠被认为是最敏感的动物模型。该试验采用 2,4-二硝基氯苯（DNCB）作为豚鼠致敏物已经在苏州大学卫生与环境技术研究所得到试验证实。

9.0 给药途径确认

试验样品通过浸提液（用一种与试验系统相容的载体浸提）与试验系统接触，被认为是最佳给药途径。

10.0 试验设计

10.1 样品制备

皮内诱导阶段 I：

无菌操作取样		惰性容器内无菌震荡浸提			最终浸提液	
取样方式	实际取样	浸提比例	芝麻油	条件	pH	是否澄清
随机取样	表面积 120cm^2	6cm^2 : 1ml	20.0ml	37℃，72h	5.5	澄清

局部诱导阶段 II：

无菌操作取样		惰性容器内无菌震荡浸提			最终浸提液	
取样方式	实际取样	浸提比例	芝麻油	条件	pH	是否澄清
随机取样	表面积 120cm^2	6cm^2 : 1ml	20.0ml	37℃，72h	5.5	澄清

激发阶段：

无菌操作取样		惰性容器内无菌震荡浸提			最终浸提液	
取样方式	实际取样	浸提比例	芝麻油	条件	pH	是否澄清
随机取样	表面积 120cm^2	6cm^2 : 1ml	20.0ml	37℃，72h	5.5	澄清

浸提前后浸提液状态未发生改变。浸提完成后 4℃保存，24h 内用于测试。浸提液 pH 值未经调整，未经过滤，离心，稀释等处理过程。不加供试品，同条件制备对照液。

10.2 仪器设备

卧式大容量恒温振荡器（SDWH897），校正有效期（2019-05-15）
压力蒸汽灭菌器（SDWH2097），校正有效期（2018-11-12）
钢直尺（SDWH463），校正有效期（2018-09-10）
电子秤（SDWH442），校正有效期（2019-05-15）

10.3 试　　剂

弗氏完全佐剂
　制造商：SIGMA
　批号：SLBV0593
十二烷基硫酸钠
　制造商：国药集团化学试剂有限公司

批号：20150113
使用浓度：10%
溶剂：蒸馏水
配制日期：2018-03-01

10.4 皮内诱导阶段 I

按图 1 所示(A、B 和 C)，在每只动物去毛的肩胛骨内侧部位成对皮内注射 0.1mL。
部位 A：弗氏完全佐剂与选定的溶剂以 50:50（V/V）比例混合的稳定性乳化剂。
部位 B：注射试验样品（未经稀释的浸提液）；对照组动物仅注射相应溶剂。
部位 C：试验样品（部位 B 中采用的浓度），以 50:50 的体积比例与弗氏完全佐剂与溶剂（50%）配制成的乳化剂混合后进行皮内注射；对照组动物注射对照液与佐剂配制成的乳化剂。

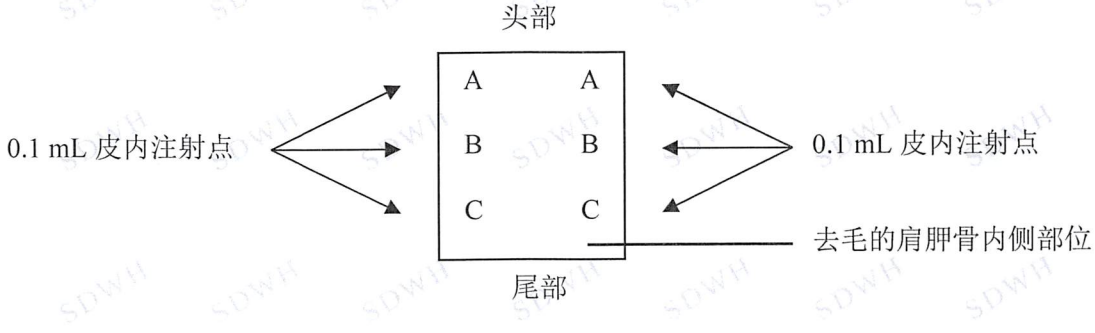

图 1 皮内注射点

10.5 局部诱导阶段 II

按注射部位B的最大浓度未产生刺激反应，在局部敷贴应用前24±2h，试验区用10%十二烷基硫酸钠进行预处理，按摩导入皮肤。

皮内注射后 7d，将约 8cm^2 大小的吸收性纱布块用 0.5ml 供试品浸提液浸透后局部贴敷于每个动物的肩胛骨内侧部位，覆盖诱导注射点。用封闭式包扎带固定样品，并于 48±2h 后除去包扎带和样品。

