



The Irritection Assay System

**The Least Cost, Most Rapid,
Accurate, Reproducible,
Irritation Testing Method
Available Today**



The Irritation Assay System (IAS)

An *in vitro* assay that
Detects,
Predicts,
and Ranks
ocular and dermal irritation



Why Use the Irritection Assay System (IAS)?

There are numerous reasons you should use the IAS. Our clients often note saving **TIME** and **MONEY** are the most beneficial reasons.

The Irritation Assay System (IAS) Provides Results 30 Times Faster Than *In Vivo* Methods

As quickly as
5 hours



At least
2 weeks



The Irritation Assay System (IAS) Controls Costs



IAS **\$135** per sample



in vivo **\$1000** per sample

An Added Marketing Advantage



A November 1995 National Consumer Survey found that 47% said they would be “somewhat” or “much” more likely to buy a health/beauty aid that indicates it has NOT been tested on animals.

How The IAS Detects, Predicts, and Ranks



Ocular
Irritation



Dermal
Irritation



Irritation Assay System

(mimics the following biochemical phenomena)

Ocular Assay



The corneal irritancy of test materials is known to be related to their propensity to promote denaturation and disruption of corneal proteins.

Dermal Assay



Chemicals that cause dermal irritation are known to induce alterations in the structure of keratin, collagen and other dermal proteins.

There Are Two Essential Components

- Membrane Disc
- Proprietary Protein Reagent



Membrane Disc

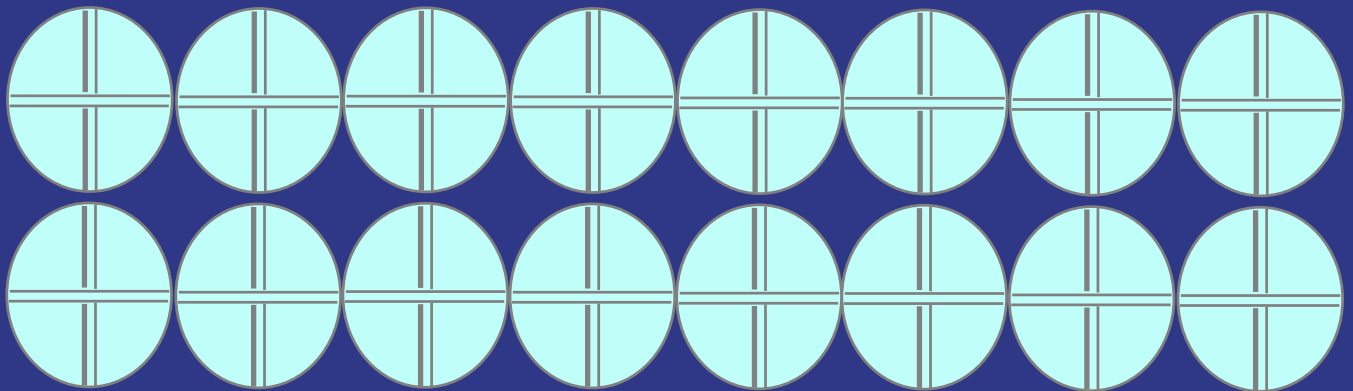
The membrane disc regulates the delivery of test materials to the reagent solution.

The Dermal disc differs from the Ocular in that it is coated with keratin and collagen mimicking the properties of the dermis.



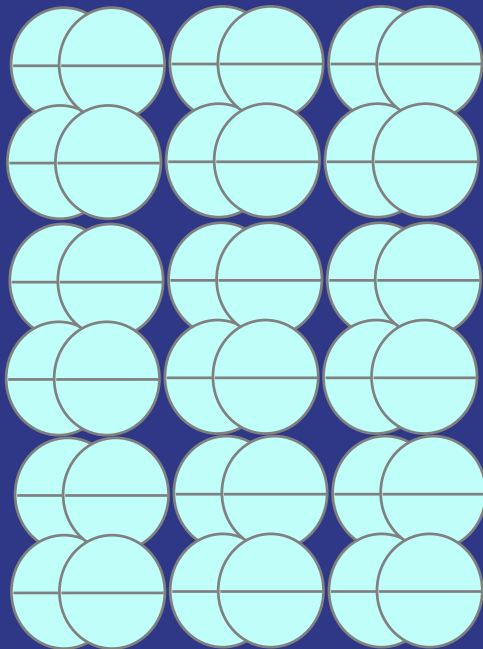
The Protein Reagent

The proprietary reagent solution is comprised of proteins, glycoproteins, lipids and low molecular weight components that self-associate, forming a complex, ordered macromolecular matrix. The Dermal reagent differs from the Ocular in that it contains additional globulins.



