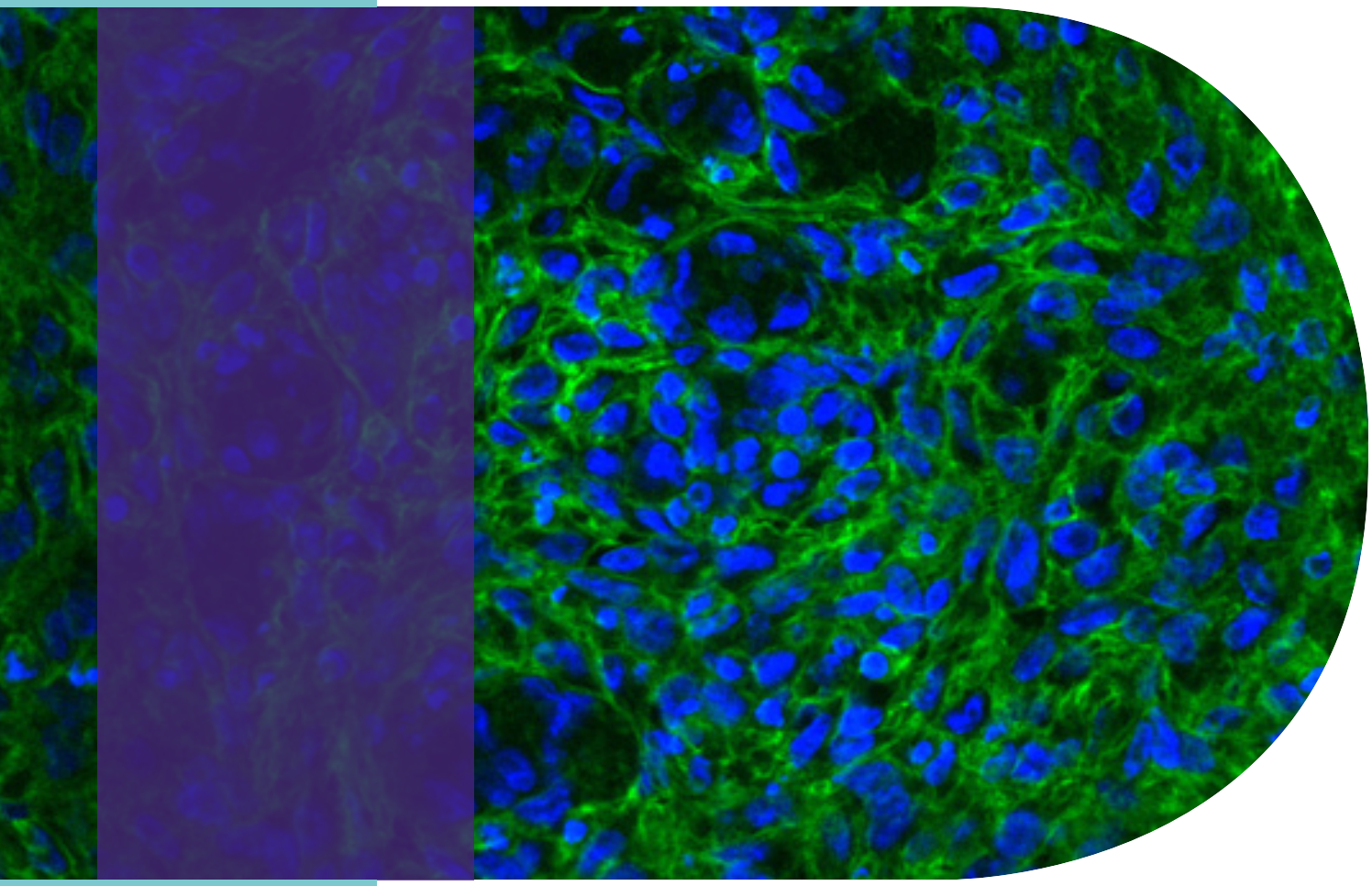
Cosmetics



VitroScreen ORA DERMIS

VitroScreen
Leading Innovation in Pre-Clinical Testing

Passion, Science and **Innovative Thinking** to better address skin health and beauty claims

- VitroScreen strongly believes that results of pre-clinical efficacy obtained by using 3D tissue models have an incredible power to create new, smart, attractive and powerful cosmetic claims.
- 20 years' expertise on 3D skin models and scaffold-free spheroids allows VitroScreen to select the best *in vitro* efficacy models to meet Customers' requirements and support their innovative challenges.
- Our experimental protocols redefine the way to model and support cosmetic products' efficacy by:
  - being beneficial and complementary to clinical evaluation
  - adding value to direct and indirect consumers' communication with deeper, stronger and visual morphological evidences
  - providing the mechanism of action and strong scientific evidences that cannot be obtained with clinical approaches, either for practical or ethical reasons
  - performing screening and comparing products with reproducible results during product development

FUNDAMENTALS OF COSMETIC CLAIMS

- Article 20 of the EC Cosmetic Products Regulation 1223/2009 (CPR) frames the requirements for cosmetic claims. Furthermore, cosmetic claims have to comply with EU Regulation 655/2013 that provides the Common Criteria to ensure that the information conveyed to the end users through claims is useful, understandable and reliable so that consumers can make informed decisions.
- The third Common Criterion, 'Evidential support', states that *"claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including where appropriate expert assessments. Evidence for claim substantiation shall take into account state of the art practices. Where studies are being used as evidence, they shall be relevant to the product and to the benefit claimed, shall follow well-designed, well-conducted methodologies (valid, reliable and reproducible) and shall respect ethical considerations."*
- Experimental studies become a key instrument to substantiate cosmetic claims.

