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EpiOcular | Data Sheet

Features

- Cornea-Like 3D Structure
- Excellent Correlation to *In Vivo* Results
- Highly Reproducible
- Easily Handled Cell Culture Inserts
- Quantifiable, Objective Endpoints
- Serum-Free Medium System
- Sustainable and Cost Effective Alternative to Animal Testing

Validated Applications

- OECD TG 492 Eye Irritation Test

Additional Applications

- MTT ET-50
- Toxicology Drug Discovery

The EpiOcular Model

Mattek's EpiOcular model consists of normal, human-derived epidermal keratinocytes which have been cultured in serum free medium to form a stratified, squamous epithelium, similar to *in vivo* human corneal epithelium (Figure 1). The epidermal cells are cultured on specially prepared membrane inserts and differentiated to form a multi-layered structure. The model consists of highly organized basal cells which progressively flatten towards the apical tissue surface, analogous to the *in vivo* corneal epithelium. EpiOcular is metabolically and mitotically active and releases many of the pro-inflammatory cytokines important in evaluating ocular irritation and inflammation.

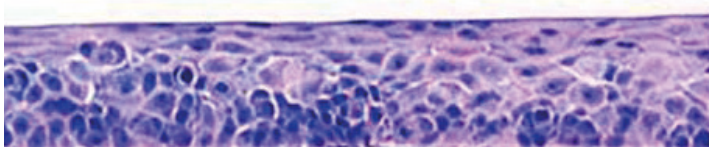
EpiOcular provides a non-animal model to assess ocular irritation, formulation toxicology, ocular inflammation and other toxicological endpoints. EpiOcular is most commonly used for ultra-mildness testing and ocular irritation studies. EpiOcular has been validated for the Eye Irritation Test as part of OECD TG 492 and is commonly used to meet regulatory testing requirements for testing of raw materials and finished products, as well as product optimization studies. Non-water soluble and neat test materials can be directly applied to the apical surface of EpiOcular tissue to mimic *in vivo* exposure conditions. Testing with standardized test materials shows a high level of correlation between *in vivo* and *in vitro* results.

Additional Information

• Weekly delivery
• Shipment from the US or Europe
• Multiple culture inserts formats
• Various media formulations*

* Available anti-fungal free, antibiotic free, hydrocortisone free and phenol red free

EpiOcular Histology



EpiOcular model (360X) Formalin Fixed, Paraffin Embedded, H&E Stained

Safety/Toxicity

EpiOcular in regulatory toxicology

For a model to be accepted for use in a regulated assay, specifically for OECD acceptance, the model must provide reproducibility, reliability, and accuracy for predicting specific endpoints. EpiOcular has demonstrated these characteristics with consistent QC values over the years (Table 1). The consistent production of the EpiOcular model resulted in acceptance of the 3D tissue in OECD TG 492 for Eye Irritation and allows for identification and classification of eye irritation or serious eye damage under UN GHS as a standalone *in vitro* method.

Table 1. Average ET-50 values from 2007 to 2016 [1].

Calendar Year	2007		2008		2009		2010		2011		2012		2013		2014		2015		2016		2007-2016	
Storage (days)	1	5	1	5	1	5	1	5	1	5	1	5	1	5	1	5	1	5	1	5	1	5
ET-50 (min)	24.4	25.9	25.0	27.4	23.2	26.1	23.6	24.4	24.6	20.8	23.9	27.2	25.3	30.5	25.1	30.3	29.5	25.0	29.9	18.7	25.5	25.6
H20 (OD)	1.49	1.32	1.73	1.38	1.57	1.30	1.36	1.20	1.29	1.13	1.51	1.17	1.51	1.28	1.45	1.29	1.52	1.20	1.62	1.07	1.50	1.20
Avg CV (%)	5.7	5.8	5.2	5.4	4.2	5.9	4.9	5.7	5.8	5.7	5.1	5.6	5.8	6.7	5.5	6	5.6	5.4	5.1	5.9	5.3	5.8
Number of tissue lots	56	5	59	23	50	15	53	12	55	23	65	30	47	34	47	43	46	21	40	26	518	232

Quality control (QC) acceptance criteria: ET-50 = 12.2-37.5min; 0.3% (v/v) Triton X-100 was used as the reference chemical for QC testing.

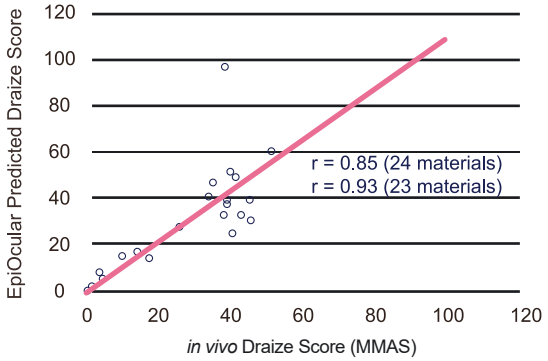
Non-regulatory toxicology

In addition to acceptance in regulatory toxicology, EpiOcular's consistent model production and similarity to the cornea ensures the model can be used for evaluation of toxicity of compounds in a non-regulated setting. These tests are typically conducted using the MTT ET-50 assay which allows for rank ordering of compounds by irritancy responses based on the time-to toxicity results (Table 2). Further, EpiOcular correlates well with *in vivo* Draize scores, making it an ideal alternative model for animal testing (Figure 2).

Table 2. Non-Regulated Toxicity Method Overview

Methods	Standard use
Sub Draize Ultra-mildness test	• Materials which the Draize test is insensitive
MTT ET-50 (Neat)	• Neat chemicals • Allows for classification into one of four categories corresponding to Rabbit Draize Eye Score
MTT ET-50 (Dilution)	• Materials diluted 20% in water • Surfactant based solutions, water-soluble material

Figure 2. Comparison of actual Draize to predicted Draize scores based on correlation equation determined from MTT ET-50 results (not shown).



1. Kandarova, H. et al. CON4EI: EpiOcularTM Eye Irritation Test (EpiOcularTM EIT) for hazard identification and labelling of eye irritating chemicals. Toxicology *in vitro* 49, 21–33 (2018).

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