EpiSensA
OECD TG 442D, TG 497
Epidermal sensitization assay

EpiSensA is an *in vitro* assay for assessing skin sensitization hazard of chemicals using a Reconstructed Human Epidermis (RhE) model.

The method provides a binary classification, identifying test substances as either skin sensitizers or non-sensitizers.

Targeting Key Event 2 of the skin sensitization AOP
Included in OECD Test Guideline 442D, EpiSensA addresses Key Event 2 (KE2) of the Adverse Outcome Pathway (AOP) for skin sensitization: keratinocyte activation.

Available data* indicate that EpiSensA is applicable to hydrophobic substances and indirectly acting haptens, providing an alternative to other KE2 assays with limited applicability for these substance types.

Complementing GARD®skin in regulatory testing
In regulatory contexts requiring multiple assays addressing different key events, EpiSensA serves as a complementary method to GARD®skin (OECD TG 442E), supporting a 2o3 defined approach for skin sensitization hazard assessment.

*OECD TG 442D, Appendix IC: EpiSensA.

2o3 defined approach enabling assessment of "difficult-to-test" samples

Use EpiSensA to complement GARDskin data in a robust "2 out of 3" defined approach for regulatory skin sensitization testing.

This combination is broadly applicable, including to substances with challenging properties such as:

- Hydrophobic substances
- Complex mixtures
- Indirectly acting haptens

Features and Benefits

Test system
- 3D Reconstructed Human Epidermis (LabCyte EPI-Model 24).

What it measures
- Gene expression changes of four biomarker genes: ATF3, GCLM, DNAJB4, IL-8.

Readout
- Binary prediction: Skin sensitizer or non-sensitizer.

Short turnaround time
- 6-8 weeks for standard studies.
- Fast track available.

Compliance
- OECD TG 442D, OECD TG 497.
- GLP-compliant laboratory.

Scientific expertise and personal support
Top reasons customers test with us

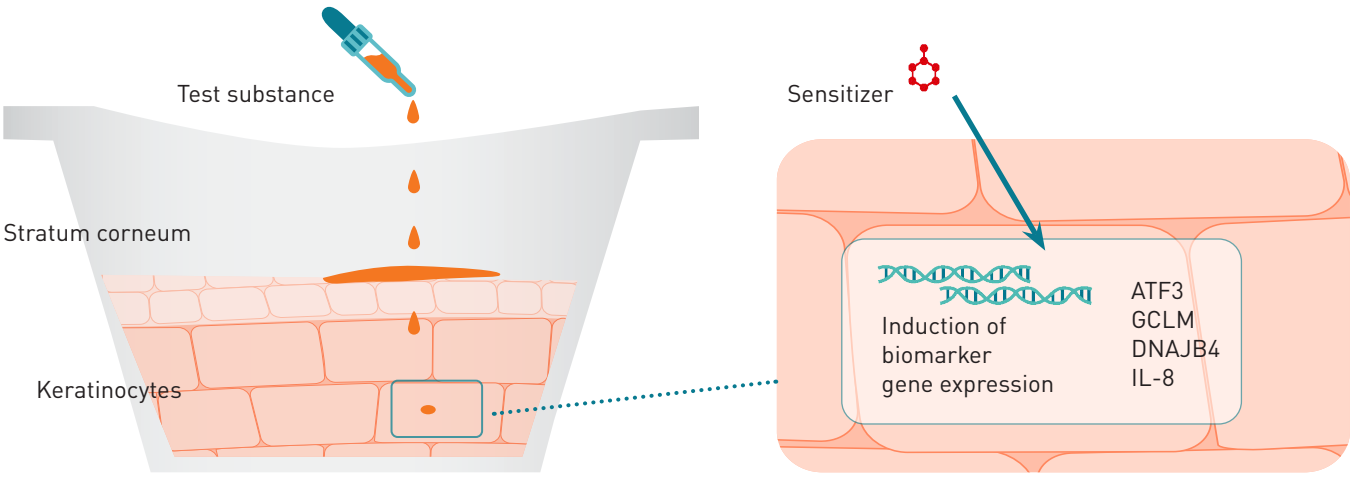

Illustration of the EpiSensA method (OECD TG 442D), based on a reconstructed Human Epidermis (RhE) model. The method measures induction of ATF3, GCLM, DNAJB4, and IL-8 following chemical exposure. A test substance is classified as a skin sensitizer when at least one biomarker shows gene-expression induction above the specified cut-off value under sub-cytotoxic conditions.

How it works

The EpiSensA test method uses a three-dimensional (3D) Reconstructed Human Epidermis (RhE) model composed of human-derived keratinocytes. These cells form a multilayered tissue structure with a functional stratum corneum, closely mimicking the biological and barrier properties of human skin.

To assess skin sensitization potential, test substances are applied directly to the surface of the tissue at the air-liquid interface. Following a 6-hour exposure, the assay measures the expression changes of four biomarker genes associated with skin sensitization: ATF3, GCLM, DNAJB4, and IL-8.

Gene expression levels are quantified using Reverse Transcription-quantitative PCR (RT-qPCR). In parallel, cytotoxicity is assessed to ensure that gene expression changes are evaluated at sub-cytotoxic concentrations (defined as cell viability ≥ 80%). The relative induction of marker genes is calculated in comparison to vehicle controls.

A test substance is classified as a skin sensitizer in the EpiSensA test method if at least one of the gene expression induction level exceeds the respective defined cut-off value (ATF3: 15-fold; GCLM: 2-fold; DNAJB4: 2-fold; IL-8: 4-fold) under sub-cytotoxic conditions. The final result is based on the mean maximum fold-induction (Imax) value observed across all test concentrations where cell viability remains ≥80%.

For a complete description of the protocol, see OECD Test Guideline 442D.