IS CONSUMER SAFETY STILL AT THE HEART OF COSMETIC PRODUCT DEVELOPMENTS

C.C.A. group

Create it. We test it.

CONTENTS

A SHORT SUMMARY OF THE PARABEN BASHING PHENOMENON

Chronicle of a death foretold

In 2012, certain parabens, some of them well-known and long since proscribed (iBu-P for example), were suspected of being Endocrine Disruptors (ED). The word got out! In just a few short weeks, without waiting for the verdict of the SCCS*, a massive media campaign was prepared, launched and spread, demanding that ALL parabens immediately became banned substances.
This media frenzy lead to the Lachaud law proposal (rejected in the end) and also, more importantly, to the cosmetic industry's systematic removal of ALL parabens as cosmetic product ingredients (Blacklist).

A few months later, the verdict of the SCCS* was published confirming the innocuousness of the main parabens currently in use (Methyl-P., Ethyl-P. and propyl-P.)... Too late! Now that they were dead and buried, the "good" parabens were to become nothing more than ghosts of the living dead haunting the nightmares of formulators.


L'alchimie zen

Le Figaro nov. 2012

The scenario could almost have been lifted straight out of some popular TV series and it would be repeated for other molecules, but it could be quite interesting to consider its consequences in terms of safety.

Between what "is perceptible" and the reality of the figures, the C.C.A. Group wiped out 10 years of our cosmetics formulation history.

What has really changed?
Have the objectives been reached?
Torn between the public demand for increased safety and the market's desire for naturalness.

The C.C.A. Group is right at the heart of cosmetics testing and has therefore been able to observe trends in cosmetics using the data it has gathered through internal tests completed over the period.

**Scientific Committee on Consumer Safety*


Les femmes, le Botox et les plantes

Le Monde nov. 2012

THESE SHORT-LIVED COSMETIC FORMULAE...

THE COSMETIC INDUSTRY WAS IN RAPID ACCELERATION BETWEEN 2013 AND 2018

From a regulatory point of view: not much has changed. No major changes were made to the Cosmetics Regulation and its appendixes. As for the SCCS, it has published opinions that were both reasonable and of little great consequence.

However, regarding the quality control of industrial tools, a lot of resources and energy were being drained:
- Application of the GMP (Good Manufacturing Practices),
- ANSM inspections (Agence Nationale de Sécurité du Médicament et des produits de santé – National Agency for Medicine and health product safety),
- Process validation, Raw materials classifications,
- Optimisation of flows

Even if some major differences remain, Europe has some of the world's best production Installations.

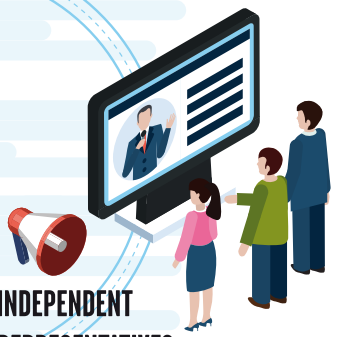
As regards formulation: An accelerated RENEWAL of formulae is under way...

Less than 3 years: we have observed that a new cosmetic formula has generally never had such a short life-span... This agitation is motivated by the need to revise all of the formulae, but will it benefit consumer safety?

INFLUENCING CHANGE

Organic, Green, Free, Clearness... Consumer expectations are complicated and constantly evolving. The balance of power between these groups is flatly changing.

EXPERTS
Legislators
Scientists
Industrial companies and Brands



INDEPENDENT REPRESENTATIVES
UFC – Que Choisir
60 M. de Consommateurs
(The leading French consumer magazines)
"Classic" media

INDEPENDENT INFLUENCERS
Applications
Bloggers
Social media

C.C.A. GROUP EXPERTISE

The C.C.A. Group brings together a number of French-based cosmetic product testing laboratories that have been operational for over 40 years. The C.C.A. Group therefore has access to a huge volume of numerical data. Stability, microbiological contamination, tolerance, all of the parameters are scrutinised to support the major cosmetic brands and industrial producers.

