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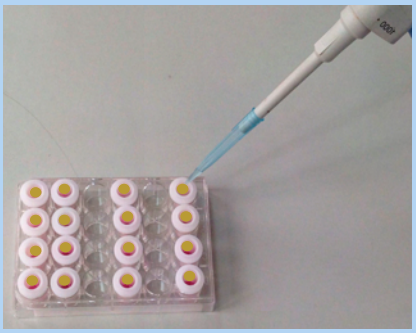
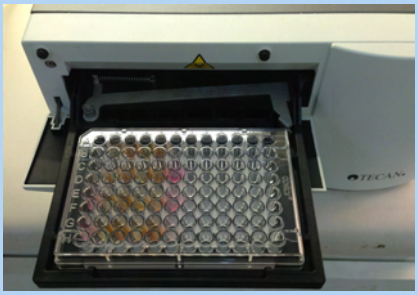
Dermal Irritection

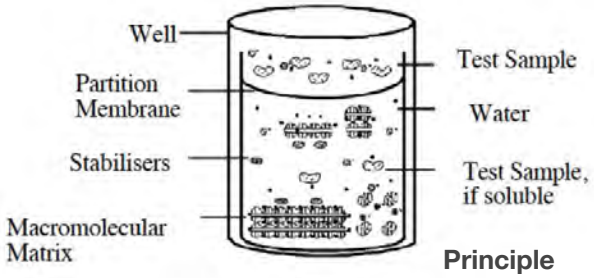
STEPS



1. Sample Preparation



2. Plate Reader



3. Reaction Cell Cross- section

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Determination of Irritancy Potential

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, loaded with dyes which also dissociate to provide colour change indicators. These 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.

Supportable Claims

- Non Animal Safety Testing.
- Low Dermal Irritation.

Principle

This in-vitro test is based on the principle that chemical compounds will promote measurable changes in target biomolecules and macromolecular structures. The proprietary Irritection assay is a standardized and quantitative in vitro test which utilizes changes of relevant macromolecules to predict the acute dermal irritancy of chemicals and chemical formulations.

Sample Preparation
The sample is serial diluted according to relevant in-use concentration.

Aliquots of these samples are mixed with reagents and positive and negative controls. All of these solutions are set up in wells which have been fitted with a partition membrane which represents the membrane of the skin.
A macromolecular matrix, composed of proteins, glycoproteins, lipids and low molecular weight components, is included in each well.

Plate Reader

After removal of the membrane and its support, turbidity of the reacted solutions is measured via a Plate Reader. More irritant substances produce greater turbidity and thus higher optical density.

Calculation of Comparative Irritancy

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 (OD470) produced by the test material to a standard curve that is constructed by measuring the increase in OD470 produced by a set of Calibration substances.

Reporting

Predicted Dermal Irritancy Classification.
0.0 - 10.90 Non Irritant
0.91- 1.20 Non Irritant/Irritant
1.21 - 5.0 Irritant

References

1. OECD TG 435

2. ISO 10993-5:2009

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Irritection - Ocular or Skin Irritation Test
Checklist for Sample Submission

1. If the sample is less than pH 2 or greater than pH 9 then it is unsuitable for the test !

3. Is the sample highly coloured in solution? If so, please advise the dye/s used as we will need to adjust the wavelength for determination.
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4. Is the sample oil based or water insoluble? If yes, we will need to solubilise it and will discuss this with you prior to running the test.
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5. Please advise if the sample contains any of the following…

Volatile ketones	No
Nonionic surfactants	No
Sorbitol > 5%	No
Urea > 5%	No
Manganese violet	No
Aluminium (chlorhydrate), (zirconium chlorhydrate) or (chloride)	No
Titanium dioxide	No
Zinc Oxide	No
Silver salts	No
Ferrous sulfate	No
Zinc sulfate	No

Company.....

Contact.....

Phone / fax/ email .....

☐ Please provide at least 20mL/gm of product

☐ Clearly identify your product name and reference number (as required on the report)

☐ Any special instructions for pre-dilution or preparation prior to testing.

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☐ Please forward the sample/s to...
Eurofins Dermatest Pty Ltd
P.O. Box 1022
Rockdale NSW Australia 2216
...or by Courier to 20 King St Rockdale