

Report of analysis

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

Date of sample received: 03/11/2008 Time: 14.56

Date of sample transferred from: Division of Cosmetics and Hazardous Substances
04/11/2008 Time: 15.00

Date of analysis: 11/11/2008

Sender: In the named of Scionic Co., Ltd

Description of sample:

Type of sample: Garment coat solution

Trade name: Scionic Nanosilver Solution with Binder

Active ingredient: -

Manufacturer: Scionic Co., Ltd

Distributor: -

Manufacturing date: 01/09/2008 Expiry date: 01/09/2008 Lot: -

Physical properties: Solution was filled in the glass bottle

Number of samples: 1 bottle Content: 100 grams/bottle

Purpose of analysis:

[] Registration [] Quality control [] Surveillance [] CPP [] Special care
[] Complaint [] GMP [] Law suit [] Others Irritation test

Date of report: 24/11/2008

Results:

Description of sample

About 100 (grams/milliliters / litter / -) of (clear / opaque / thick /
fine / course / -) (colorless /) (solid / liquid / power /
cream / gel / -) size - (was / were) contained in
(a / a sealed / an) (clear / colorless / opaque / -) (cylindrical / oval / -)
(plastic / zip-type plastic / glass / paper / metal / enamel coated / -) (bottle / pot / case
/ enamel coated case / tube / casket/box / -) (sealed / covered) with a
(clear / colorless / opaque / -) (plastic / metal / -) (sheet / lid) and
covered with a

[] (clear / colorless / opaque / gold color) (metal / plastic / rubber / -)
(flip-top / cap / nozzle / pump dispenser / -).

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

.....1..... (bottle / 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 Scionic Co., Ltd

Importer n/a

Distributor n/a

Registration number n/a

Batch / Lot n/a

Manufacturing date n/a 01/09/2008 **Expiry date** n/a 01/09/2009

Contents n/a 100 grams **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: 13-51-33604

Method of analysis:

1. ISO 10993-10, 2002. Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity
2. ISO 10993-12, 2002. Biological evaluation of medical devices-Part 12: Sample preparation and reference materials.

Conclusion:

The Test item

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

M Boonyareth (Analyst)
(Mr. Maskiet Boonyareth)
Veterinarian 6
24/11/2008 (D/M/Y)

Raywadee (Analysis Approver)
(Mrs. Raywadee Butraporn)
Veterinarian 7
24/11/2008 (D/M/Y)

Laboratory Animal Center

**This report certifies only the result (s) of the tested sample (s).
Modification, reproduction and advertisement of this report are prohibited.**