

# ZOOM #26



Newsletter #26 - 12/2022

edito

Skinobs is glad to bring you some news of testing experts for the Beauty Industry. Skinobs will attend **Cosmet'Agora** booth 92 in Paris in January. Then we will organize in May 2023 the second edition of **Cosmetotest** in collaboration with Cosmet'in Lyon, a Symposium dedicated to preclinical and clinical tests with the participation of evaluation experts sharing their vision and their latest innovations of the field. For this 26th ZOOM edition, we will share with you information about **tolerance evaluation** and we are happy to give you the latest news of our partners: **Dr. Goya, Cortex, Ellead, Pixience, Helioscreen, IEC, Microfactory, Validated Claim Support, proderm, Evalulab, Miravex, Expertox, Courage+Khazaka and Imasens.**

Anne Charpentier, CEO

## WHAT'S INSIDE THE BOX

Skinobs platforms are today **2 international databases** renowned as a reference in the testing field of actives and personal care. It represents, with users from 93 nationalities, a **unique tool for clinical and preclinical testing** giving crucial and qualified information. You can retrieve classical or innovative tests that are continually updated with the latest instrumentation and methods, connected to the testing laboratories around the world.

### You can now find your consultant!

On the preclinical testing platform, the filter #11 - Advice on regulations, toxicology or efficacy - in the first menu «**Category of tests or services**» is dedicated to advice providers. This category is organized in **3 poles of expertise** for a support on regulation, toxicology, PIF or the choice of efficacy tests for example... :

**1. Toxicological expertise:** Advice on container-content interactions, Safety assessment, Advice on product safety, Toxicological profiling, Ecotoxicology advice.

**2. Regulatory advice:** Classification, Notification, Reporting, Claims Compliance, BIP drafting and review, Responsible person EU - UK.

**3. Advice on efficacy testing:** Scientific definition of the test project, Coordination of tests with laboratories, Marketing valorization of the results.

Log in now, [www.skinobs.com](http://www.skinobs.com) for free to access the search or send us your specific request directly at [contact@skinobs.com](mailto:contact@skinobs.com). We will be happy to provide you special advice to help you in your evaluation projects.



- 892 Methods
- 49 Skins mechanisms
- 176 CRO's

- 403 Methods
- 188 Claims
- 161 CRO's

Since 1<sup>st</sup> January 2022

7 700  
USERS

+80 000  
VIEWED PAGES ON  
THE PLATFORMS

6 min  
TIME OF  
CONNECTION

+45%  
USERS  
VERSUS 2021

CONNECT FOR FREE SKINOBS.COM

## Safety Testing of Cosmetic Products by Dr. Goya



**ANMAR Clinical Services** have been specializing monographically in the in vivo safety evaluation of cosmetics for over ten years. Safety studies such as Patch Test, Photopatch, ROAT (Repeated Open Application Test),

In-Use or HIRPT tests are performed under medical supervision. **The studies babies and children** have special relevance and the inclusion and exclusion criteria are important for extrapolating the results obtained to the expected behavior on the market. It is important to evaluate each category of a cosmetic for designing the best type of study. At **ANMAR**, alongside **DR. GOYA ANÁLISIS** and **GAIKER**, we are ready to advise you on any needs that your final product may require, offering the entire portfolio of services to put your product into the market. The quality in the execution and the agility in the performance of safety testing is the hallmark of our company.

[www.laboratoriogoya.com](http://www.laboratoriogoya.com) | Corporate and testing sheet : <https://skinobs.com/preclinical/labo.php?id=404php?id=124>

## Best Standards for Confirming Skin Tolerance by Evalulab



International regulatory bodies require skin care products to be safe for use and not harmful to human health when applied under normal and reasonably foreseeable conditions. To ensure product safety, manufacturers must obtain adequate information, which may require clinical studies and specific testing techniques such as **the Human Repeat Insult Patch Test (HRIPT), non-comedogenicity test, and Tear-Free Test**. These tests can help them identify any potential issues with the product and make necessary changes before it gets introduced into the market. For example, HRIPT is designed to assess the potential irritation or allergic reactions that a product may cause on users.

<https://www.evalulab.com/en/> | Corporate and testing sheet: <https://skinobs.com/preclinical/labo.php?id=272>

## Global Expertise in Safety Tests from In-vitro to Multi-ethnic Clinical Studies by IEC Group



With more than 30 years of experience, IEC maintains its international reputation in safety testing by offering global expertise with its in vitro GLP laboratory in France and its 9 clinical

centers in France, Bulgaria, South Africa, and Asia (Japan, Singapore, Korea and China):

. **OECD GLP in vitro tests:** 3T3NRU, Het CAM, NRR, BCOP, Reconstructed Epidermis, Human Cornea Epithelium (HCE)...

