

Report of analysis

National Institute of Health, Department of Medical Sciences, Ministry of Public Health
Tiwanon Road, Nonthaburi 11000, Thailand

Date of sample received: 11 Mar. 2011 Time: 02.18 PM

Date of sample transferred from: Division of Cosmetics and Hazardous Substances
14 Mar. 2011 Time: 03.30 PM

Date of analysis: 22 Mar. 2011

Sender: In the name of Bodysteel and Silver Co., Ltd.

Description of sample:

Type of sample: Enamel

Trade name: Enamel

Active ingredient: -

Manufacturer: Bodysteel and Silver Co., Ltd.

Distributor: -

Manufacturing date: - Expiry date: - Lot: -

Physical properties: Enamel coated plastic

Number of samples: 20 pieces Content: 20 pieces / bag

Purpose of analysis:

Registration Quality control Surveillance CPP Special care
 Complaint GMP Law suit Others Export

Date of report: 05 Apr. 2011

Results:

Description of sample

About 20 (grams/milliliters / litter / pieces) of (clear / opaque / thick / fine / various) (colorless / color) (solid / liquid / power / enamel coated plastics) size - (was / were) contained in (g / a sealed / an) (clear / colorless / opaque /) (cylindrical /) (plastic / zip-type plastic / glass / paper / metal / enamel coated /) (bottle / pot / case / enamel coated case / tube / casket/box / bag) (sealed / covered) with a (clear / colorless / opaque /) (plastic / metal /) (sheet / lid) and covered with a
 (clear / colorless / opaque /) (metal / plastic / rubber /)
(flip-top / cap / nozzle / pump dispenser /).

- wrapped with (plastic / paper / _____).
- (clear / colorless / opaque / _____) plastic cover.

_____ I _____ (bottle(s) / pot(s) / case(s) / enamel coated case(s) / tube(s) / casket(s) / box(es) / bag (s) / _____) (was / were) contained in (a / a sealed) (plastic / zip-type plastic / glass / paper / metal / _____) (bottle / case / enamel coated case / _____ bag _____) and fastened with (rubber band / staples / _____).

No label

The detailed on the label is

hand written printed hand written and printed

Specially controlled substance n/a _____

Controlled substance n/a _____

Active ingredient n/a _____

Manufacturer n/a _____ Bodysteel and Silver Co., Ltd.

Importer n/a _____

Distributor n/a _____

Registration number n/a _____

Batch / Lot n/a _____

Manufacturing date n/a _____ Expiry date n/a _____

Contents n/a _____ Quantity n/a _____

Sampling by _____ Sampling date _____

Primary Irritation Index (PII) = 0.0

Irritation response categories in the rabbit

Primary Irritation Index (PII)		Conclusion
Medical Devices Sample	Cosmetics Sample	
0 to 0.4	0 to 1	Negligible Irritant
0.5 to 1.9	> 1 to 2	Slight Irritant
2 to 4.9	> 2 to 5	Moderate Irritant
5 to 8	> 5 to 8	Severe Irritant

Details of test and raw data are presented in the attached documents.

Analysis identification number: 13-54-04951

LAC. Received sample number: LAC. SI 54-03-14/025

Method of analysis:

1. ISO 10993-10, 2010. Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity.
2. ISO 10993-12, 2007. Biological evaluation of medical devices-Part 12: Sample preparation and reference materials.

Conclusion:

The Test item

- did not produce skin irritation in rabbits.
- produce slight skin irritation in rabbits.
- produce moderate skin irritation in rabbits.
- produce severe skin irritation in rabbits.

M. Boonyareth (Analyst)

(Mr. Maskiet Boonyareth)

Veterinarian, Professional Level

05 Apr. 2011 (D/M/Y)

Raywadee Butraporn (Analysis Approver)

(Mrs. Raywadee Butraporn)

Veterinarian, Professional Level

05 Apr. 2011 (D/M/Y)

Laboratory Animal Center

This report certifies only the result (s) of the tested sample (s).

