PERSONAL SAFETY CORPORATION
1655 PROGRESS DRIVE, HIAWATHA, LOWA 52233, USA

The following sample was submitted and identified on behalf of the client as

Sample Description	: PVC SHEET
Sample Receiving Date	: Sep 02, 2011
Testing Period	: Sep 02, 2011to Oct 04, 2011
Test Requested	: 1) Skin Irritant 2) Skin Sensitization
Test Method	: 1-2) ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
Test Summary	: 1) The primary Irritation Index (PII) of the submitted sample is 0, no erythema and oedema. 2) The hypersensitivity scale of the submitted sample is 0, no visible change.

Signed for and on behalf of
SGS-CSTC Ltd.

Yan Lau
Approved Signatory

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1) Skin irritant test

Species: Rabbit
Strain: New Zealand Rabbit (Certificate No. 0091400)
Source: GUANGDONG MEDICAL LABORATORY ANIMAL CENTER
Sex: 3 female
Body weight range: 2.0kg-3.0kg
Number of animals: Three
Sample preparation: The submitted thin sheet sample was cut into 2.5cm×2.5cm and used in the experiment directly. (Negative control: 0.5 mL 0.9% saline solution per site)

Experimental procedure Summary:
1) Primary skin irritant
Fur was generally clipped within 24h before testing on the backs of the animals on both sides (about 10cm×15cm respectively). The submitted sample and the negative control were applied to the test sites and control sites respectively shown in Figure 1. The application sites were covered with two layers of gauze patch and a layer of cellophane, and then were wrapped with a semi-occlusive bandage for 4h. At the end of the contact time, remove all the patches, mark the sites followed by water washing. At 1h, 24h, 48h and 72h following removal of the samples, describe and score the skin reactions for erythema and oedema, determine the Primary Irritation Index (PII) and the response categories according to ISO 10993-10:2010. Results are shown in Table 3.

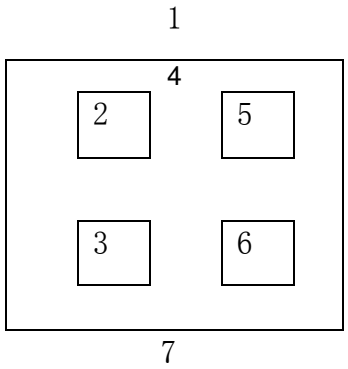

Figure 1. Applied sites on the skin
Note: 1-Head; 2-test site; 3-control site; 4-clipped region on the back; 5-control site; 6-test site; 7-tail.

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2) Cumulative skin irritant

72 hours after removal of the primary skin irritant samples, cumulative skin irritant test was directly conducted on the same sites as shown in Figure 1. The sample sheet and the negative control were applied on the test and the control sites respectively. The application sites were covered with two layers of gauze patch and a layer of cellophane, and then the application sites were wrapped with a semi-occlusive bandage for 4h. At the end of the contact time, removed all the patches, marked the sites followed by water washing. Recorded the appearances of the application site within 1 h after removal of the patches and immediately prior to the next application. The number of exposures was 14 days. From the second exposure, fur was clipped before every exposure. After the last exposure, describe the appearance of each application site at 1 h, 24 h, 48 h and 72 h following removal of the samples. For each animal, add together the Primary Irritation Scores for both erythema and oedema at each time specified. Divide this total by the total figure of observations to obtain the Irritation Score per animal. Add together the Irritation Scores of all animals and divide by the total number of animals. This value is the Cumulative Irritation Index. The Cumulative Irritation Index is compared to the categories of Irritation Response defined in Table 2 according to ISO 10993-10:2010 to obtain the Response Category.

Table 1 Scoring system for skin reaction

Skin reaction	Value
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 of 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

Table 2 Irritation Response categories in rabbit

Mean score	Response category
0~<0.4	Negligible
0.5~<1.9	Slight
2~<4.9	Moderate
5~8.0	Severe

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Test result:

Table 3 Scoring board for primary dermal irritation

Animal No.	Sex	Body weight (g)		Sample									Reference sample								
				24h			48h			72h			24h			48h			72h		
		Before test	After test	Erythema	Oedema	Score	Erythema	Oedema	Score	Erythema	Oedema	Score	Erythema	Oedema	Score	Erythema	Oedema	Score	Erythema	Oedema	Score
1	♀	2437	2493	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	♀	2359	2401	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	♀	2526	2553	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
primary dermal irritation Score								0									0				
Category															0						

Table 4 Scoring board for Cumulative Skin irritation

Date	Animal Amount	Sample			Negative Sample		
		Erythema	Oedema	Score	Erythema	Oedema	Score
1	3	0	0	0	0	0	0
2	3	0	0	0	0	0	0
3	3	0	0	0	0	0	0
4	3	0	0	0	0	0	0
5	3	0	0	0	0	0	0
6	3	0	0	0	0	0	0
7	3	0	0	0	0	0	0
8	3	0	0	0	0	0	0
9	3	0	0	0	0	0	0
10	3	0	0	0	0	0	0
11	3	0	0	0	0	0	0
12	3	0	0	0	0	0	0
13	3	0	0	0	0	0	0
14	3	0	0	0	0	0	0