The data that will be presented, and which will be used as the basis for the analyses, are the fruit of many years of tests.

B

STATE OF PLAY

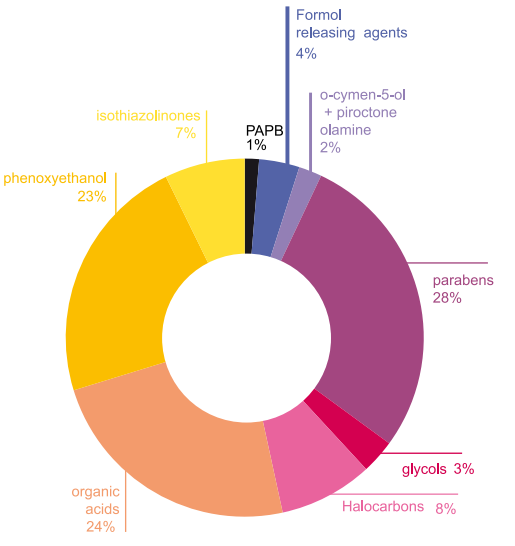
DEVELOPMENTS IN PRESERVATIVES

If we consider the chemical and physicochemical point of view, and more particularly the distribution of preservatives before 2012 and after the changes enacted by the businesses involved, we can clearly see that the cards have been shuffled and dealt out for a second time.

Whilst the use of parabens in formulae had already become increasingly rare, as was also the case with isothiazolinones, 2013 saw a significant drop in the use of both of these two groups of preservatives.
Phenoxyethanol use lowered significantly during the same period.
In reflection to this the number of formulae using organic acids has "exploded". The other listed preservatives have also maintained their places.

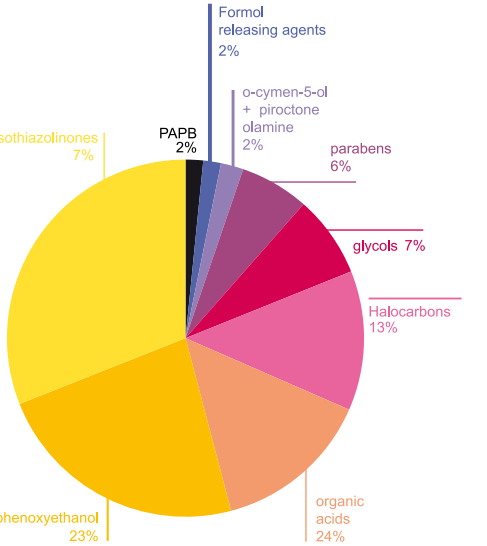
However the statistics do not show (with reason) any massive use of, non-regulated and therefore not-dosed, "multi-functionals" - (glycols), or any major increase in formulae without any listed preservatives.

In 2018, half of all formulae produced in France contained organic acids.



