



Data Sheet

NeoEpidermis™ 3D Skin Model

Product Name: NeoEpidermis™ 3D Skin Model

Product Number: NEP3D1-12

Format: 6-well, 12-well, 24-well

Storage Conditions: 37°C incubator with 5% CO₂

Product Description:

NeoEpidermis™ is a fully stratified, three-dimensional reconstructed human epidermal (RhE) model that closely mimics the structure and function of native human skin. Constructed from normal human epidermal keratinocytes (NHEKs), the model develops a multilayered epidermis comprising basal, spinous, granular, and stratum corneum layers, replicating the in vivo tissue architecture. NeoEpidermis™ provides a reliable, human-relevant platform for studying skin biology, drug efficacy, and cosmetic product safety, offering an ethical alternative to animal testing.

Key Features & Benefits

Feature	Benefit
Physiologically relevant 3D structure	Stratified epidermis with functional barrier properties mirrors human skin responses
Multiple well formats (6, 12, 24)	Scalable for high-throughput screening and large-volume assays



Feature	Benefit
Regulatory validation	Compliant with OECD Test Guidelines for skin irritation, corrosion, and sensitization testing
Ethical alternative	Replaces animal testing with human-relevant in vitro data
Reproducible and standardized	Manufactured from characterized primary cells with batch-to-batch consistency

Tissue Architecture & Biomarker Expression

NeoEpidermis™ exhibits the full spectrum of epidermal differentiation markers, confirming its structural and functional authenticity .

Marker Expression Profile

Marker	Function	Location
Ki67	Proliferation marker	Basal layer
Keratins 1 & 10	Early differentiation markers	Suprabasal layers
Involucrin	Early differentiation marker	Suprabasal layers
Filaggrin	Terminal differentiation marker; barrier function	Granular layer

Marker	Function	Location
Profilaggrin	Terminal differentiation marker	Granular layer
Keratin 14	Basal keratinocyte marker	Basal layer
Transglutaminase 1 (TGM1)	Cornification marker; lipid barrier formation	Stratum corneum
ZO-1	Tight junction protein; barrier integrity	Granular layer
Loricrin	Terminal differentiation marker	Granular layer
Collagen IV	Basement membrane integrity	Dermal-epidermal junction
Collagen VII	Anchoring fibrils; structural integrity	Dermal-epidermal junction
Fibrillin-1	Extracellular matrix integrity	Dermal-epidermal junction

Tissue Structure

- **Basal layer:** Proliferating keratinocytes (Ki67-positive) attached to basement membrane
- **Spinous layer:** Differentiating keratinocytes expressing K1/K10 and involucrin
- **Granular layer:** Cells containing keratohyalin granules; expressing filaggrin and ZO-1

- **Stratum corneum:** Cornified envelope with functional lipid barrier; expresses TGM1 and loricrin
- **Basement membrane:** Collagen IV and VII positive; intact dermal-epidermal junction

Quality Control Specifications

Parameter	Specification
Tissue viability	>85% by MTT assay
Histology	Stratified epidermis with all four layers present
Barrier function	Permeability consistent with native human epidermis
Marker expression	Positive for Ki67, K10, involucrin, filaggrin, loricrin, ZO-1
Sterility	Negative for mycoplasma, bacteria, and fungi
Batch-to-batch consistency	All quality parameters within acceptance criteria

Intended Applications:

- **Skin irritation and corrosion testing** (OECD TG 439, TG 431 compliant)
- **Skin sensitization assays** (OECD TG 442D compatible)
- **Drug efficacy and toxicity screening**



- **Cosmetic product safety assessment**
- **Dermatological research and disease modeling**
- **Wound healing and regenerative medicine studies**
- **Oxidative stress and anti-aging compound evaluation**

6. Regulatory Compliance

NeoEpidermis™ has been developed in alignment with internationally recognized standards and is included in:

- **OECD Test Guideline 439** – In Vitro Skin Irritation
- **OECD Test Guideline 431** – In Vitro Skin Corrosion
- **OECD Test Guideline 442D** – In Vitro Skin Sensitization
- **ISO 10993-23** – Biological Evaluation of Medical Devices (Skin Irritation Test)

The model supports the 3Rs (Replacement, Reduction, Refinement) initiative by providing a scientifically validated alternative to animal testing for regulatory safety assessments.

Storage & Handling Instructions

Required Conditions

- **Storage:** 37°C in a humidified incubator with 5% CO₂
- **Media:** Supplied maintenance medium (replace every 2-3 days)
- **Handling:** Aseptic technique required; use sterile forceps for tissue transfer

Important Notes

- Do not allow tissues to dry out during handling



- Maintain liquid-air interface culture conditions (media level below insert membrane)
- Allow tissues to equilibrate at 37°C for 1-2 hours before experimental use
- Recommended maximum culture period post-arrival: 5-7 days (refer to Certificate of Analysis for specific lot data)

Ordering Information

Product	Format	Product Number
NeoEpidermis™ 3D Skin Model	6-well	NEP3D1-6
NeoEpidermis™ 3D Skin Model	12-well	NEP3D1-12
NeoEpidermis™ 3D Skin Model	24-well	NEP3D1-24

Related Products

- **NeoEpidermis™ Maintenance Medium** – NEP-MED
- **NeoEpidermis™ Assay Kit (MTT)** – NEP-ASSAY
- **NeoEpidermis™ Positive Controls (Irritation/Cytotoxicity)** – NEP-CTRL

Disclaimer

This product is intended for research and preclinical safety testing use only. Not intended for human therapeutic or diagnostic applications.



Manufacturer Contact

For technical support or additional information, contact our scientific support team.

NeoEpidermis™ is a trademark of NeoBioPharma. Specification subject to change without notice. For the most current information, please refer to the Certificate of Analysis accompanying your shipment.