Average Sore for 14 days per animal	Sample: 0	Negative Sample：0
Average Sore for per day per animal	Sample: 0	Negative Sample：0
Cumulative Score	0	0
Irritation Response categories	Negligible	Negligible

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3) Delayed-type hypersensitivity

Species: Guinea Pigs
Strain: SPF Grade Hartley Guinea Pig (Certificate No. 0091286)
Source: GUANGDONG MEDICAL LABORATORY ANIMAL CENTER
Sex: 15 Male
Body weight range: 250~300g
Number of animals: Fifteen
Sample preparation: The sample was washed with distilled water and dried with filter paper, then cut into pieces of 0.5cm×1cm, extracted by 0.9% saline solution (6 cm^2 sample / 1 mL saline solution), 37±1℃, 24h. (Negative control: 0.9% saline solution). 10 mL sample extract solution and 10 mL negative control solution were prepared.

Experimental procedure Summary:
15 Guinea Pigs were randomly divided into two groups: 5 for control group and 10 for testing group.

Induction: Clip furs from the back of guinea pig's cervix before test. Clean the fur-clipped area with 75% ethanol. Make intradermal injections into each animal at the injection sites as shown in Figure 2.

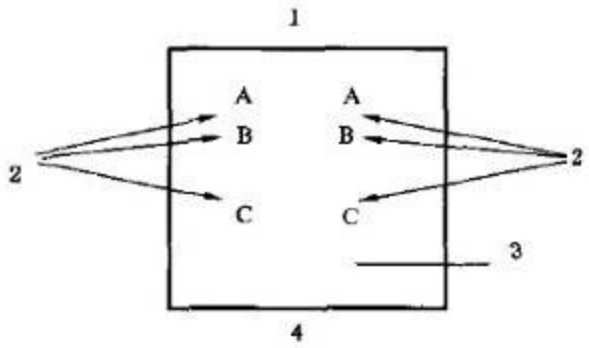

Figure 2 Intradermal injection sites

Note:
1 – Head;
2 – 0.1 mL intradermal injection sites
A – For testing group: 0.05 mL FCA (Freund's complete adjuvant) + 0.05 mL 0.9% saline solution;
For control group: 0.1 mL FCA;
B – For testing group: 0.1 mL sample extract solution;
For control group: 0.1 mL negative control solution;
C – For testing group: 0.05 mL sample extraction solution + 0.025 mL FCA + 0.025 mL saline solution;
For control group: 0.05 mL FCA + 0.05 mL negative control solution.
(Note: Use high-speed dispersion machine to facilitate liquid mixing.)
3 – Fur-clipped inner part of scapulas
4 – Tail

Seven days after injection, clip furs from the injection area again, clean with 75% ethanol. If no irritation produced, pretreat the area with 10% sodium dodecyl sulfate massaged into the skin 24h before the patch was applied. 2cm×4cm filter paper patches immerged in the sample extract solution till saturated were applied on the injection sites and secured with an occlusive dressing. Remove the dressings and patches after 48h.
Treat the control animals similarly, using the negative control solution.

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Observation: At 14 days after the above induction phase, immerge 2cm×4cm patches into the sample solution till saturated. Clip furs from untested sites of both side of the stomach as challenge sites, clean with 75% ethanol, apply the patches on the challenge sites and secure with an occlusive dressing for 24 hours. Observe the appearance of the challenge sites of testing and control groups 24h and 48h after removal of the dressing and patches. Describe and grade the skin reaction for erythema and oedema according to the Magnusson and Kligman grading given in Table 5 for each challenge site and at each time interval.

According to Magnusson and Kligman Grade Standard, provided the grade is less than 1 for the animals in control group, while the grade is bigger than 1 for the testing group, the result normally indicate sensitization. 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 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 5 — 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 swelling	3

Test result:

Table 6 Scoring board for delayed-type hypersensitivity

Group	No.	24h after remove test sample		48h after remove test sample		Grade
		erythema	**oedema**	**erythema**	**oedema**	
Test group	1	0	0	0	0	0
	3	0	0	0	0	
	4	0	0	0	0	
	5	0	0	0	0	
	8	0	0	0	0	
	9	0	0	0	0	
	11	0	0	0	0	
	12	0	0	0	0	
	13	0	0	0	0	
	14	0	0	0	0	
Control group	2	0	0	0	0	0
	6	0	0	0	0	
	7	0	0	0	0	
	10	0	0	0	0	
	15	0	0	0	0	

Remark :This test was subcontracted to qualified subcontractor.

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Sample photo:

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