食品實驗室-高雄
FOOD LAB-KAOHSIUNG
測 試 報 告
Test Report

FORMOSA PLASTICS CORPORATION
No. 100, Shui-Guan Rd., Ren-Wu Dist.,
Kaohsiung City 814, Taiwan R.O.C.

Report No. : VA/2017/11767A-03
Page : 1 of 13
Date : 2017/03/02

THE FOLLOWING MERCHANDISE WAS(WERE) SUBMITTED AND IDENTIFIED BY THE CLIENT AS :

PRODUCT NAME :	TAISAP
SAMPLE CONDITION:	Please refer to the photos for sample shown at the last page of this report
ITEM NO. :	--
LOT. NO.:	--
APPLICANT :	FORMOSA PLASTICS CORPORATION
MANUFACTURE DATE:	--
EXPIRY DATE:	--
TEST ITEM :	Skin Irritation Study
SAMPEL RECEIVED :	2017/01/13
TESTING DATE :	-refer to the following pages-

TESTING RESULTS : -refer to the following pages-

SGS TAIWAN LTD
Mandy Yu/ Manager
Signed for and on behalf of
SGS TAIWAN Ltd.

Link to SGS safety information platform
Contact person：Sonny Ren, Ph.D.

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Schedule

Study	White Rabbit Skin Irritation Test
Test article	TAISAP
Service No.	KL20170116
Experimental starting date	2017.02.06
Experimental completion date	2017.02.09

Test Institution

This testing item was performed by Biocompatibility Lab. of LEON Biotech. Co., Ltd.

Name	Biocompatibility Lab. of LEON Biotech. Co., Ltd.
Address	4F.-2, No.288-8, Xinya Rd., Qianzhen Dist., Kaohsiung City 806, Taiwan, R.O.C.

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Test Article Information

Name	TAISAP
Expiry Date	N/A
Lot No.	N/A
REF	N/A
Storage Condition	Room temperature
Sterilization Condition	No
Package	Plastic bag
Physical Description	N/A
Appearance Description	White powder
Category	Other
Pre-treatment	N/A

✦ **Sponsor, who provided test facility with the test article information, will take full responsibility for all the facts of it.**

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Archiving

All the study-related raw data, records, protocol and the final report will be kept in archives room of Leon Biotech. for 5 years.

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Address

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Objective

The study was performed following OECD #404 and internal document of standard operating procedure SOP-T04, to investigate the response of skin irritation of "TAISAP" on New Zealand White Rabbits.

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Test System

Species/ Strain	New Zealand White Rabbit (NZW)
Resource	Taiwan Livestock Research Institute (based on SOP-Q02)
Reason	According to OECD #404
Body weights/Age	>2 kg/ 2-12 month
Sex	Female
Numbers	3
Quarantine/ acclimation	Once animals are introduced in-house, they are subjected to quarantine and acclimatize before treatment. Animals are selected based on health status by qualified staff. (according to SOP-A02)
Animal restraint	The restraint of animals was according to internal document of standard operating procedure SOP-T00.
Identification	
Individual identification	Animals are identified by ear-marking.
Cage identification	Cages are properly labeled for identification including species/ strain, sex, in-housing date, IACUC number, animal I.D. number.
Housing condition (according to SOP-A01)	
Environment temperature	20~26℃
Humidity	30~70%
Cage and animal number	1 animals/cage
Fodder/ Supply	Lab Diet; *ad libitum*
Drinking water/ Supply	Tap water; *ad libitum*

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Material and Method

Reagent

1. 0.9% normal saline (Tai Yu Pharmaceutical Co., Ltd. Lot No. QL3003)

Test article handling

According to OECD#404, 0.5g of test article was tested directly.

Grouping

Test group	Control group
3 animals	
test article	0.9% saline

Note: The control solution and the test article are applied on different regions of the same rabbit.