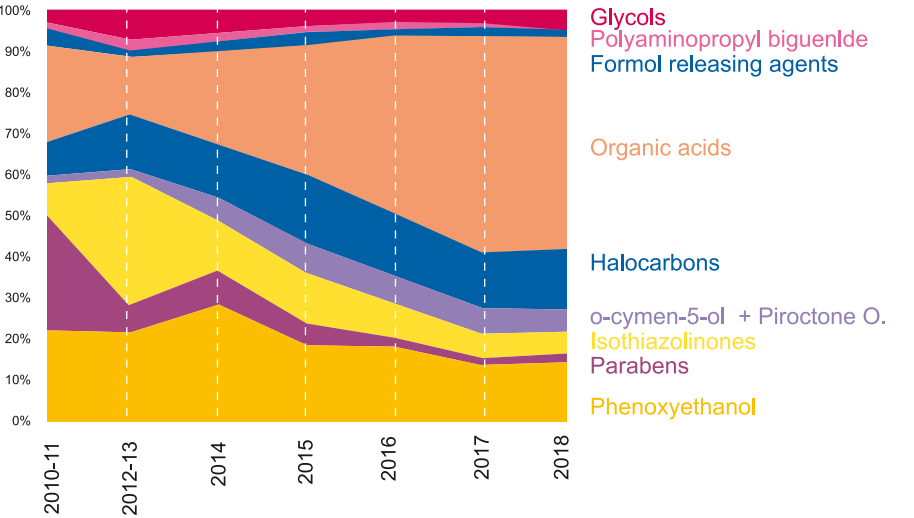
2010-2011

Phenoxyethanol, organic acids and parabens in equal proportions



2012-2013

The proportion of parabens in the cosmetic formulae drop significantly mostly in favour of isothialonones and phenoxyethanol



THE PRESERVATIVES LANDSCAPE 2010-2011

Over a period of 10 years, the cosmetics industry has gambled hugely on organic acids, mostly to replace of paraben

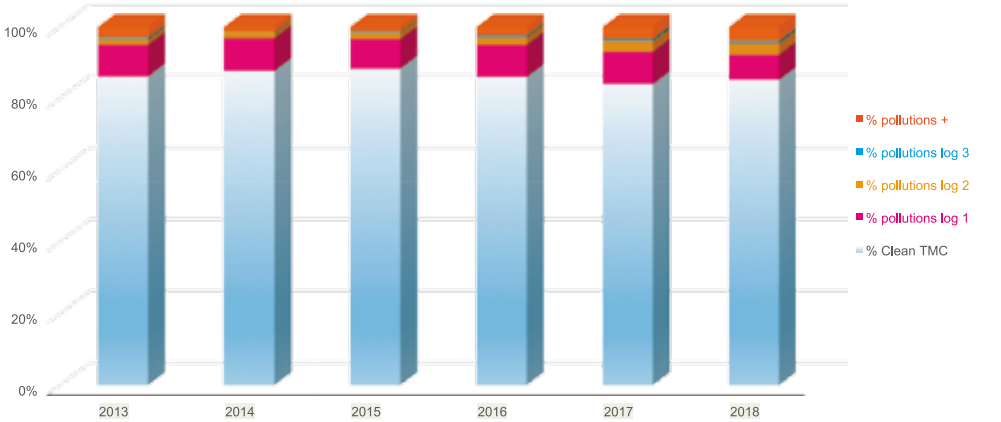
ARE NEW FORMULAE SAFER?

The two graphs opposite show the levels of contamination observed between 2013 and 2018. Whether it be the enumeration of all germs or the detection of pathogen germs, we have not observed a greater number of microbiological incidents.

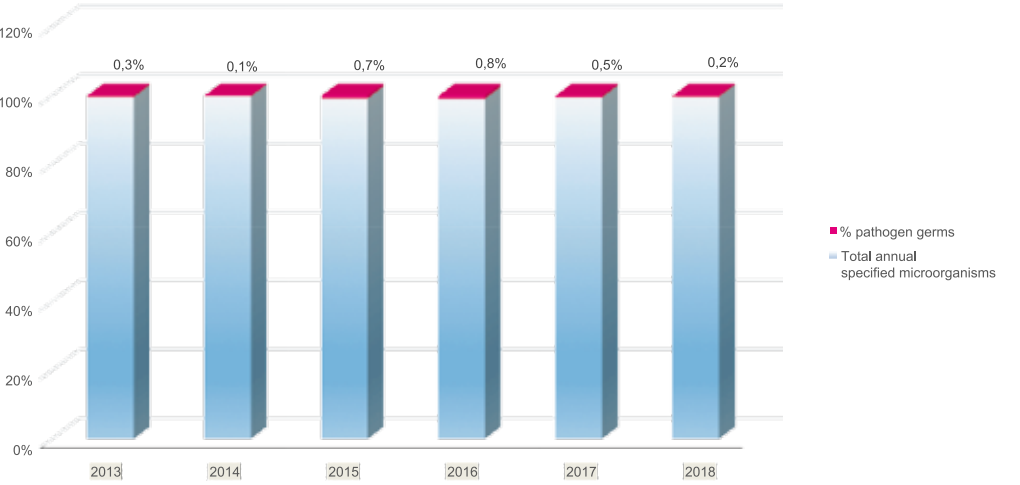
No more contamination then... but no less either.