对照组动物使用对照液同法操作。

10.6 激发阶段

于局部诱导后 14d，用试验样品对全部试验组动物和对照组动物进行激发。用 0.5ml 供试品浸提液和对照液浸透后的 2.5cm×2.5cm 大小吸收性纱布块分别局部贴敷于诱导阶段未试验部位，用封闭式包扎带固定，并于 24±2h 后除去包扎带和贴敷片。

10.7 结果观察

除去样品后 24±2h 和 48±2h，分别观察供试品组和对照组动物激发部位皮肤情况，在全光谱光线下观察皮肤反应。按表 1 Magnusson 和 Kligman 分级标准对每一激发部位和每一观察时间皮肤红斑和水肿反应进行描述并分级。

10.8 结果评价

按表 1 Magnusson 和 Kligman 分级标准，如果对照组动物等级小于 1，而试验组中等级大于或等

于 1 时一般提示致敏。

如对照组动物等级大于或等于 1 时，试验组动物反应超过对照组中最严重的反应则认为致敏。

如为疑似反应，推荐进行再激发以确认首次激发结果。

试验结果显示为试验和对照动物中的阳性激发结果的发生率。

表 1　Magnusson 和 Kligman 分级

贴敷试验反应	等级
无明显改变	0
散发性或斑点状红斑	1
中度融合性红斑	2
重度红斑和水肿	3

10.9 结　　果

激发后皮肤反应结果列于表 2。

10.10 结　　论

在本试验条件下，样品医疗卫生用非织造布的浸提液未见对豚鼠引起皮肤致敏反应的证据。

11.0 记录存储

所有与本次试验有关的原始数据和记录都被保存在指定的 SDWH 档案文件中。

12.0 保密协议

签订检测委托合同即认为双方接受保密协议。

13.0 试验偏离声明

本次试验严格按照方案执行，未发生影响实验数据有效性的偏离。

表 2　豚鼠致敏皮肤反应

分组	动物编号	阶段 II 局部敷贴应用前 24±2h		激发斑贴移去后 24±2 h		激发斑贴移去后 48±2 h		激发后阳性发生率
		左	右	试验部位	对照部位	试验部位	对照部位	
试验组	1	0	0	0	0	0	0	0%
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	
阴性对照组	11	0	0	0	0	0	0	—
	12	0	0	0	0	0	0	
	13	0	0	0	0	0	0	
	14	0	0	0	0	0	0	
	15	0	0	0	0	0	0	

表 3 豚鼠临床观察和体重变化

分组	动物编号	体重（g）		皮肤反应外的临床表现
		初体重	终体重	
试验组	1	311	377	正常
	2	318	385	正常
	3	339	419	正常
	4	319	389	正常
	5	347	432	正常
	6	306	369	正常
	7	330	402	正常
	8	323	394	正常
	9	325	398	正常
	10	319	388	正常
阴性对照组	11	323	396	正常
	12	302	361	正常
	13	327	400	正常
	14	345	425	正常
	15	355	444	正常

表 4 阳性对照致敏皮肤反应

分组	动物编号	阶段Ⅱ局部敷贴应用前 24±2h		激发斑贴移去后 24±2 h		激发斑贴移去后 48±2 h		激发后阳性发生率
		左	右	试验部位	对照部位	试验部位	对照部位	
阳性对照组	1	3	3	2	0	2	0	100%
	2	3	3	2	0	2	0	
	3	3	3	2	0	1	0	
	4	3	3	2	0	2	0	
	5	3	3	1	0	1	0	
阴性对照组	6	0	0	0	0	0	0	—
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	

