

6-Pack Toxicity Testing

The acute toxicity "six-pack" is a **battery of animal tests used to evaluate acute systemic toxicity by three major routes of exposure, skin and eye irritation/corrosion, and skin sensitization.**

This provides information about potential health hazards associated with chemicals.

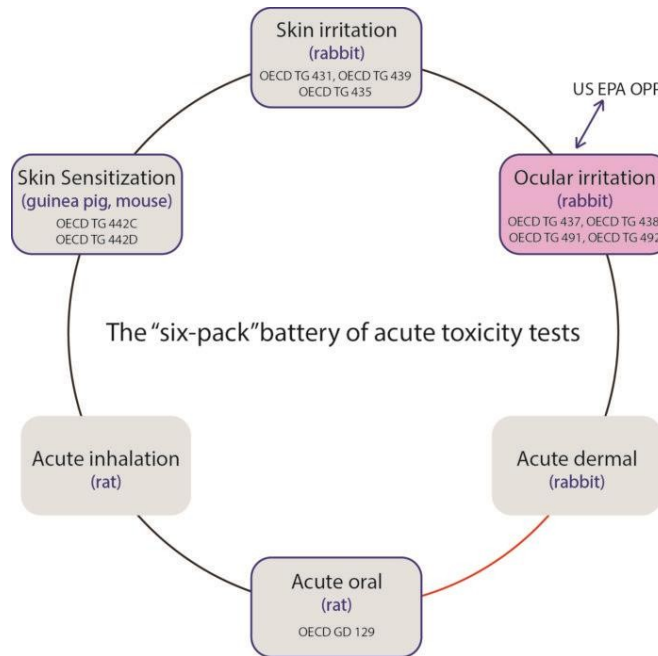
The most common type of animal assays for acute toxicity assessment of chemicals used as pesticides, pharmaceuticals, or in cosmetic products is known as a "6-pack" battery of tests, including three topical (skin sensitization, skin irritation and corrosion, and eye irritation and corrosion) and three systemic (acute oral toxicity, acute inhalation toxicity, and acute dermal toxicity) end points.

Acute Toxicity

Acute systemic toxicity testing involves an assessment of the general toxic effects of a single dose or multiple doses of a chemical or product, within 24 hours by a particular route (oral, dermal, inhalation) and that occur during a subsequent 21 day observational period.

**These tests no longer require animals.
Repeat.**

These tests no longer require animals.



Before we even start to test, the materials i.e .skin, eyes researchers need to use do not require animals at all:

- We no longer need to use animals for any skin tests as we have labskin that is timestamped, validated and reproducible data on tests.



WHO WE ARE

LabSkin Creations is a **biotechnology CRO** specializing in **ADVANCED 3D SKIN** and **ADIPOSE TISSUE ENGINEERING**.

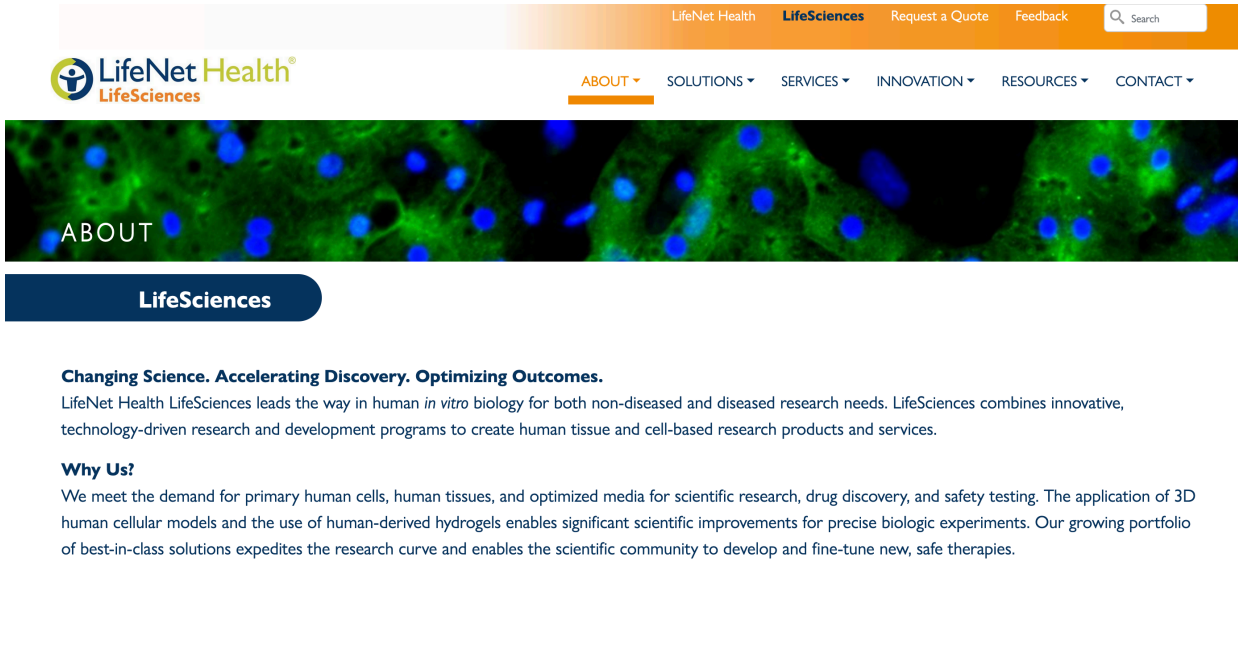
By combining **INNOVATIVE cell culture** techniques as well as **PROPRIETARY technologies** based on **scaffolding biomaterials** and **3D bioprinting approaches**,