This is another way of looking at the results considering the effort made.

TRENDS: MICROBIOLOGICAL RELEASE TESTING



Distribution of contaminants:
Enumeration of aerobic mesophillic bacteria, yeasts and moulds



Percentage of analyses that detected one of the four pathogen germs

In spite of the efforts agreed on by the Cosmetics Industry, the contamination rate has not diminished. So the formulae are not safer.

CHALLENGE TEST

There is a test-bench for preservative effectiveness: the challenge test!

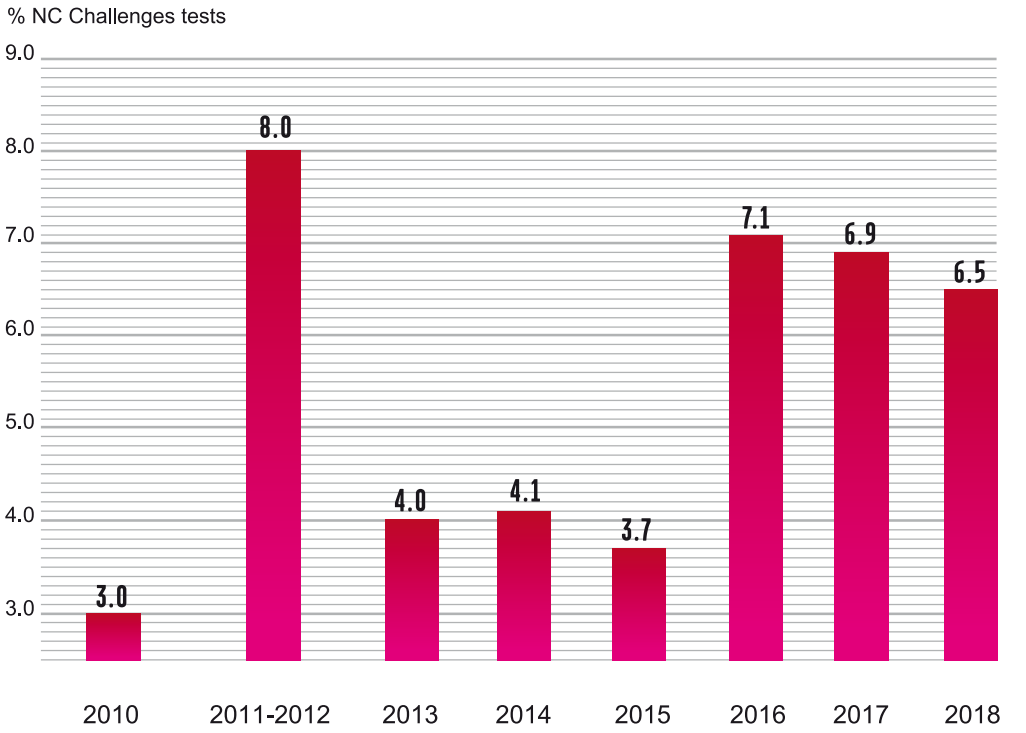
OBSERVATIONS MADE IN 2013:
The graph opposite shows that there is a growth peak in the "non-compliant" proportion for anti-microbial performance tests around 2011/2012.

THE TRENDS:
Since they have stopped using parabens, the whole industry is hesitating. We have observed a lot of failures for formulae and a lot of time spent looking for new preservative solutions...

Since 2013, control is better.
Over the last 3 years, no major changes have been observed; but a constant 7% threshold has been maintained, twice that of 2014 et 2015.

