Adhensive bra wings

(Lot No.: 8861)

Acute Dermal Irritation Study

FINAL REPORT

Client: **SING YOUNG HONG LTD.**
Testing Institution: **SGS Taiwan Ltd.**
Report No. : **UB/2013/80298A-01**
Report Date: **2013/09/24**

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3. The results shown in this test report refer only to the article(s) tested.
4. The report is the Chinese version of translations UB/2013/80298

Acute Dermal Irritation Study

Adhensive bra wings

Report No.:	UB/2013/80298A-01
Test article registration date:	2013/08/09
Experimental starting date:	2013/09/16
Experimental completion date:	2013/09/19
Animal grouping:	2013/09/13
Test article administration:	2013/09/16
Observation of dermal reaction:	2013/09/16～2013/09/19

Testing Institution

Name: SGS TAIWAN LTD.

Address: No. 38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku Dist., New Taipei City 24890, Taiwan (R. O. C.)

Subcontract Lab

Name: LEON Biotechnology Company Limited Biocompatibility Testing Laboratory

Address: 4F.-2, No. 288-8, Xinya Rd., Qianzhen Dist., Kaohsiung City 806, Taiwan (R.O.C.)

Client / Sponsor

Name: SING YOUNG HONG LTD.

Address: 5/F, NO. 26, Chin Hwa St., Taipei 10093, Taiwan, R. O. C.

TEST ARTICLE INFORMATION

INFORMATION FOR ☒ TEST ARTICLE / ☐ CONTROL ARTICLE

Sponsor Company Name	SING YOUNG HONG LTD.
Sponsor Address	5/F, NO. 26, Chin Hwa St., Taipei 10093, Taiwan, R.O.C.
Contract study item	☒ Base on the contract ☐ Others _____
Name of Test article/ Control article	Adhesive bra wings
Batch/Lot number	☐ Base on the specific number on the package : _____ ☐ Base on the date on the package : _____ ☐ Base on the arrived date ☒ Others : 8861
Specification & Amount	10 PCS/PACK (e.g.10ml / bottle * 6 bottles)
Retention amount (Note 2)	The amount of the same lot is sufficient for ☒ One test ☐ Two test (for retention)
External features	External features: ☐ liquid ☐ powder ☐ tablet ☐ capsule ☒ Other SHEET Color : TRANSPARENT
Major components & Purity	Major components: _____ Purity: _____
Solvent and solubility	N/A
Storage condition	☒ Room temperature ☐ 4℃ ☐ Dry ☐ Light sensitive ☐ Others _____
Expiration date(Note 3)	☐ Date: ____/____/____(YYYY/MM/DD) or ☒ Period : 2 year ____ month ____ day
Attachment(Note 4)	☐ Certificate of Analysis ☐ Material Safety Data Sheet ☐ Stability Test Result ☐ Other : _____ ☐ No attachment (Note4)
Sterilization	Has been sterilized ☐ YES ☒ NO (If Yes, please select the following item) Methods ☐ EOsterilization ☐ Gamma sterilization ☐ Steam sterilization ☐ Other _____
Categorization of devices (The column is only for device used)	1. ☐ Contact with intact skin or mucosa (cumulative contact duration) ☐ Short-term (no greater than 4 hr) ☐ Long-term (exceeding 4 hr) Maximum duration is _____ hrs 2. ☐ Implanted device
Specific requirement (Note 5)	N/A

Sponsor Signature/ Date : Chin Tong Chen

Note 1. Above all information is disclosure by the sponsor.
Note 2. If the sponsor doesn't provide the retention of test article/control article, the retention of a reserved test article/control article from each batch of test article /control article is the responsibility of the Sponsor.
Note 3. If the effective period is less than 5 years, the test article/control article will be retained till the expiry date. If the effective period is longer than 5 years, the test article/control article will be retained for 5 years only.
Note 4. Determination and documentation of identity, strength, purity, stability, composition, method of synthesis, fabrication, derivation or other characteristics of the test article/control article are the responsibility of the Sponsor.
Note 5. The test article/control article which has been destroyed or cutting will be discarded after the end of experiment. For retention or return of the kind of test article/control article, please indicate in the "special requirement". The human intake suggests or dose requested by the sponsor also can fill in the "special requirement". Note treatment method after test if the test article need to be retreated
Note 6. The code number of test article is the same as the report number.
Note 7. Note 'N/A' if not applicable. Do not leave blank.

版次：3.1 試驗-對照物質資料表 Information for test article-control article
發行日期：2013.06.14

SGS

SIGNATURE OF STUDY PERSONNEL

Acute Dermal Irritation Study

Adhensive bra wings

Study Director:

Howard Kao — 2013.10.17

Howard Kao / SGS Taiwan Ltd. — **Date Completed**

Deputy of Facility Manager:

Amy Liu — 2013.10.17

Amy Liu / SGS Taiwan Ltd. — **Date Completed**

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ARCHIVING

All the study-related the final report will be kept in archiving room in SGS (TAIWAN) LTD. for 3 years. Agent authorized by the sponsor can apply for review according to SGS procedure.

Archiving Room Address:

No. 38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wugu Dist., New Taipei City 24890, Taiwan (R.O.C.)

ABSTRACT

The experiment was performed following OECD #404. The furs of the animals were shaved, and the test substance should be applied to the skin. After 4 hours, the application was rinsed thoroughly by distilled water, and dermal reactions were observed at the time points of 1h, 24h, 48h and 72h thereafter.