we **DESIGN** and **CREATE** unique and **versatile 3D reconstructed models** for the performance evaluation of **skin and personal care** products and their ingredients.

<https://www.labskincreations.com/>

Guide 1 Six pack Toxicity testing.

1. Replacement of the entire 6 pack battery of tests.
<https://lnhlifesciences.org/lifesciences>



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ABOUT

LifeSciences

Changing Science. Accelerating Discovery. Optimizing Outcomes.

LifeNet Health LifeSciences leads the way in human *in vitro* biology for both non-diseased and diseased research needs. LifeSciences combines innovative, technology-driven research and development programs to create human tissue and cell-based research products and services.

Why Us?

We meet the demand for primary human cells, human tissues, and optimized media for scientific research, drug discovery, and safety testing. The application of 3D human cellular models and the use of human-derived hydrogels enables significant scientific improvements for precise biologic experiments. Our growing portfolio of best-in-class solutions expedites the research curve and enables the scientific community to develop and fine-tune new, safe therapies.

2. STopTox: An *in Silico* Alternative to Animal Testing for Acute Systemic and Topical Toxicity

<https://pubmed.ncbi.nlm.nih.gov/35192406/>

An official website of the United States government [Here's how you know](#)

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> [Environ Health Perspect.](#) 2022 Feb;130(2):27012. doi: 10.1289/EHP9341. Epub 2022 Feb 22.

STopTox: An *in Silico* Alternative to Animal Testing for Acute Systemic and Topical Toxicity

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Abstract

Background: Modern chemical toxicology is facing a growing need to Reduce, Refine, and Replace animal tests (Russell 1959) for hazard identification. The most common type of animal assays for acute toxicity assessment of chemicals used as pesticides, pharmaceuticals, or in cosmetic products is known as a "6-pack" battery of tests, including three topical (skin sensitization, skin irritation and corrosion, and eye irritation and corrosion) and three systemic (acute oral toxicity, acute inhalation toxicity, and acute dermal toxicity) end points.

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The first animal assay within the “six-pack” that **was eliminated** is acute dermal toxicity. Through an extensive data research, it has been concluded by the EPA (Environmental Protection Agency) that this assay does not provide any more value for tox categorization than the data from the other assays. Thus, per EPA, this assay can **be waived for all formulated products.**

Secondly, data for primary eye irritation evaluation can **now be wholly generated using a group of in vitro assays**, namely, the Bovine Corneal Opacity and Permeability (BCOP) assay (OECD 437), EpiOcular™ (EO) (OECD 492), and, if necessary, the Cytosensor Microphysiometer (CM). These assays can entirely replace the animal primary eye irritation test.