What is a challenge test?
Before commercial release, the formula of a cosmetic product will be intentionally contaminated with listed pathogenic agents (Inoculum). Over a period of 28 days, one observes at specific points in time whether these agents disappear, increase or stagnate in number.

PROPORTION OF NON-COMPLIANT CHALLENGE TESTS (B AND NC* CRITERIA)



In 2011-2012 the proportion of NC Challenge tests was significantly high (8%). The industry just did not know what to do. The figures then stabilised. But for the last few years a stable figure of around 7% has been reached.
We have never returned to the preservative performance figures of 2010: over ten years, the number of non-compliant challenge tests has doubled.

*Challenges test results are expressed as 3 levels: NC (non-compliant), criteria B, criteria A.

A SURVEY OF THE ANTI-MICROBIAL PERFORMANCE OF FORMULAE

And so the post-paraben era advances precariously.

The recorded data shows that there has been no increase in microbiological incidents during production but nor has there been any decrease; and at the same time the number of failed Challenge Test has in fact increased over the last 3 years.
In addition, the figures do not show:

Any explosion in "Objectionables", those undesirable germs, agents of deterioration and opportunist pathogens (Burkolderia sp., Pluralibacter sp., Pseudomonas sp.) which have newly "set-up home" in cosmetic formulae.

The more frequent activation of micro-organism destroying processes after production. Heat-treatment and irradiation remain the most common processes used.

Brands have increased the hygiene standards of all of their tools

Brands have lowered anti-microbial capacity of formulae

The two phenomena compensate each other

New formula specifications increase the difficulties of preserving the products correctly. So cosmetic formula are more fragile in 2019.

Three types of micro-biological contaminants in cosmetics· Les micro-organismes standards (sans réel impact).
· Standard micro-organisms (no great impact).
· Pathogen agents: considered as dangerous to human health.
· The "objectionables": a mixture of the first two. Those which can affect the colour, odour and which can present a risk in terms of the quantity, application zone and the consumer's age.

ARE NEW FORMULAE BETTER TOLERATED?

CUTANEOUS TOLERENCE IN 2013

A cyclic effect has been observed.

Figures showed that the number of irritant patch tests had doubled between 2008 and 2013.

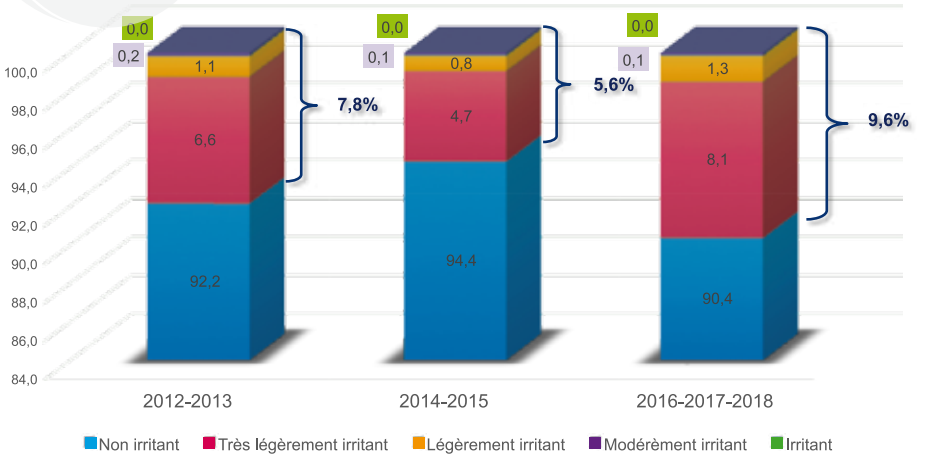
Then after a short cutaneous tolerance control phase during 2014-2015, the increase in irritation problems went on to increase over the last three years.