注：阳性对照引用 SDWH- M201801772-2（完成日期：2018-07-12）

表 5 阳性对照豚鼠临床观察和体重变化

分组	动物编号	体重（g）		皮肤反应外的临床表现
		初体重	终体重	
阳性对照组	1	351	434	正常
	2	315	386	正常
	3	317	385	正常
	4	318	387	正常
	5	307	371	正常
阴性对照组	6	327	403	正常
	7	334	411	正常
	8	317	383	正常
	9	353	436	正常
	10	318	389	正常

注：阳性对照引用 SDWH- M201801772-2（完成日期：2018-07-12）

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Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH-M201801609-3

Skin Sensitization Test of
Non-woven Medical And Hygiene Fabric
Using ISO 10993-10:2010 Test Methods
Guinea Pig Maximization Test
Sesame oil Extract

Sponsor
Jinxinda Textile Technology (Changzhou) Co.,Ltd.

Manufacturer
Jinxinda Textile Technology (Changzhou) Co.,Ltd.

Sanitation & Environment Technology Institute, Soochow University
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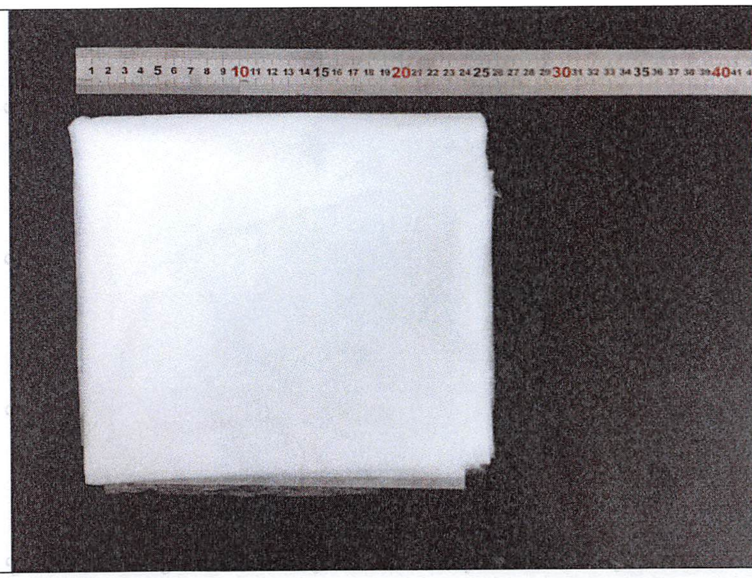
SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days of receiving the report if there are any objections.
2. Any erasure or without special inspection and testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2018- 05-30
Protocol No:	SDWH- PROTOCOL- GLP-M201801609-3
Protocol Effective Date:	2018- 06-11
Technical Initiation Date:	2018- 06-12
Technical Completion Date:	2018- 07-12
Final Report Completion Date:	2018- 07-19

Edited by : Fang Yanan   2018-07-19
Date

Checked by : Zhang Yan   2018-07-19
Study Director   Date

Approved by : Pang Songji   2018-07-23
Authorized signatory   Date

Sanitation & Environment Technology Institute, Soochow University

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of SDWH, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to SDWH's Management.

INSPECTIONS	DATE OF INSPECTION	DATE REPORTED STUDY DIRECTOR	DATE REPORTED MANAGEMENT
EXPERIMENTAL PROCEDURE	2018-06-19	2018-06-19	2018-07-19
RAW DATA	2018-07-19	2018-07-19	2018-07-19
FINAL REPORT	2018-07-19	2018-07-19	2018-07-19

Quality Assurance Unit : Zhou Ying / QA　　2018-07-19 / Date

1.0 Study Summary

The extract of the test article Non-woven Medical And Hygiene Fabric (extraction in Sesame oil) was evaluated for its potential to induce skin sensitization in the Guinea Pig Maximization Test.
The test article extract was intradermally injected and applied topically for induction to ten guinea pigs. Five control animals were treated accordingly but with the solvent alone. The topical challenge with the test article extract elicited no skin reaction in the test and in the control animals. The skin sensitization rate was determined with 0%.
As defined by the scoring system of Magnusson and Kligman the test article extract showed no signification evidence of causing skin sensitization in the guinea pig under the conditions of this study.