Complex, Ordered Macromolecular Matrix

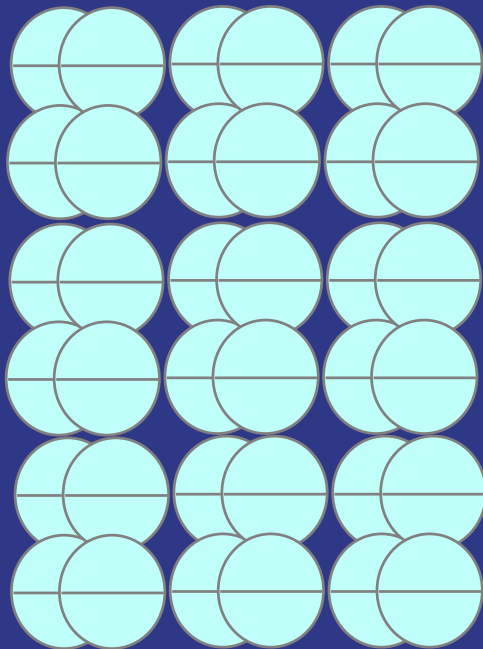
Applying irritants to the ordered
macromolecular matrix promotes
protein denaturation. . .



Ordered Macromolecular
Matrix Clear Solution



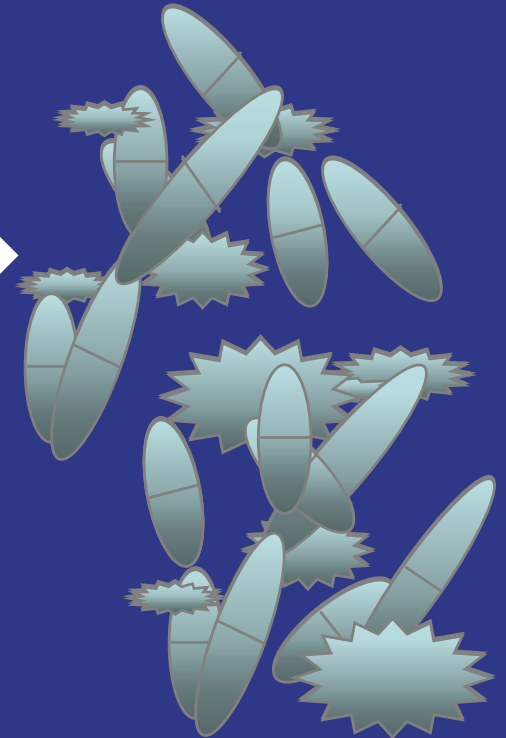
... minute, insoluble particles
(denatured proteins) begin to form. . .



Ordered Macromolecular
Matrix Clear Solution

ADD Irritant

INDUCE
Denaturation



Denatured Proteins
Disordered Matrix
Cloudy Solution

Results In 30 Seconds

These changes are rapidly quantitated by measuring the turbidity (cloudiness) of the reagent solution using a spectrophotometric plate reader.





Calculation of An “Irritancy Score”

- Plate reader measurements are compared to standard irritants, thus permitting...
- A calculation of an “irritancy score” which is...
- Directly related to the potential irritancy of the test material.



Windows[™] Irritection Software

(performs 4 important functions)

- 1) Compilation of the spectrophotometric readings;
- 2) Comparison of test sample results with standard irritants (known *in vivo* data);
- 3) Calculation of an “irritancy score” for each test sample; and...
- 4) Graphical presentation of assay results.

Example of Sample Results

Sample being tested

Sample Name	Study Conc.	Optical Density (OD)	Irritancy Score	Irritancy Classification
Industrial Cleaner	1%			
	10%			
	25%			
	50%			
	100%			

Sample analyzed at 5 concentrations/volumes

Example of Sample Results

Sample being tested

Sample Name	Study Conc.	Optical Density (OD)	Irritancy Score	Irritancy Classification
Industrial Cleaner	1%	85		
	10%	260		
	25%	700		
	50%	1100		
	100%	1999		

Sample analyzed at 5 concentrations/volumes

Measurement obtained from plate reader

Example of Sample Results

Sample being tested

Interpolated from calibration curve

Sample Name	Study Conc.	Optical Density (OD)	Irritancy Score	Irritancy Classification
Industrial Cleaner	1%	85	4.2	Minimal
	10%	260	12.6	Mild
	25%	700	25.3	Mild
	50%	1100	35.3	Moderate
	100%	1999	>51.0	Severe