CLAIMS related to LIFE'S STYLE

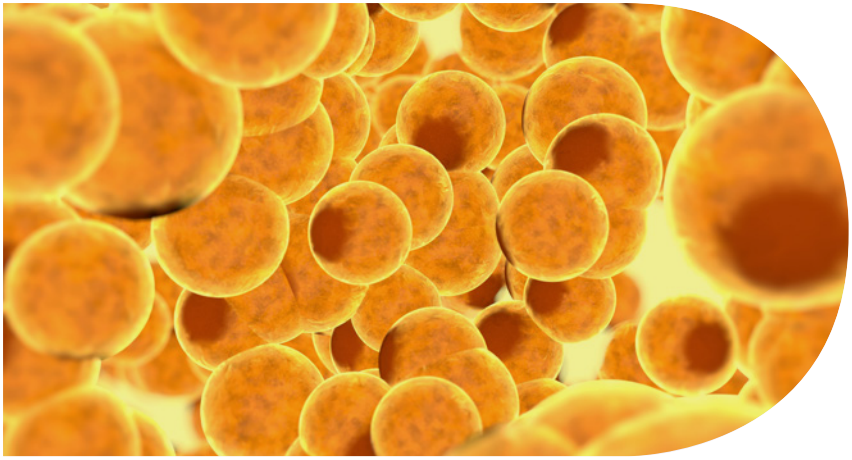
+ **To assess cosmetics' efficacy on skin basic properties and primary functions**
+ **To explore skin responses to cosmetics in homeostasis and everyday's life stress related conditions**

SKIN BARRIER RHE RHE pigmented FT-skin	Development, differentiation, protection, repairing when impaired, film forming, emollience, re-epithelization, TJs structure, filaggrin boosting, increasing epidermal strength, targeting ECM, SC peeling and skin renewal, anti-scare, barrier function and SC lamellar structure restoring.
MOISTURIZATION RHE RHE pigmented FT-skin VitroScreen ORA DERMIS	Active water flux restoring, counteracting epidermal dryness conditions, every day's life moisturizing, shield effect against extreme dryness, physiological water gradient restoring, soothing efficacy on dry skin, anti-redness, skin elements localization by EDX.

CLAIMS related to INDOOR & OUTDOOR EXPOSOME

+ **To explore damages derived from exposome elements: environment, UV, chemicals, toxicants, indoor and outdoor pollution**

Protecting and boosting **SKIN HOMEOSTASIS**	Daily induced skin damages, detoxification, anti-oxidative stress, antipollution, counteracting hypoxic stress, hypersensitivity, inflammasome, particulate matter induced damages.
SKIN DAMAGES: protection from UVA and UVB	Pigmentation, tanning activation, anti dark spot, depigmentation, counteracting phototoxic reactions, DNA damage/repair, anti-sun burn cells, DNA methylation, photo-allergy, immuno-suppression, repeated UVA exposure model and photo-aging dynamic model.



CLAIMS related to ADIPOSE TISSUE

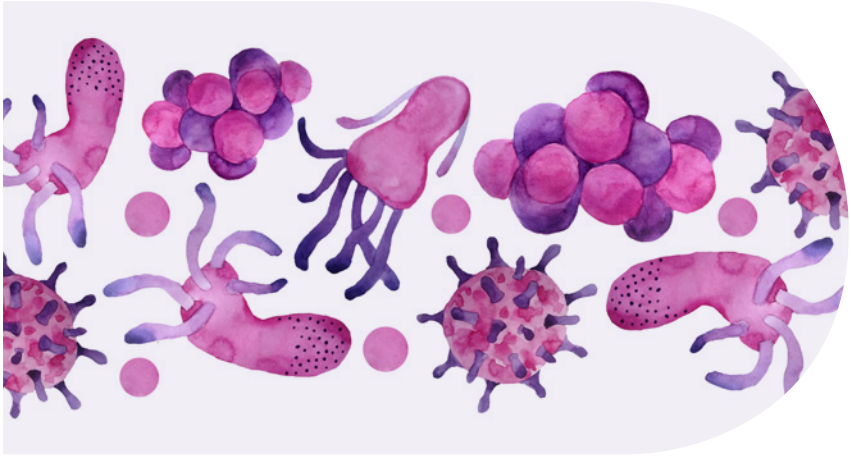
+ **To explore mechanism of action on standard and customized models of adipose tissue**
+ **Long-term experimental models with clinical relevance**

VitroScreen ORA ADIPE with donors of different BMI or IPSC	Adipocytes differentiation, lipids accumulation, metabolism and de-stock, inflammatory pathways, fibrosis co-colture model, matrix production and secretory panel, influence of hormonal stimuli, qRT-PCR and high content 3D imaging analysis are proposed on relevant biomarkers or specific gene signature. Advanced protocols developed to assess the efficacy of bacterial secretome and postbiotics.