. **Clinical tests:** patch tests, in use tests under Dermatological and Ophthalmological controls, comedogenicity, tests on sensitive and reactive skin, ocular tests for cleansing or sunscreen products...

Experience consolidated by a database of **several thousand tested products on all types of skin and ethnicities** allowing recognized expertise that meets the quality and safety requirements of cosmetic brands and international regulations.

[www.iecfrance.com](http://www.iecfrance.com) | Corporate and testing sheet : <https://skinobs.com/preclinical/labo.php?id=196>

# TOLERANCE THE ESSENTIAL EVALUATION ON HUMAN

After the first validations of the product toxicology, preservation [challenge test], stability and innocuity (in-vitro test), comes the necessity to ensure the consumers safety. The tolerance assessments implemented on human subjects highlight the absence of irritant, sensitization, photo-irritant and sensitization potential on normal or reasonably foreseeable conditions of use.

The safety assessment is conducted by experts (doctor, toxicologist or equivalent qualified person authorized by the regulation). Depending on the country regulation and on the clinical study design (babies, ethnicities, repeated applications, sun exposure...), the protocols can be submitted to the ethics committee.

There are 4 categories of tests:

### 1. Assessment of the irritation potential by Patch-Test

The patch test allows the study of skin tolerance by simple contact. It consists in a single application of the product, normally for 24, 48, 72 or 96 hours on volunteers under occlusive or semi-occlusive patch on the arm or the back. Then the outbreak of any skin reactions at patch removal [under medical or dermatological supervision].

### 2. Use test under medical control: dermatologists, ophthalmologists, gynaecologist or ophthalmologist, paediatricians

- Use test with repeated applications under the normal conditions of use
- Repeat Open Application Test (ROAT)
- No comedogenicity
- Ocular projection or instillation

### 3. Assessment of the allergenic potential

The sensitizing potential includes an induction phase, a resting phase, and a triggering phase  
TCFS, Final clinical safety test, Human Repeat Insult Patch Test (HRIPT-Marzulli & Maibach)

### 4. Phototolerance: toxicity and sensitization

Clinical evaluation by scoring of the skin aspect after 1 single application and a UV exposure. One application during 24 h on 3 areas under occlusive or semi-occlusive patch. The conclusion regarding the product safety represents the final analyses of the data and the results of the cosmetics tests under several criteria: exposure, conditions of use, risks of misuse validated by a medical assessment.

### 5. Sensitive skin

The claim «sensitive skin» is possible if both of the following conditions are met:

- a) The volunteers included in the test of use carried out under normal conditions of use declared recent and repeated history of functional symptomatology of skin discomfort (e.g., tingling, tightness, warm-up, itching, burning, redness...).
- b) These volunteers did not show an increase in symptomatology during the usual test functional skin discomfort analyzed as relevant.

You can retrieve all the tolerance tests and protocols in the Clinical Testing Platform:

- 27 methods
- 80 laboratories in 33 countries.



## Tolerance Evaluation - C-Cube by Pixience



The inflammatory response is a way for the body to defend itself. Local irritations are initiated by the contact of everyday substances. Anti-inflammatory agents are being incorporated into skin care products to improve skin tone and texture. The C-Cube Clinical Research allows you to **image and measure the degree of severity of erythema**. Thanks to the data contained in each pixel and the placement of ROI in the image, you ensure control and accuracy in your studies.

- Inflammation
- Swelling
- Soothing
- Sensitive skin

As always, remember that you can also outsource your data analyses to us through Pixience Cloud.

<https://www.pixience.com/> | Corporate and testing sheet : <https://skinobs.com/instrumentation.php?id=107>

## Clinically Ensuring your Products are Safe and Effective with Validated Claim Support



Proving that products work and how well they're tolerated are equally important in clinical studies. Certain ingredients are commonly known to cause skin irritation. If a product includes such ingredients, the skin is assessed by an expert grader or board-certified dermatologist. This assessment includes **objective and subjective grading** to monitor dryness, erythema, and edema as well as sensations like stinging, tingling, and itching.

VCS takes pride in making the safety of consumers a priority while substantiating claims and ensuring that companies are not releasing products that could have potential adverse reactions. VCS was chosen as Business of the Year in Teaneck, NJ.