2.0Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

3.0Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

4.0Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58
ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)
China National Accreditation Service for Conformity Assessment
Laboratory Accreditation Certificate No.CNAS L2954
Accreditation Criteria for the competence of Inspection Body (Certification and Accreditation Admin istration of the People's Republic of China CMA 180015144061)

5.0Identification of test and control articles

5.1 Test article

Test article name: Non-woven Medical And Hygiene Fabric
Test article initial state: Not Sterilized

CAS Code: Not supplied by sponsor (N/S)
Model: N/S
Size: double S hydrophilic non-woven fabric
Lot/ Batch: JXD2018005
Test Article Material: Non Woven Fabric
Packaging Material: N/S
Physical State: Solid
Color: white
Density: N/S
Stability: N/S
Solubility: N/S
Storage Condition: Room Temperature
The information about the test article was supplied by the sponsor wherever applicable.
The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

5.2 Control article

5.2.1 Negative Control

Article Name: Sesame oil (SO).
Manufacturer: Ji'an luyuanxiangliao. Co. Ltd
Size: 25kg
Lot/ Batch#: 20180523
Physical State: Oily liquid
Color: Pale yellow
Storage Condition: Room Temperature

5.2.2Positive Control

Article Name: 2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer: Xiya Reagent^{R}
Size: 100g
Lot/ Batch#: W5656
Induction Concentration: 0.5%
Challenge Concentration: 0.1%
Solvent: Sesame oil
Date prepared: 2018-06-19
Physical State: Liquid
Color: light yellow
Storage Condition: Room Temperature

6.0Identification of test system

Species: Hartley Guinea Pig (Cavia Porcellus)
Number: 15 (10 Test +5 Negative Control)
Sex: males
Initial body weight: 300～500g

Health status: Healthy, not previously used in other experimental procedures
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date, etc
Animal identification: Stain with picric acid
Cages: Plastic cage
Acclimation Period: 7 days under the same conditions as for the actual test

7.0Animal Care and Maintenance

Animal purchase: Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: Corncob, Suzhou shuangshi laboratory animal feed science Co.,Ltd
Feed: Guinea Pig Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26℃
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained
Selection: Only healthy, previously unused animals were selected
There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data

8.0Justification of the test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 2, 4-Dinitrochlorobenzene (DNCB) has been substantiated at SDWH.

9.0Route of administration

The test article was extracted and administered in vivo through a medium compatible with the test system. Dermal application corresponds to the likely route of human exposure.

10.0Experiment design

10.1 Sample and Control Preparation

Intradermal induction phase Ⅰ:

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	sesame oil	Condition	pH	Clear or Not

Random	Surface area 120cm^2	6cm^2 : 1ml	20.0ml	37℃, 72h	5.5	Clear

Topical induction phase II :

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	sesame oil	Condition	pH	Clear or Not
Random	Surface area 120cm^2	6cm^2 : 1ml	20.0ml	37℃, 72h	5.5	Clear

Challenge phase:

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	sesame oil	Condition	pH	Clear or Not
Random	Surface area 120cm^2	6cm^2 : 1ml	20.0ml	37℃, 72h	5.5	Clear

There is no change in the extraction solvent (pre- and post-extraction). The extract was stored at 4℃ and tested within 24h after extraction without the process of pH value adjustment, filtering, centrifugation, dilution, etc.

The vehicle (without the test article) was similarly prepared to serve as the control.

10.2 Equipment

Horizontal Large Capacity Constant Temperature Vibrator (SDWH897), Calibration Expire (2019-05-15)

Autoclave (SDWH2097), Calibration Expire (2018-11-12)

Steel Straight Scale (SDWH463) ,Calibration Expire（2018-09-10）

Electronic scale (SDWH442) ,Calibration Expire（2019-05-15）

10.3 Reagents

Freund's Adjuvant,Complete liquid

Manufacturer: SIGMA

Lot No: SLBV0593

Sodium dodecyl sulfate (SDS)

Manufacturer: Sinopharm Chemical Reagent Co.Ltd

Lot No: 20150113

Concentration: 10%

Solvent: Distilled water

Date prepared: 2018-03-01

10.4 Intradermal induction phase I

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%); the control animals were injected with an emulsion of the blank liquid with adjuvant.

