eurofins | Dermatest

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Dermal Irritection Results

Client: UNSW - Sydney

Contact: Tariq Nazir

Sample Desc: Mech Render

Date of Test: 21/10/2020

Our Ref: IR02p73-2

Client o/n:

Results:

Dose	HIE Score	Predicted Irritancy Classification
25 mg	1.21	Non-irritant/Irritant
50 mg	1.20	Irritant
75 mg	1.32	* Irritant
100 mg	1.34	Non-irritant/Irritant
125 mg	1.18	
Maximum Qualified Score: *	1.34	

Key:

Human Irritation Equivalent (HIE) Classification	Predicted Dermal Irritancy	
0.00 - 0.90	Non-Irritant	
0.91 - 1.20	Non-Irritant/Irritant	
1.21 - 5.00	Irritant	

Signed:

IR02p73- Evgenia Platarou

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Dermal Irritection Study Report

STUDY OBJECTIVE

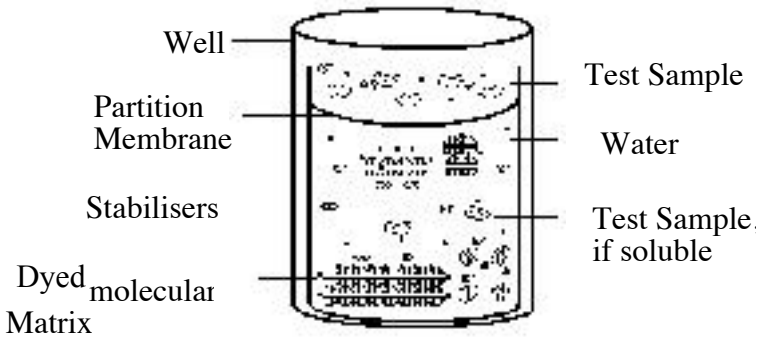
samples provided by UNSW - Sydney were evaluated with the Irritection Assay System in order to predict potential to cause irritation. The test was conducted on 21/10/2020.

To achieve this objective, a standard concentration-dependent dose-response study was performed using the Dermal Irritection test method.

BACKGROUND

The proprietary Irritection assay is a standardized and quantitative in vitro test which utilizes changes of relevant macromolecules to predict the dermal irritancy of chemicals and chemical formulations.This assay, depicted schematically in Figure 1 below, is based on the principle that chemicals that dermal irritation are known to induce alterations in the structure of keratin, collagen and other dermal proteins and will promote measurable changes in target biomolecules and macromolecular structures. Previous studies have clearly demonstrated that the processes of protein denaturation and disaggregation 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.

Figure 1. The Irritection Model



Additionally, the quantitative Irritection in vitro assay has been found to be highly reproducible. Of even greater relevance, the 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. The optical density was detected spectrophotometrically at a wavelength of 450 nm.

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MATERIALS AND METHODS

The Irritection assay is a quantitative *in vitro* test method that mimics an acute dermal irritation test. To perform this standardized assay, the test sample is applied to a synthetic biobarrier composed of a semi-permeable membrane. Following application, the sample is absorbed by and permeates through this synthetic biobarrier to gradually come into contact with a proprietary solution containing 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.

The irritancy potential of a test sample is expressed as an Human Irritancy Equivalent (HIE) score. This score is defined by comparing the changes 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.

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

Human Irritation Equivalent (HIE)	Predicted Dermal Irritancy Classification	
0.00 - 0.90	Non-Irritant	
0.91 - 1.20	Non-Irritant/Irritant	
1.21 - 5.00	Irritant	

A detailed description of the Irritection test procedure may be found in InVitro International's Irritection® Assay System Instruction Manual or at www.invitrointl.com All data are calculated and analyzed via a computer program which determines assay result acceptance based upon qualification parameters defined in the program. In general, the program has been designed to accept sample data as qualified if the following criteria are met: the OD values of Calibrators and internal Quality Control samples fall within previously specified ranges; sample blanks are less than 500 optical density (OD) units; the net sample OD is greater than -15; and an Inhibition Check is negative.