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TEST REPORT

REPORT NO: R206/13/B19/05	PAGE: 1 of 3
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Applicant : Trumer Medicare Sdn Bhd.
No. 16-2, Jalan SS19/1G,
47500 Subang Jaya,
Selangor.
(Mr. KC Yap)

Manufacturer / Company : -

Sample : Nano Colloidal Argentum

Method of Test : Dermal Irritection[®] Test

Description of Sample : Received one sample for testing with the following identifications:

a) Colour	: Clear
b) Shape/Form	: Liquid
c) pH	: 5.5
d) Quantity	: Approximately 100 mL

Date Received : 21 June 2013

Job No. : J206/13

Issue Date : 16 JUL 2013

Approved signatories,

**SIRIM Berhad**

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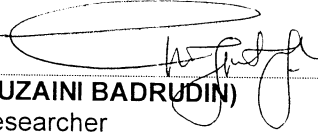
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Approved signatories,


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1.0 Test timetable

Receipt of sample : 21 June 2013
Study : 11 - 12 July 2013
Report : 16 July 2013

2.0 Test method

2.1 Study Objective

The Nano Colloidal Argentum provided by Trumer Medicare Sdn Bhd was evaluated with the Irritection® Assay System in order to predict its potential to cause dermal irritation.

To achieve this objective, a standard volume-dependent dose-response study was performed using the Dermal Irritection® assay system.

2.2 Background

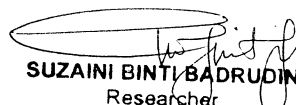
The proprietary Dermal Irritection® assay is a standardized and quantitative *in vitro* test that utilizes changes of relevant macromolecules to predict the acute dermal irritancy of chemicals and chemical formulations. This assay is based on the principle that chemical compounds that cause dermal irritation are known to induce alterations in the structure of keratin, collagen and other dermal proteins. Previous studies have clearly demonstrated that this process of conformational change that are induced in this *in vitro* assay mimic the effects that are produced when these types of irritants are applied to the skin. Consequently, this *in vitro* test may be employed to predict the *in vivo* toxic effects of chemicals and formulations.

The quantitative Dermal Irritection® *in vitro* assay has been found to be highly reproducible. Of even greater relevance, the Dermal Irritection® assay method can be readily employed to evaluate multiple samples at varying volumes or concentrations. Thus, the test serves as an extremely useful screening tool that facilitates all stages of raw material selection, formulation development and final product selection.

2.3 Materials and Methods

The Dermal Irritection® assay is a quantitative *in vitro* test method that mimics an acute dermal irritation test. The test sample was applied to a synthetic biobarrier composed of a semi-permeable membrane containing a keratin-collagen matrix coated with a dye. Following application, the sample was absorbed by and permeates through this synthetic biobarrier to gradually come into contact with a proprietary solution containing highly-ordered globulins and glycoproteins. Reaction of the test sample with these proteins and macromolecular complexes promotes conformational changes that may be readily detected as an increase in the turbidity of the protein solution. In addition, the dye that has been dissociated from the biobarrier during transit of the applied sample may be detected spectrophotometrically at a wavelength of 450 nm.

The irritancy potential of a test sample is expressed as a Human Irritancy Equivalent (HIE) score. This score is defined by comparing the increase in optical density (OD₄₅₀) produced by the test material to a standard curve that is constructed by measuring the increase in OD₄₅₀ produced by a set of Calibration substances. These Calibrators have been selected for use in this test because their irritancy potential has been previously documented in a series of *in vivo* investigations. The predicted *in vivo* classification, based on this scoring system, is shown in Table 1.


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Table 1. Relationship of Human Irritancy Equivalent (HIE) Score to Irritancy Classification for the Dermal Irritection® Test Method

Human Irritancy Equivalent (HIE) Score	Predicted Dermal Irritancy Classification
0.0 – 0.90	Non-Irritant
0.90 – 1.20	Non-Irritant / Irritant
1.20 – 5.00	Irritant

All data were calculated and analyzed via a computer program that determines assay result acceptance based upon qualification parameters defined in the program. Irritancy score that correlates most closely with the *in vivo* irritancy properties of a test article is the highest qualified score calculated by the Irritection software. This value is defined as the maximum qualified score.

A standard volume-dependent dose-response study was performed with the Dermal Irritection® test method.

3.0 Results and Discussion

Results and the predicted *in vivo* classifications analyzed via the Irritection software are shown in Table 2.

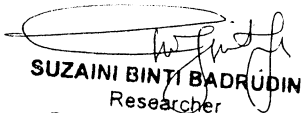
Table 2. Summary of Dermal Irritection® Results
(^a Maximum Qualified Score)

Sample Description	Volume (µL)	HIE Score	Predicted Dermal Irritancy Classification
Nano Colloidal Argentum	50	1.01	Non-Irritant/Irritant
	75	0.97	Non-Irritant/Irritant
	100	^a 1.02	Non-Irritant/Irritant
	125	1.00	Non-Irritant/Irritant

The Nano Colloidal Argentum was classified as Dermal Non-Irritant/Irritant with a HIE score of 1.02.

4.0 Conclusion

The **Nano Colloidal Argentum** was classified as **Dermal Non-Irritant/Irritant** under the condition of this test.


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