The results showed that there was no erythema finding in treatment group, and there was no mortality and any local toxic effects. Therefore, a single topical application of “Adhensive bra wings” did not cause skin irritation.

PURPOSE

In this study, white rabbit skin irritation study is performed to evaluate the possibility of local irritant after a single topical application of test article on the skin of New Zealand White Rabbits. The experiment is performed following OECD #404.

EXPERIMENTAL DESIGN

A. Animals

1. Species/Strain	New Zealand White Rabbit
2. Resource	ANIMAL HEALTH RESEARCH INSTITUTE
3. Body weights (sex)	>2 kg (female)
4. Quarantine/acclimation	Once animals were introduced in-house, animals were subjected to quarantine and acclimation before treatment. Rabbits were selected by veterinarians based on health status.

B. Feeding and care

1. Environment	
Temperature(Humidity)	23±3°C (30~70%)
2. Cage and animal no.	
Quarantine/acclimation	1 rabbit/cage
Study period	1 rabbit/cage
3. Feed	
Name	Altromin 2023
Brand	Altromin, Germany
Way to supply	*ad libitum*
4. Drinking water	
Sort	RO Water
Way to supply	*ad libitum*

C. Individual and group identification

1. Individual identification	Animals were labeled by ear-marking.
2. Group identification	Cages were properly labeled for identification including the Study Title/No., Administration/ Observation Period, Room No., Cage No., cage, Species, Strain, Sex, In House Date, In Age, Animal ID No., Keeper and Deputy.

D. Grouping

Group	Treatment
Number of animals	3
Dose levels	0.5 g

E. Administration of test substances

1. Preparation

   Test substances are generally used directly.

2. Method, route and frequency of administration

   A single dose of test substance should be applied to the skin.

3. Volume of administration

   0.5 g of test substance was administered.

F. Procedures

1. Approximately 24 hours before the test, the furs of animal's backside are trimmed with an electric animal shaver (approximately 6 cm^2). Animals with scratches or skin diseases on the clipped skin surfaces are excluded from the study.
2. On the treatment day, 0.5 g of the test substance was applied on backsides of the animal. The test material shall be moistened sufficiently with 0.9% saline (TAI YU PHARMACEUTICAL CO., LTD.).
3. The application sites are wrapped with elastic and porous bandages.
4. After 4 hours, the test substance is removed and washed off with distilled water.

G. Animal observations and items for examination

1. Animal observations

   The dermal reactions at the treated areas are observed and recorded at the time points of 1h, 24h, 48h and 72h after the removal of the test substances, including erythema, oedema, irritation, corrosion, recovery and other toxicity. In addition to the observation of irritation, all local toxic effects, such as defatting of the skin, and any systemic adverse effects (e.g., effects on clinical signs of toxicity and body weight), should be fully described and recorded.

2. Score

   After a single dose treatment, the skin responses at time point of 1h, 24h, 48h and 72h are checked and evaluated, according to Appendix 1.

RESULTS

The dermal reactions were observed at the time points of 1h, 24h, 48h and 72h thereafter. The results showed that there was no erythema finding in treatment group, and there was no any local toxic effects and obvious weight loss in treatment group (Table 1~2; Figure1~4), and there was no mortality.

CONCLUSION

The results showed that there was no any local toxic effects in treatment group, and there was no mortality. Therefore, a single topical application of “Adhensive bra wings” did not cause skin irritation.

REFERENCES

1. Acute dermal irritation/corrosion, OECD guideline for the testing of chemicals. #404 (2002) OECD.

2. ISO 10993-10 (2010) Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity.

Table 1. Grade of clinical observation of each rabbit

Animal No.	Items for Grading	Clinical Observation (time point/h)			
		1	24	48	72
0806-SR-01	Erythema and eschar formation	0	0	0	0
	Oedema formation	0	0	0	0
0806-SR-02	Erythema and eschar formation	0	0	0	0
	Oedema formation	0	0	0	0
0806-SR-03	Erythema and eschar formation	0	0	0	0
	Oedema formation	0	0	0	0

Table 2. Bodyweight of each rabbit

Sex	Animal No.	Starting Day (kg)	Completion Day (kg)
Female	0806-SR-01	2.5	2.5
	0806-SR-02	2.6	2.7
	0806-SR-03	2.3	2.3

Figure 1. Observation at 1h after removal of the patches.

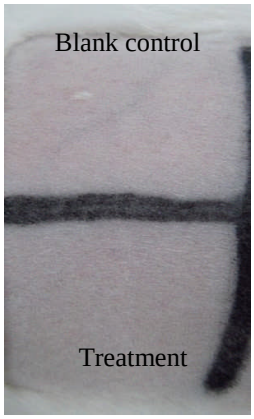

Figure 2. Observation at 24h after removal of the patches.

Figure 3. Observation at 48h after removal of the patches.

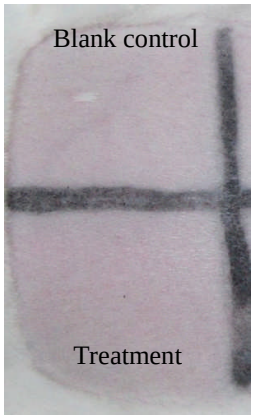

Figure 4. Observation at 72h after removal of the patches.

Appendix 1. Grading of Skin Reactions (OECD #404)

Reaction	Primary Irriation 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

TEST ARTICLE PHOTO

UB/2013/80298