Thirdly the development of in vitro skin irritation and skin sensitization assay, such as the EpiDerm™ Skin Irritation Test (SIT) (OECD 439), EpiDerm™ Skin Corrosion Test (SCT) (OECD 431), Corrositex & Skin Corrosion (OECD 435), Direct Peptide Reactivity Assay (DPRA) (OECD 442C), KeratinoSens™ assay (OECD 442D) and Human Cell Line Activation Test (h-CLAT) (OECD 442E)

Skin Sensitisation

SENSITISATION

Skin Sensitisation - Direct peptide reactivity assay (DPRA),
Amino acid derivative reactivity assay (ADRA)
OECD TG 442C
XCellR8

BASF and Givaudan
Vitroscreen
Senzagen GARDskin
IIVS

Life science health
Skin Sensitisation – ARE-Nrf2 luciferase test method - The
LuSens Test, KeratinoSens

U-SENS
LifeScience Health
BASF and Givaudan
Vitroscreen
Senzagen GARDskin

Senzagen/Gardskin
XCellR8
BASF and Givaudan
IL-8 Luc Assay

OECD TG 442D
KeratinoSens
LifeSciencehealth
Vitroscreen
BASF and Givaudan
XCellR8
Senzagen GARDskin
Cyprotex
IIVS

Skin Sensitisation - h-CLAT, IL-8 Luc assay, U937 skin
sensitisation test (U-SENS)
OECD TG 442E
XCellR8

CORROSION AND IRRITATION

Integrated approach on testing and assessment (IATA) for skin corrosion and irritation OECD GD

203Skin Irritation

OECD GD 203 (fish)

Chemical toxicity assessment strategy for skin corrosion

and irritation – European Chemicals Agency

In vitro membrane barrier test Corrositex for skin corrosion

Skin Corrosion

OECD TG 435

Corrositex

Iontox

IVI

IIVS

In vitro skin corrosion: Reconstructed human epidermis

Corrositex

Vitroscreen

Senzagen

GARDskin

Toxfinder

Skin Corrosion

OECD TG 430

Iontox

EpiSkin

EpiDerm

SkinEthic

EpiCS

(RhE) test

Skin Corrosion

OECD TG 431

EpiSkin

EpiDerm

Skin Ethic

RHE SCT

epiCS SCT

XCellR8

Iontox

Skin Corrosion

OECD TG 430

Iontox

EpiSkin

EpiDerm

Cyprotex

LabCyte EPI-MODEL 24 SCT

Vitrolife-skin

IIVS

SkinEthic

EpiCS

Skin Corrosion

OECD GD 20

Skin Corrosion – EURL ECVAM

TM1998-05 – Murine local lymph node assay

Skin Corrosion – EURL ECVAM

TM1998-05 – Murine local lymph node assay

In vitro skin irritation: Reconstructed human

epidermis (RhE) test

Skin Corrosion

OECD GD 20

Skin Irritation

OECD TG 439

EpiSkin

EpiDerm SIT

Skin Ethic

XCellIR8

LabCyte EPI-MODEL 24 SIT

epiCS RHE SIT

Iontox

Vitroscreen

Senzagen GARDskin

Toxfinder

Cyprotex

Skin+

KeraSkin

Vitroscreen

IIVS

Labskin

IN VITRO OCULAR

Integrated approach on testing and assessment (IATA) for serious eye damage and irritation OECD GD 263

OECD TG 460

Ocular Corrosion and Irritation – Fluorescein leakage (FL)

OECD TG 491 – Short-time exposure (STE) IIVS

**Vivotechnia

OECD TG 437 – Bovine Corneal IIVS

**Labcorp

**Charles River

OECD TG 438 – Chicken Eye

**Labcorp

**Charles River

** Labcorp

**Charles River

OECD TG 496 – Ocular Irritation Test XCellR8

IVI (In Vitro International) IIVS

OECD TG 492 – Reconstructed Human Cornea EpiOcular
HCE

SkinEthic HCE EIT LabCyte

XCellR8 Iontox Vitroscreen MatTek

Senzagen GARDskin IIVS

**Syngene

The companies with *'s next to them – these offer CHOICE and ADDITIONAL animal tests. Yet in the UK the law specifically says no animals to be used where there are replacements. There isn't a choice and those businesses who buy these additional tests and pay for them and the businesses that provide them are BREAKING THE LAW.**

ORAL & INHALATION

Epithelix

MucilAir 3D

MucilAir HF

SmallAir 3D

SmallAir HF

Human Airway Epithelial...