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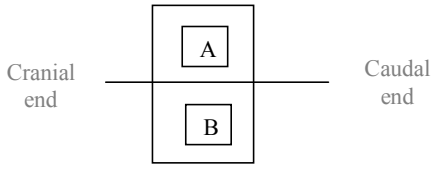
Test Method

1 Administration of test article

1.1 Prior to the test 4~24h, furs of NZW rabbit backside from scapula to middle back were clipped before test. Clipped zone are about 4cm x 6cm to exposure skin surface.

1.2 A maker pen was used to divide clipped zone into two regions (see figure below). Animals with scratches or skin diseases in the clipped zone are rejected from study.



1.3 The test article should first be applied to the gauze patch(2.5cmx2.5cm), 0.5g of test article were moistened sufficiently with 0.9% saline and applied on B sites (see figure above). In addition, A site was applied with sterile gauze (2.5cmx2.5cm) saturated with 0.5 ml of 0.9% saline for control. The application sites were wrapped with elastic and porous bandages. After 4 hours, the elastic and porous bandages and gauzes were all removed, and then the test article and control solution were washed off with distilled water.

2 Irritant reaction evaluation

2.1 The dermal reactions at the treated areas were observed and recorded at the time points of 1±0.1h, 24±2h, 48±2h and 72±2h after the gauze removed. The observation items included erythema, oedema, and other toxicity reactions.

3 Determination of dermal reaction

3.1 After a single dose treatment, the skin responses at time point of 24h, 48h and 72h were checked and evaluated, according to “Scoring system for skin reaction” described in Table 1.

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Result

1. Body weight of animals.

Animal No.	Sex	Weight before test (kg)	Weight after test (kg)
RB-160922-03	Female	3.4524	3.5550
RB-160922-10	Female	3.7058	3.7350
RB-161103-07	Female	3.5316	3.5444

2. Grades in clinical observation of individual rabbit were as below.

Applied Regions	Treated article	Sex	Animal No.	Items for Grading	Clinical Observation (time point/h)			
					1	24	48	72
Site B	Test article	F	RB-160922-03	Erythema and eschar formation	0	0	0	0
				Oedema formation	0	0	0	0
		F	RB-160922-10	Erythema and eschar formation	0	0	0	0
				Oedema formation	0	0	0	0
		F	RB-161103-07	Erythema and eschar formation	0	0	0	0
				Oedema formation	0	0	0	0
Site A	0.9% normal saline (control solution)	F	RB-160922-03	Erythema and eschar formation	0	0	0	0
				Oedema formation	0	0	0	0
		F	RB-160922-10	Erythema and eschar formation	0	0	0	0
				Oedema formation	0	0	0	0
		F	RB-161103-07	Erythema and eschar formation	0	0	0	0
				Oedema formation	0	0	0	0

F: Female

The results showed that there was no significant erythema and oedema finding in either the control or test group, and there was no mortality and significant weight loss.

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Conclusion

The results showed that there was no significant erythema and oedema finding in either the control or test group, and there was no mortality and significant weight loss. Therefore, a single topical application of "TAISAP" did not cause skin irritation.

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Table

1. Score System of Skin Reaction

Reaction	Primary Irritation Score
Erythema and eschar formation	
· No erythema	0
· Very slight erythema (barely perceptible)	1
· Well-defined erythema	2
· Moderate erythema	3
· Severe erythema (beet redness) to eschar formation preventing grading or erythema	4
Oedema formation	
· No oedema	0
· Very slight oedema (barely perceptible)	1
· Well-defined oedema (edges of area well-defined by definite raising)	2
· Moderate oedema (raised approximately 1 mm)	3
· Severe oedema (raised more than 1 mm and extending beyond exposure area)	4

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Reference

1. Acute dermal irritation/corrosion, OECD guideline for the testing of chemicals. #404 (2002) OECD.
2. Biological evaluation of medical devices- Part 2: Animal welfare requirements. ISO 10993-2:2006.
3. Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization, ISO 10993-10:2010.
4. Biological evaluation of medical devices- Part 12: Sample preparation and reference materials. ISO 10993-12:2012.

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Sample Photo

VA/2017/11767