Sample analyzed at 5 concentrations/volumes

Measurement obtained from plate reader

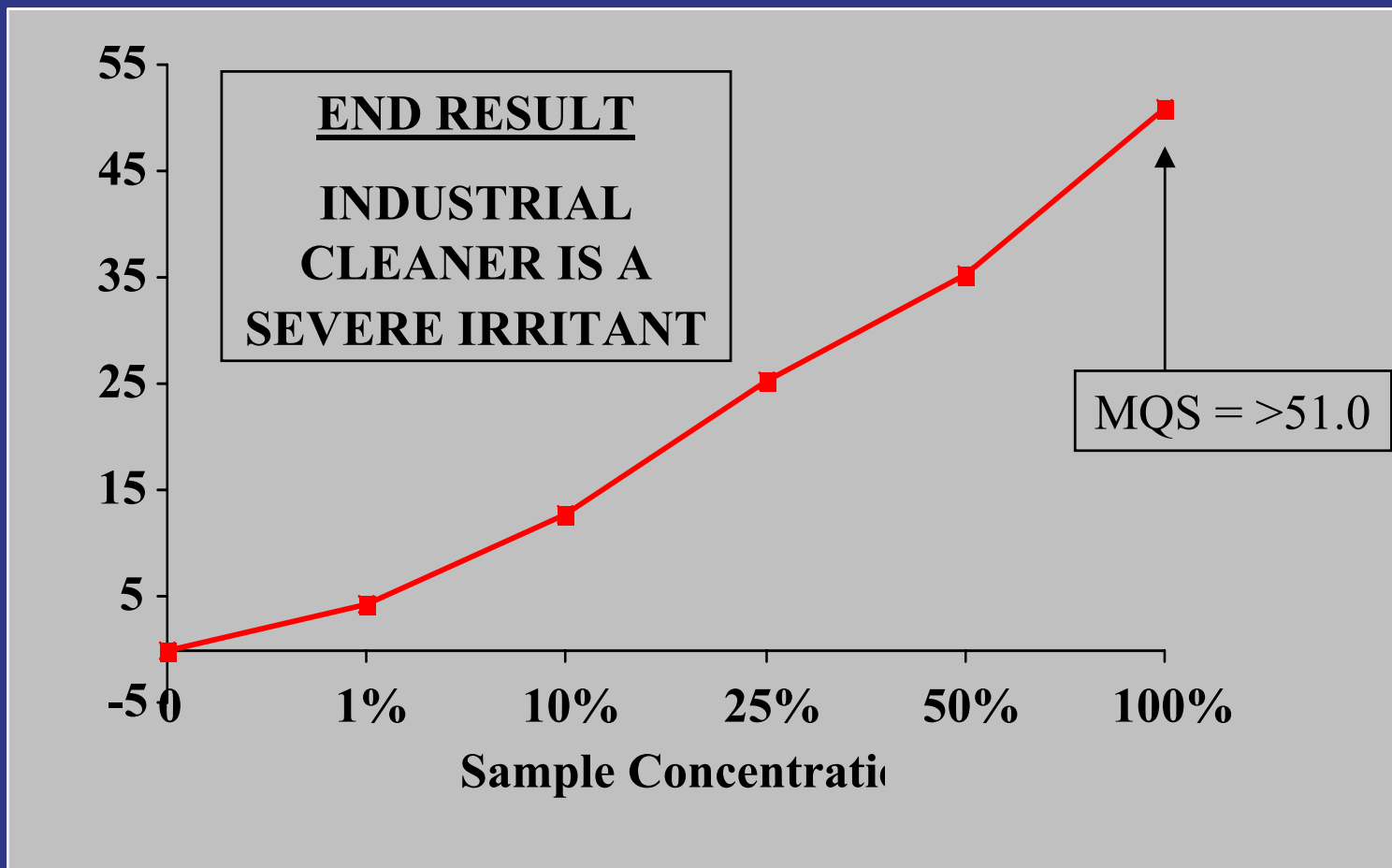
Interpretation of Results

The Maximum Qualified Score (MQS) is selected from the data because the MQS is the best correlated IAS result when compared to animal test results.

Sample Name	Study Conc.	Irritancy Score	Irritancy Classification	Qualification
Industrial Cleaner	1%	4.2	Minimal	Qualified
	10%	12.6	Mild	Qualified
	25%	25.3	Mild	Qualified
	50%	35.3	Moderate	Qualified
	100%	>51.0	Severe	Qualified



The Irritection Software Constructs A Dose-Response Curve





The Irritation Assay System Summary

- Advantages
 - Cost-Effective
 - Rapid
 - Reproducible
 - Objective
 - Quantitative
 - Sensitive



The Irritation Assay System Summary

- Utility for Ocular and Dermal Irritancy
 - Detects
 - Predicts
 - Ranks



The Irritation Assay System Summary

- Applications
 - Evaluate Product Safety
 - Accelerate Product Development
 - Assess Competitor's Products
 - Develop Material Safety Data Sheets



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