On the basis of equal parts rinsed and non-rinsed formulae, eye irritation problems have also seen a significant increase over the last 3 years **and are now settled at just under the 10%.**

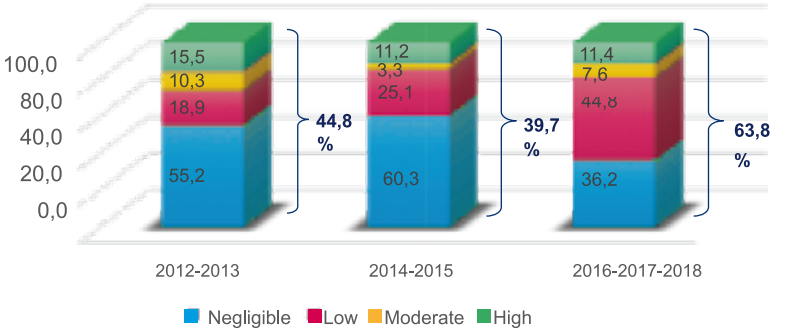
However: the significant variability of usage test input data (number of subjects, skin-type, etc.) makes it very difficult to come to any acceptable conclusion on the subject of tolerance. These figures have no proportional relation with cosmetovigilance data.

Conclusion: the profession is seeking new formulation solutions.

TRENDS SINCE 2012: DEVELOPMENTS TO TOLERANCE



EVALUATION OF CUTANEOUS IRRITANT POTENTIAL (PATCH TEST)



EVALUATION OF EYE IRRITANT POTENTIAL (CYTOTOXICITY)

1 IN 10 FORMULAE TOLERANCE ISSUES

E

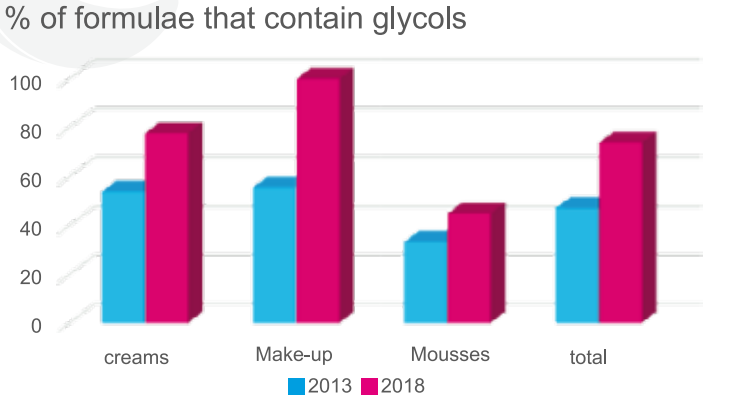
INTERPRETATIONS

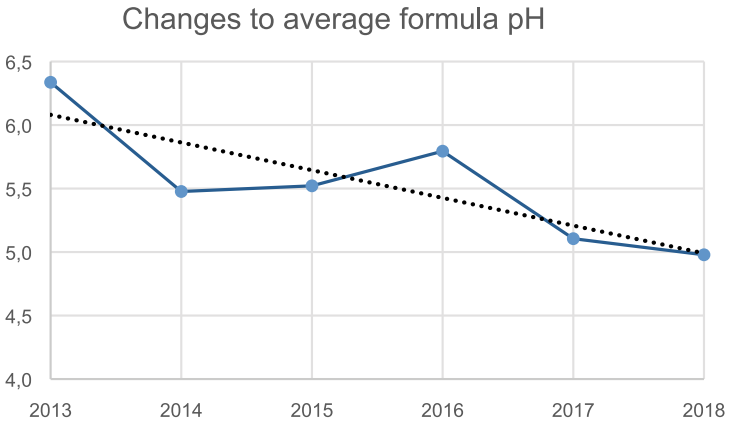
INTERPRETATION OF MICROBIOLOGICAL SAFETY

- The anti-microbial performance of formulae is regressing as molecules are less controlled
- The contaminated product rate has stagnated
- At the same time, the application of GMP (Good Manufacturing Practises) and the massive revision of production tools have managed to offset some formula protection failures.