<https://www.validatedcs.com/> | Corporate and testing sheet : <https://skinobs.com/labo.php?id=222>



## Ellead Conducts the Clinical Evaluation and In-vitro Test of Ocular Irritation Test



Depending on the characteristics of the ingredients in the cosmetics, some people feel pain or irritation symptoms in the eyes, so it is as important as skin irritation evaluation to make sure that the use of cosmetics is safe for the eyes. Ellead provides two services: **clinical evaluation and alternative animal testing method for eye irritation evaluation**. In the case of clinical evaluation, ophthalmologist conducts visual evaluation through «recurrent corneal erosine,» «hyperemia,» «inflammation,» and «TBUT» before and after using the product. The alternative animal testing method is an in-vitro test method that can be used under certain and limited conditions to classify and display hazards to chemicals with short-term exposure (STE) in accordance with the MFDS guidelines. The relative viability of SIRC cells is quantitatively measured using MTT assay.

<http://www.ellead.com/eng/1 Corporate and testing sheet> : <https://skinobs.com/labo.php?id=72>

## SAFETY TESTS AND THE 3R PRINCIPLE

The cosmetics industry needs testing alternatives especially in safety to replace animal testing that are just not anymore ethically acceptable. For safety testing, in-silico, in-vitro or ex-vivo methods represent **essential and reliable proof as predictors of the tolerance on human**.

The safety of the cosmetic product is the first step in its evaluation. In Europe a report is required, in the form of the **Product Information File (PIF)**, before it is placed on the market according to Regulation (EC) No 1223/2009 (Cosmetic Product Safety Report). This report on the safety of the cosmetic product includes a **Part A on the safety of the product** which gathers,

among other things, information on the formula composition, its physico-chemical and microbiological characteristics, its stability, its toxicological profile. **Part B is dedicated to the safety of the product** and the conclusions of its evaluation carried out by toxicologist experts. Preclinical testing verifies the margins of safety for each ingredient and determines what tests are needed, analytical, preclinical, or clinical, to ensure the product safety.

Tests such as **irritant, sensitization or photo toxicity potential** can be evaluated by **in-silico approach** or (Q)SAR ([Quantitative] Structure-Activity Relationship). This analysis defines, via mathematical models, the correlation between a chemical structure and a biological or chemical activity.

Then, safety tests are conducted on **chemical, cell cultures or 3D skin models**, through standardized or innovative assays. European Centre for the Validation of Alternative Methods (ECVAM) has developed several **OECD test guidelines** to provide reliable and scientifically satisfactory standards for in vitro assays. For each specific target, valuable diagnostic methods are proposed in many varied assays:

### 1. Skin toxicity

- **Corrosion:** Electrical Resistance TER | RET [OECD 430], Corrosion Skin 3D Model [OECD TG 431], Corrositex [OECD 435]...
- **Irritation:** HET-CAM, MTT cytotoxicity, XTT cytotoxicity, Dermal Irritation ET50 ...
- **Sensitization:** DPRA Direct Peptide Reactivity Assay [OECD 442C], Genomic categorization [Sens-is], H-CLAT [OECD 442E], U-SENS | IL-8 Luc [OECD 442], MTT- IL-8 [epiCS-SSPT], ARE-Nrf2 Luciferase KeratinoSens or Lusens Test [OECD 442D], Genomic categorization [GARDPotency OECD TGP 4.106], Genomic categorization [GARDSkin OECD TGP 1.406], ARE-Nrf2 Luciferase KeratinoSens or Lusens Test [OECD 442D], Combined approach [OECD 497] ...
- **Phototoxicity:** 3T3 NRU [OECD 432], INVITTOX 121, OECD 498, Photo-hCLAT, Photo-Comet Assay ...
- **Photosensitization:** Photo & Kinetic-DPRA Assay ...

### 2. Mucosa irritation: Irritation Assay System [OECD TG 496], Cellular viability [OECD TG 439], Zein solubilization test ...