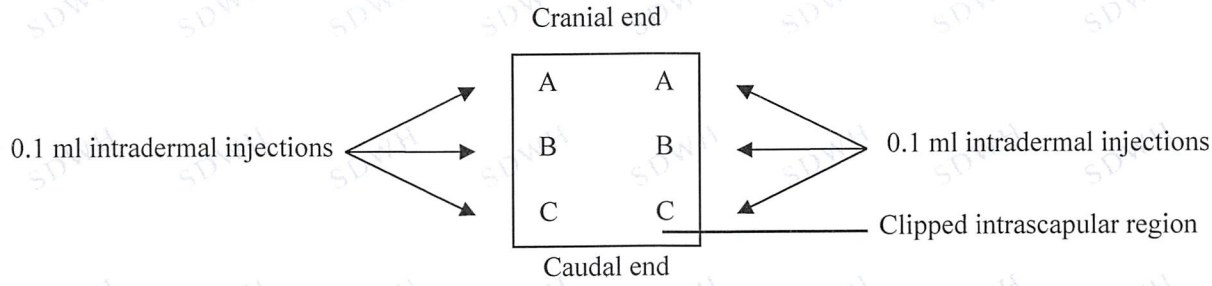


Figure 1 Location of intradermal injection sites

10.5 Topical induction phase Ⅱ

The maximum concentration that can be achieved in Intradermal induction phase Ⅰ did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.
At 7 d after completion of the intradermal induction phase, administer 0.5ml test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.
Treat the control animals similarly, using the blank liquid alone.

10.6 Challenge phase

At 14 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer 0.5ml test article extract by topical application to sites that were not treated during the induction stage, using absorbent gauze (2.5cm×2.5cm) soaked in the test article extract. Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

10.7 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2)h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval.

10.8 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.
If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

10.9 Results

Individual results of dermal scoring for the challenge appear in Table 2.

10.10 Conclusion

Under the conditions of this study, the test article Non-woven Medical And Hygiene Fabric extract showed no significant evidence of causing skin sensitization in the guinea pig.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

13.0 Deviation statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Table 2 Guinea pig Sensitization Dermal Reactions

Group	Animal Number	24±2h before phase II patch application		24±2 h following Challenge phase		48±2 h following Challenge phase		Positive rate after challenge phase
		Left	Right	Test sites	Control sites	Test sites	Control sites	
Test Group	1	0	0	0	0	0	0	0%
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	
Negative control	11	0	0	0	0	0	0	—
	12	0	0	0	0	0	0	
	13	0	0	0	0	0	0	
	14	0	0	0	0	0	0	
	15	0	0	0	0	0	0	

Table 3 Weigh change and Clinical observation

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Test Group	1	311	377	Normal
	2	318	385	Normal
	3	339	419	Normal
	4	319	389	Normal
	5	347	432	Normal
	6	306	369	Normal
	7	330	402	Normal
	8	323	394	Normal
	9	325	398	Normal
	10	319	388	Normal
Negative control	11	323	396	Normal
	12	302	361	Normal
	13	327	400	Normal
	14	345	425	Normal
	15	355	444	Normal

Table 4 Guinea pig Sensitization Dermal Reactions of Positive Group

Group	Animal Number	24±2h before phase II patch application		24±2 h following Challenge phase		48±2 h following Challenge phase		Positive rate after challenge phase
		Left	Right	Test sites	Control sites	Test sites	Control sites	
Positive Group	1	3	3	2	0	2	0	100%
	2	3	3	2	0	2	0	
	3	3	3	2	0	1	0	
	4	3	3	2	0	2	0	
	5	3	3	1	0	1	0	
Negative control	6	0	0	0	0	0	0	—
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	

Note: The data of positive control come from SDWH-M201801772-2(Completed Date: 2018-07-12)

Table 5 Weigh change and Clinical observation of Positive Group

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Positive Group	1	351	434	Normal
	2	315	386	Normal
	3	317	385	Normal
	4	318	387	Normal
	5	307	371	Normal
Negative control	6	327	403	Normal
	7	334	411	Normal
	8	317	383	Normal
	9	353	436	Normal
	10	318	389	Normal

Note: The data of positive control come from SDWH-M201801772-2(Completed Date: 2018-07-12)