OncoCilAir

MatTek Corp – Oral Irritation and Inhalation

EpiAirway

EpiAlveolar

EpiOral and Gingival

EpiOral

EpiNasal

Iontox

HuDMOP (human dynamic organ platform)

Epithelix MucilAir

<https://www.iontox.com/in-vitro-6-pack-toxicity-testing/in-vitro-acute-oral-toxicity-predictor/>

Vitrocell

Cloud System

Automated Exposure Station <https://www.vitrocell.com/inhalation-toxicology>

ABSORPTION/PENETRATION

Skin Absorption/Penetration

Dermal absorption OECD GD 28 (2004)

Skin Absorption/Penetration

OECD Guidance Notes no. 156

Skin Absorption/Penetration

OECD TG 428

Vitroscreen

Senzagen GARDskin

Toxfinder

SkinEthic

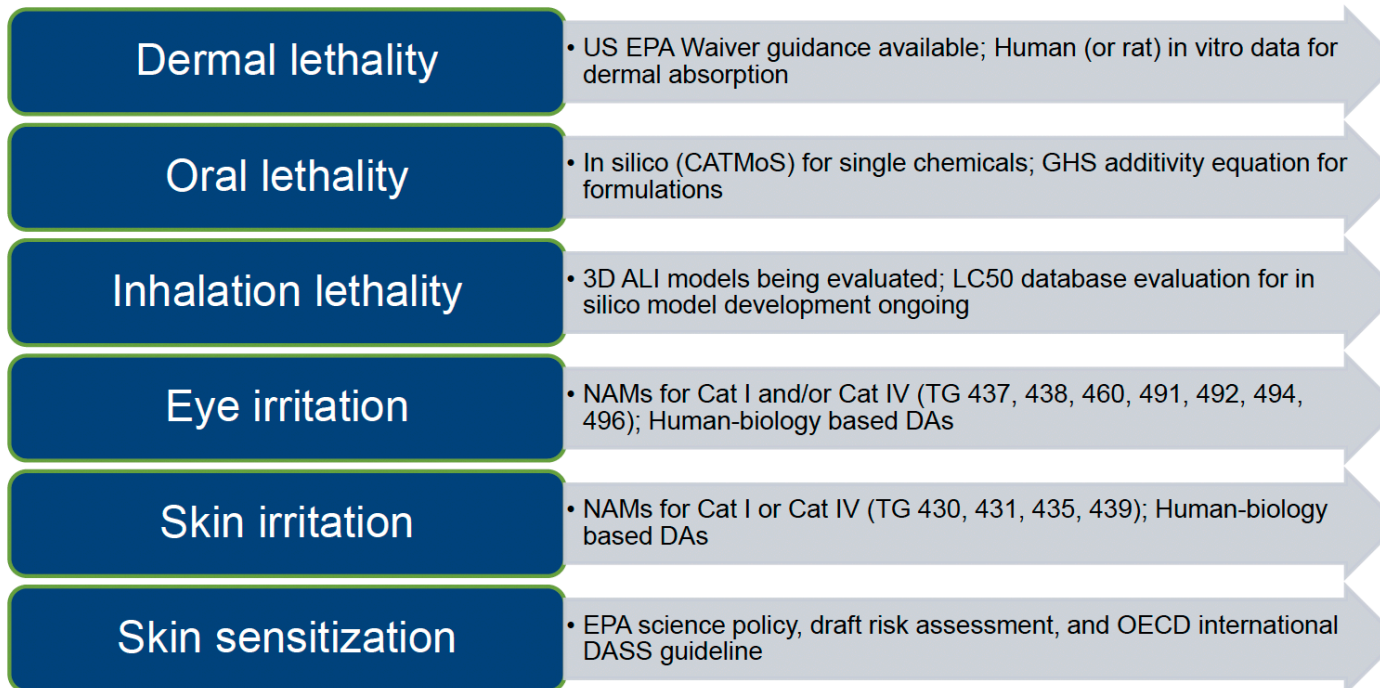
SkinEthic HOE/Oral Epithelium

SkinEthic HE Gingival Epithelium

Senzagen

GARDair <https://senzagen.com/gardair/>

Progress Towards a Six-Pack Replacement



Mansouri et al. 2021 EHP; Clippinger et al. 2021 Cut Ocu Tox; Rooney et al. 2021 Reg Tox Pharm; Allen et al. 2021 ALTEX; Hamm et al. 2021 Reg Tox Pharm