CLAIMS related to SKIN'S AGES

+ **To explore how cosmetics can delay, counteract, repair and possibly reverse early and delayed signs of skin aging**
+ **Long-term, up to 21 days experimental designs**

VitroScreen ORA DERMIS Standard and advanced customized spheroids (co-coltures) to address multi-target claims RHE FT-skin	Re-pulping, biorestructuring, film forming, new ECM deposition and ECM remodelling, boosting dermis moisturization, targeting wrinkle's biomarkers, stretchmarks prevention and treatment, photo-aging dynamic model, biological response of fibroblasts from different donor's age and ethnicity.



CLAIMS related to SKIN MICROBIOME

Within its *In vitro* Innovation Center, VitroScreen has established the Microbiome Research Unit, a specialized platform with a unique expertise in colonizing 3D human reconstructed tissues. Its main focus is to assess the impact of ingredients and formulations on fully functional and site-specific microbiome strains.

CUSTOMIZED MODELS

+ Scalp specific microbiome model (co-culture) and dandruff model
+ Bacterial secretome modulatory efficacy on ECM matrix on VitroScreen ORA DERMIS
+ Microbiota and aging
+ Microbiota and pigmentation
+ *In vitro* SNIFF test: suitable for odor inhibition semi-quantification

3D COLONIZED TISSUES: EFFICACY MODELS

- Bacterial adhesion, boosting or inhibiting bacterial growth and proliferative capacity: customized protocols with specific strains
- Microbiome's impact on barrier function development and innate immunity, specific pathways modification
- Competition models: based on two strains or on multiple step procedure
- Mechanism of action and efficacy of prebiotics, probiotics, postbiotics after acute and long-term exposure: multiple host targets
- Prebiotics, probiotics, postbiotics efficacy and recognition mechanisms
- Biofilm models (strain specific): anti-biofilm formation efficacy, influencing of EPS matrix production, biofilm disruption after acute or repeated treatments
- Microbiome safe claim: suitable for surfactants based formulations and medical devices
- Microbiota acute and long term exposures on injured models: infection customized models
- Immuno-competent models: 3D tissues in co-culture with THP-1 monocytes
- Atopic Dermatitis (*S. aureus*), Acne lesions and inflammation (*C. acnes*)

CLAIMS related to HAIR CARE

+ To explore how cosmetic ingredients can influence the hair life cycle by a patented model of dermopapilla developed as a 3D spheroid

VitroScreen ORA HAIR FOLLICLE and DERMOPAPILLA (patent n. WO 2019/092667)	A unique *in vitro* co-culture model allowing to mimic the full hair cycling: anagen/catagen transition, telogen resting and involution.
DANDRUFF MODEL on RHE: co-culture *M. furfur/M.* restricta with C. acnes	The dandruff formation based on its associated microbiome is fully reproduced in our colonized 3D scalp model. Applicable to assess dandruff formation and its symptoms (itching, rash) and to study the recovery of scalp's homeostasis.

CLAIMS related to SKIN DIVERSITY

+ **To explore skin diversity, stressed, sensitive, fragile and ethnic skin compared to standard models**
+ **Skin pathologies and skin disorders models to assess dermo-pharmaceutical products**

RHE (fully differentiated, immature, injured, inflammatory) RHE co-cultured with THP-1 cells FT-skin FT-skin co-cultured with THP-1 cells	Immunocompetent Atopic Dermatitis, Psoriasis, Acne lesions, Acne colonized model, dermal wound model, diabetic skin and diabetic ulcers, rosacea, fragile skin, sensitive skin, detoxification of sensitive skin, hypersensitivity, ethnic skin, skin induced atrophy (corticoids).

COSMETIC PRODUCTS SAFETY ASSESSMENT: a robust VitroScreen's expertise

The Multiple Endpoint Analysis (MEA) approach coupled with standard or customized protocols has allowed VitroScreen to fine-tune the mechanisms of toxicity. Products are tested with realistic exposure conditions taking into account product type. **Data obtained on 3D reconstructed human tissues are used to generate a robust body of evidences for safety assessment evaluation: these data are quantitative, robust and predictive of human response, more sensitive, more ethical and in some cases also more discriminating compared to clinical tests.** Customized prediction models for skin irritation and sensitization potential are defined based on *in vivo* reference data. Dedicated protocols are proposed for sensitive skin, baby skin and high mildness claims where a specific evaluation is requested according to the CPR.

Nowadays the increased diffusion of cosmetic or borderline products with sanitizing action with alcoholic content higher than 70% raises concerns about the safety of the skin frequently exposed to these products. To address this issue, a new series of assays based on colonized tissue models has been developed to investigate cosmetic interference with resident microbiota (customized protocols).

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