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DETAILS OF THE TEST AND RESPONSE DATA OF PRIMARY SKIN IRRITATION TEST

1. DETAILS OF THE TEST.

1.1 Animal: The test was made on three albino rabbits of the stock from National Laboratory Animals Center, Mahidol University. The rabbits weighed not less than 2 kg and were earmarked with permanent marker.

1.2 Housing conditions: During a pre-period of one week and throughout the experiment, the rabbits were housed individually in standard cage with perforated floor and kept in room No. AE229. The room temperature was $20\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$, the relative humidity was $55\% \pm 15\%$. Lighting was artificial, the sequence was 12 hours light, 12 hours dark.

1.3 Test conditions:

Patch materials: Four-ply gauze patches, size 25 mm x 25 mm and semi-occlusive bandage.

Preparation of test sample: () 0.5 _____ - _____ per patch

() (dissolve/dilute) sample to concentration _____ - _____% w/v with sterile (distilled water/olive oil / _____ - _____). Use 0.5 (ml/g) per patch.

() extract the test sample with sterile distilled water at $70^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ for 24 hours \pm 2 hours. Use 0.5 ml per patch.

() cut the test sample into 25 mm X 25 mm pieces.

() cut the test sample into 25 mm X 25 mm pieces. Moisten with 0.5 ml sterile distilled water.

() use the test sample of 25 mm diameter. Moisten with 0.5 ml sterile distilled water.

Controlled sample: 25 mm X 25 mm gauze patch [moisten with 0.5 (ml / g) sterile (distilled water / olive oil / _____ - _____)] per test patch.

Exposure and removal: 4 hours, then the patches were removed. Mark the test area with permanent ink and wash the test skin with lukewarm water and let dry.

2. IRRITATION RESPONSE DATA

Analysis identification number 13-54-04951

LAC. Received sample number LAC. SI 54-03-14/025

Name Enamel

Table 1: Table show irritation response data of test sample for each individual rabbit for 1 hr, 24 hr, 48 hr and 72 hr.

Rabbit				*Numerical grading of the reaction erythema and oedema following removal of the patches (hr)												PIS of rabbits				
No.	Sex	Weigh (Kg)	Site	Left test site								Right test site								
				1		24		48		72		1		24			48		72	
				E	O	E	O	E	O	E	O	E	O	E	O		E	O	E	O
D0310	F	3.01	Test	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
D0311	F	3.15	Test	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00	
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
D0312	F	3.67	Test	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00	
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

Table 2: Table show irritation response data of controlled sample for each individual rabbit for 1 hr, 24 hr, 48 hr and 72 hr.

Rabbit				*Numerical grading of the reaction erythema and oedema following removal of the patches (hr)												PIS of rabbits				
No.	Sex	Weigh (Kg)	Site	Left test site								Right test site								
				1		24		48		72		1		24			48		72	
				E	O	E	O	E	O	E	O	E	O	E	O		E	O	E	O
D0310	F	3.01	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
D0311	F	3.15	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00	
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
D0312	F	3.67	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00	
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

*, Numerical grading of the reaction 0 – 4; E, Erythema; O, Oedema; PIS, Primary Irritation Score. Only the score from the three readings (at 24, 48 and 72 hours) are included in the calculation of the individual values.

Calculations for Primary Irritation Index (PII)

$$\text{Primary Irritation Score (PIS) of test sample} = \frac{\text{Sum of the Erythema and Oedema Score of test sample}}{\text{Number of observations}}$$

$$\text{Primary Irritation Score (PIS) of control sample} = \frac{\text{Sum of the Erythema and Oedema Score of control sample}}{\text{Number of observations}}$$

Number of observations = 6

Primary Irritation Score (PIS) of each rabbit = PIS of test sample - PIS of control sample

PIS of control sample of each rabbit = 0.00, 0.00 and 0.00 respectively.

$$\text{Primary Irritation Index (PII)} = \frac{\text{Sum of PIS of each rabbits}}{\text{Number of rabbits}}$$

$$= \frac{0.00 + 0.00 + 0.00}{3}$$

$$= 0.0$$

Irritation response categories in the rabbit:

Primary Irritation Index (PII)		Conclusion
Medical Devices Sample	Cosmetics Sample	
0 to 0.4	0 to 1	Negligible Irritant
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