The consumer is not benefiting from any global improvement in microbiological safety but production and its efforts seem to be offsetting the phenomenon for the moment.

INTERPRETATION OF TOLERANCE





The figures have swung back and forth over the last 10 years but a trend can be confirmed : the formulae are less well tolerated.

There has been a significant increase in the use of glycols in formulae to reduce water activity; Irritants often encourage the permeability of the stratum corneum and transcutaneous penetration.

Organic acids are now massively used as preservatives.

The average pH of formulae is gradually getting lower, they are becoming increasingly acid.

CONCLUSION & PERSPECTIVES

If we could reduce all of this to an image one could imagine the gearwheels inside the mechanism of a clock.

Any modification to an active ingredient in a formula can have an impact on consumer safety.

The chemical, physicochemical, microbiological and toxicological safety parameters are all interdependent, just like the gear-wheels and their springs, and depending on their diameters and force.

As the formulae are developed, the combined monitoring of all of these different systems is absolutely essential.

If we can observe that certain substances are about to disappear (such as phenoxyethanol), others are gradually appearing on the scene, such as HEPB - Ethylzingerone.

Common sense is not incompatible with innovation. This is one of the identifying traits of an industry that is in a constant state of renewal.

C.C.A. GROUP

The C.C.A. Group is made up of 3 perfectly complementing specialised centres:
· Microbiological expertise
· Physicochemical trials
· Clinical trials

COSMEPAR
Clinical Testing

MORE THAN 6,000 VOLUNTEERS
8 DOCTORS ON A SINGLE SITE

·Ocular and cutaneous primary tolerance tests
·Medically supervised iterative tolerance tests (Dermatologists, Ophthalmologists, Odontologists, etc.)
·Dermoscopic analyses (skin radiance, cutaneous isotropy, anti-blemish, long-lasting make-up, etc.)
·Measurements (cutaneous micro-relief, cutaneous firmness, hydration, transepidermal water loss, etc.)
·Imaging (2D HD, 3D, electron microscope, etc.)

COSMEBAC
Microbiological Expertise

12,000 QUALITY CONTROL ANALYSES PER YEAR
5,000 CHALLENGE TESTS PER YEAR

· Challenge test Express (Biolumix screening)
· Challenge test ISO 11930 and Ph. Eur.
· Quality control
· Express 24h using flow cytometry
· Standardised (ISO) total germ enumeration
· Standardised (ISO) pathogen detection
· Identification by mass spectrometry
· Cryo-conservation of bacterial strains service

ANALYTEC
Physicochemical Trials

RELEASE WITHIN 48H
600 CATALOGUE TESTS
EXPRESS COSMETIC PRESERVATIVE AND ACTIVE INGREDIENT DOSING

Listed and unlisted preservatives, anti-oxidants, UV filters (organic, mineral, etc.), colouring agents, perfumes, whitening agents, auto-tanning, vitamins, anti-dandruff agents, hair-removal products, fatty acid profiles

Verification of the absence of undesirable substances
Parabens, allergens, residual solvents (VOC), phthalates, bisphenol A, pesticides, HAP, heavy metals, nano-particles, formaldehyde, hydroquinone

Chemical analyses
Stability / compatibility, DDM / PAO evaluation, interaction, container / content migration, sun test, industrial tool cleaning process validation, methods validations in keeping with the ISO 12787 Standard

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Contributors:

Jean-Louis FIACRE Toxicologist, Commercial Director, C.C.A. Group
Gaël GERVAIS Doctor of Chemistry, Laboratory Manager, ANALYTEC
Justine PENNEL Clinic Regulatory Coordinator COSMEPAR
Charles REINIER Engineer in Microbiology, Technical Director C.C.A. Group

Technical data: C.C.A. Group

C.C.A. Group - Tél: +33 (0)2 40 68 50 50 - adv@cosmepar.fr
Espace performance La Fleuriaye, 2 rue Alessandro VOLTA,
44470 CARQUEFOU - FRANCE
www.cca-group.fr