### 3. Oral toxicity: OECD 129

- 4. **Eye irritation:** Neutral Red, Fluorescein Leakage Test [OECD 460], Short Time Exposure [OECD 491], EpiOcular Eye Irritation Test [EIT] [OECD 492], Bovine Corneal Opacity and Permeability [adapted OECD 437], Cytotoxicity [OECD 492 Like], Agarose Overlay, Acute and repeated exposure, Isolated Chicken Eye [OECD 438], Ocular Irritation Assay System [OECD 496], Chorioallantoic Membrane Vascular Assay, NociOcular Assay, Vitrigel®-Eye Irritation Test [Vitrigel®-EIT] [OECD 494], Serious eye damage and eye Irritation [OECD 263], Acute Eye Irritation/Corrosion [OECD 405]
- 5. **Genotoxicity - Mutagenicity:** Ames test [OECD 471], HPRT Gene mutation assay [OECD 476], Mammalian Cell Micronucleus Test [OECD 487], Genotoxicity, Comet Assay Mammalian Cell Gene Mutation [OECD 490], Micronucleus test, Chromosomal aberration test [OECD 473], Reconstructed Skin Micronucleus [RSMN], Adductomics, 3D skin Comet Assay.

For the skin sensitization test a combination of two in-vitro studies and an in-tubo test leads to hazard potential classification using an DA [defined approach]. These studies target three different key events in an Adverse Outcome Pathway (AOP). Two concordant results lead to the classification as sensitizer/non-sensitizer (UN GHS 1 or NC). In addition to this the new OECD 497 provides an Integrated Test Strategy (ITS) based on these studies plus in silico prediction (e.g. QSAR or DEREK Nexus database) and allows GHS Classification into Potency subcategories 1A and 1B.

**New Approach Methodology / Non-Animal Alternative Methods are now part of the routine toxicity testing of ingredients and cosmetics.** These methods are a response to the **3R principle– the Replacement, Reduction and Refinement of animal experiments.**



## SKINOBS NEXT EVENTS

**COSMET'AGORA** with support of COSMETOLOGIE  
Cosmet'Agora 2023  
Les 10 et 11 janvier 2023  
à l'Espace Champéret  
de 9h00 à 18h00  
15<sup>th</sup> EDITION  
Booth 92

**in-cosmetics®**  
global  
28-30 March 2023  
Barcelona, Spain  
Booth Z10

NEW YORK CHEMISTS SUPPLIERS' DAY  
**SAVE THE DATE FOR 2023**  
**SUPPLIERS' DAY 2023**  
MAY 2-3, 2023  
JACOB K. JAVITS CONVENTION CENTER  
NEW YORK CITY  
Booth 775

**cosmetotest**  
Cosmetic Testing Symposium  
25&26 May 2023  
Lyon  
Cosmet' in Lyon skin science | skinobs

## NEWS

Read the latest news on cosmetics testing.  
Subscribe to the free online Newsletter.

[www.skinobs.com/news](http://www.skinobs.com/news)

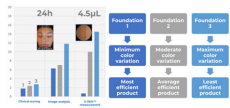
## New updated Colorimeter DSM-4 by Cortex Technology



What you need to know about skin color!  
The professional Colorimeter DSM-4 provides you with **accurate 4-in-1 measurements** at the same location for color, pigmentation, erythema, gloss.  
The DSM-4 features advanced software with fast and accurate automatic classification of skin phototype (ITA) in **6 groups: very light, light, intermediate, tan, brown and dark**. High quality working standards ensure reliable measurements over time. The Colorimeter delivered in a portable case with integrated calibrator – and in a high-end design.

<https://cortex.dk/> Corporate and testing sheet : <https://skinobs.com/instrumentation.php?id=90>

## U-Skin™: a Correlated Technology by Microfactory



U-Skin™ **reproduces the sebum and sweat excretion mechanisms** that our skin performs all day. This innovative technology allows the acceleration of such a process and can show the efficiency of your cosmetic products **within 4 hours** thanks to the controlled excretion flow rate.

Now, U-Skin™ is proved to be even more reliable in predicting the **products' long-lasting efficiency** since the results have been correlated in-vivo / in-vitro with the help of our **CIDP partner**. Three bench foundations were screened, and the three evaluations (clinical scoring, image analysis, and U-Skin™ measurement) show similar results which indicates a strong correlation between in-vivo / in-vitro results.

<https://www.microfactory.eu/> Corporate and testing sheet : <https://skinobs.com/preclinical/labo.php?id=266>

## A New Solar Light Simulator for Helioscreen Cosmetic Science



Helioscreen, a laboratory for the in-vitro evaluation of sun protection **for more than 20 years**, and which performs tests such as SPF, UVAPF, Infrared, Blue Light or Water Resistance, has received its second solar simulator. This second simulator will allow the team to perform twice as many tests to irradiate cosmetics and to determine the different UV (UVA, UVB and UVC).

In 2022 it is about 1300 products which were irradiated within their laboratory.

