XenoSkin – Ex vivo human skin, porcine mucosa explants and bovine nails

For in vitro permeation testing IVPT and services OECD TG428, MDR 2017/745, EU No 528/2012, EFSA

Broad selection of ***ex vivo*** human and animal skin samples: Full thickness skin, dermatomic sections, single bovine nail sheets, porcine buccal mucosas. The skins are prepared under high quality standards after cosmetic surgery. Human skin samples are collected from donors who gave their informed consent.

Ex vivo human skin explants, porcine mucosa models or bovine nail sheets are important for the (agro)chemical, pharmaceutical, cosmetic industries as well as for substance based medical devices and are designed for:

- characterisation of pharmaceuticals in topical dosage form OECD TG428, EFSA Guidance
- classification of substance based medical devices MDR 2017/745
- safety assessment of agrochemcials, biocides, Reg. EU No 528/2012
- safety evaluation of chemicals or pesticides
- safety evaluation of cosmetic active ingredients
- selecting a suitable vehicle
- selecting drug candidates for dermal application

XENOMETRIX

Swiss Commitment for Bioassays

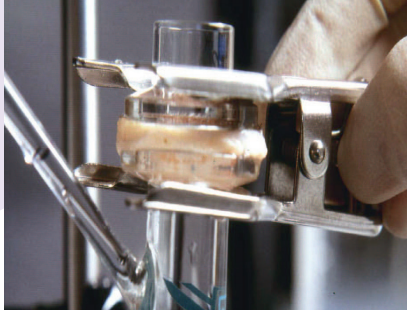
Alternatives to animal testing

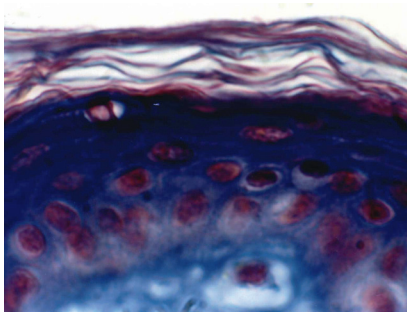
The ***ex vivo*** XenoSkin H offers an excellent alternative to animal testing for the efficacy and safety of a chemical, pharmaceutical pharmaceutical, biocides, substance based medical devices or cosmetic compounds. It fulfills the criteria of multiple guidelines.

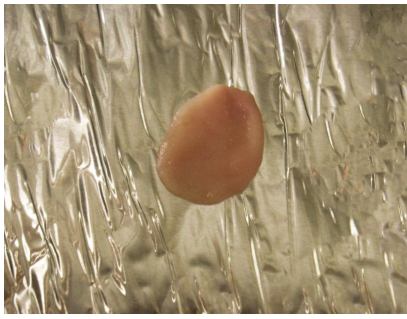
- «Ban on animal testing» directive in the EC which prohibits to market cosmetic products or its ingredients tested on animals.
- 3Rs directive to replace, reduce and refine animal use in safety and efficacy evaluations.

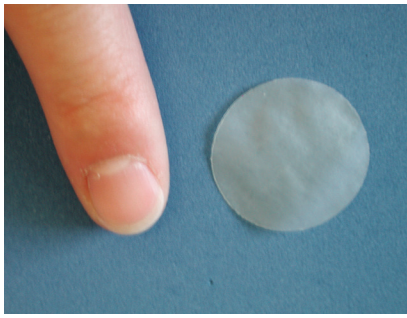
XenoSkin H delivers

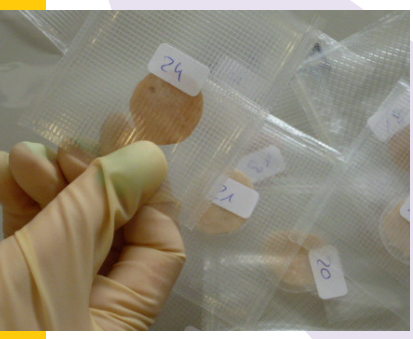
- High quality human skins samples which are prepared according to high quality standards. All skin samples are collected under strict ethical restrictions. Time from surgery to lab is < 6 hours.
- Average age of donor is 45 years, with a skin thickness found in the average population.
- XenoSkin H is tested for absence of HBV, HCV, HIV-1, HIV-2.
- ***Ex vivo*** human and animal XenoSkins are available in squares, discs or other formats in different sizes from 1–550 cm^2, full thickness or dermatomed skin. Larger unpunched skin pieces, customized skins or quality control with mannitol or caffeine are available.
- Thickness of dermatomed skin 400–600 µm, virological status, transit time and temperature, documentation of donor data, desinfectant used before surgery, microscopic examination, RSD (%).
- Skin explants are compliant with guidelines OECD TG428, EU Reg. 528/2012 (Biocides), EFSA Journal 2017:15(6):4873, MDR 2017/745 Substance Based Medical Devices.











Available in vitro Skin Permeation Testing Services

- Regulatory studies under GLP according to OECD TG 428, EFSA, EMA, FDA guidelines and MDR 2017/745
- Bio-equivalence studies
- Characterization and regulatory classification of substance based medical devices according to Rule 21 in Appendix VIII of MDR EU Regulation 2017(745)
- Drug Delivery and Controlled Release Projects
- Absorption, Distribution, Metabolism and Excretion (ADME)
- Metabolites toxicokinetic on fully viable tissues
- HPLC-MS/MS, UPLC analytical techniques without radiolabelling
- Investigation of local distribution at application site
- Test compounds: chemicals, agrochemicals, cosmetics, pharmaceuticals (API), substance based medical devices
- Also available: Skin irritation (OECD TG439), Skin corrosion (OECD TG431), DPRA, formulation analysis

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