<https://www.helioscreen.fr/en/> Corporate and testing sheet : <https://skinobs.com/preclinical/labo.php?id=201>

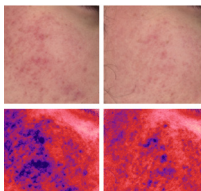
## The Impact of the European Strategy for a Toxic Free Environment on the Future Cosmetic Regulation by Expertox



In the context of the European strategy for a toxic free environment, EXPERTOX can support you either for the **analysis of your materials, or also for regulatory procedures** and risk assessment in order to comply the future regulation requirements of the cosmetic regulation. These changes are pushing manufacturers to innovate. Concerning active substances, as for example UV filters, since some of them are suspected endocrine disruptor, and could impact or deteriorate the marine environment, new substances are now being developed, including UV-tolerant compounds derived from algae. Indeed, they are considered safe and have negligible cytotoxicity effects on humans, a full ecotoxicity and toxicity profile should be evaluated within this future regulation context.

<http://www.expertoxcabinet.fr/> Corporate and testing sheet : <https://skinobs.com/preclinical/labo.php?id=199>

## Evaluation of Sensitive Skin by Antera 3D by Miravex



Sensitive skin is a common and frequently occurring skin disorder that may affect about 30-50% of the global population, which can be manifested as facial erythema accompanied by pruritus, burning or tingling sensation, and skin tightness.

**A recent publication has proposed the Antera 3D as a method** to objectively detect and quantitatively evaluate sensitive skin by analyzing **texture, hemoglobin, and influenced area**. The ANTERA 3D provides accurate values of hemoglobin and influenced area, helping to quantitatively evaluate the degree of inflammation in subjects with sensitive skin.

<https://miravex.com/> Corporate and testing sheet : <https://skinobs.com/instrumentation.php?id=72>

**Skinobs map:**  
a worldwide view  
of your testing



## Efficacy Tests and Sensory Evaluation of Suncare Products by Imasens



Imasens has been offering its expertise for **16 years in the sensory experience** of the consumer for the evaluation of the effectiveness and sensoriality of

- The **efficacy tests** are carried out on different continents with target users (men, women, seniors, children) who will evaluate the suncare product in daily photoprotection and/or prolonged exposure to the sun at the beach, in the mountains, at the pool, after swimming, etc. The objective is to validate the specific claims of the suncare product in real conditions of use.
- The **sensory phase** will allow to describe the product visually, the feelings when applying and the result of the product on the skin. The interactions of the product with sand/water can also be studied with our panel of experts.

The combined results of these 2 methodologies will allow you to propose suncare products adapted to the market demand.

<https://imasens.fr/> Corporate and testing sheet : <https://skinobs.com/labo.php?id=188>

## Global Claims, Global Recruitment by proderm



SGS proderm conducts an average of about **600 clinical trials every year**. Most of these studies are in vivo investigations with healthy volunteers or patients with different skin diseases.

With regard to the recruitment of study participants, one topic is currently very present: the **integration of multi-ethnic groups**. Depending on the study specifications and requirements, recruiting such a panel can be very challenging. Based on our dedicated recruitment strategy and our cooperation with colleagues from SGS Institut Fresenius GmbH, we have now doubled the capabilities in enrolling multi-ethnic panels.

<https://www.sgs-proderm.de/en/> Corporate and testing sheet : <https://skinobs.com/labo.php?id=9>

## A Flexible Way to Look at Skin & Hair Colour and More by Courage + Khazaka



The **Skin-Colorimeter Flex CL 440** is a new generation of colour measurements on skin, hair and other material in the CIE L\*a\*b\* colour space. With **two interchangeable measuring tips and new placement aid feature**, even small skin areas can be captured precisely.

- Maximum accuracy, LEDs with high CRI (colour rendering index)
- Interchangeable measuring tips: cylindrical for skin & hair and conical for particularly small skin areas, pigmented spots and lesions, nails, lips or other materials.
- Unique placement aid: Light spots overlapping each other indicating where the measurement will take place.
- Sealed electronics and removable tips can be cleansed easily.
- Automatic calculation of ITA (Individual Typology Angle) for each measurement.
- Hair clip for convenient placement on hair surface.

<https://www.courage-khazaka.de/de/> Corporate and testing sheet : <https://skinobs.com/instrumentation.php?id=80>



## CONTACT US

[contact@skinobs.com](mailto:contact@skinobs.com) | [www.skinobs.com](http://www.skinobs.com)

14 avenue de Verdun  
73100 Aix-les-Bains - FRANCE