

# **Cosmetics** Consulting, Analysis and Expertise

## SAFE | INDEPENDENT | COMPETENT







### Safety and harmlessness to health

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The harmlessness to health, quality, safety and stability as well as consumer protection are of fundamental significance for all cosmetic products. Cosmetic products are subject to the provisions set out in Regulation (EC) No 1223/2009. The national ordinance on cosmetic products (Kosmetik-Verordnung) is applied in addition, regulating in particular requirements regarding language and national obligations of disclosure.

We support our customers in the cosmetics industry with state-of-the-art laboratory analysis methods and excellent expertise – from our analysis in laboratories, appraisal services to the certification of your products. In our capacity as a leading cosmetics testing laboratory we work on the basis of approved standard methods as well as individual customer requirements. We offer customer-specific solutions for chemical, physico-chemical and microbiological tests as well as for the development and validation of methods.

The WESSLING experts provide answers to your questions about the legal provisions regarding cosmetics. Our expertise in the field of cosmetics comprises labelling reviews, safety reports and notifications as well as marketability certificates. Our cosmetics experts also support you on site in the optimisation of your production processes by way of competent sampling, audits as per GMP (Good Manufacturing Practice) and hygiene trainings.







### Microbiological tests



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- → Overall microbiological status, microbial purity test
- → Aerobic and anaerobic bacteria, yeasts and moulds
- → Pathogenic germs: Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans etc.
- ightarrow Identification of microorganisms
- ightarrow Testing for other microorganisms such as Lactobacilli, Enterobacteriaceae etc.

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- ightarrow Bacteria endotoxins
- ightarrow Validation of methods and suitability test

### Preservative challenge test – Testing for sufficient preservation



## The quality and safety of cosmetics is of the highest importance both for manufacturers and consumers.

The used preservation system is a decisive factor for microbiological product safety. The preservative challenge test is used to assess the microbiological stability of the product. This is a mandatory part of the safety report, depending on the product.

The test is carried out using generally approved and published methods, usually as per ISO 11930. During testing, the cosmetic product is inoculated with suspensions of select microorganisms. After specific storage periods, the decay rates of the respective germs are assessed, expressed in log rates. The product's preservation characteristics are assessed on the basis of the thus determined reduction rates.

#### Our services:

- → Testing for sufficient preservation (preservative challenge test)
- ightarrow Testing with standard germs according to relevant standards
- → Additional consideration of other product-specific microorganisms in the testing for sufficient preservation
- ightarrow Single inoculation of the product
- ightarrow Repetitive test methods (repeat inoculation of the product)
- → Customer-specific test design
- ightarrow Interpretation of results and troubleshooting



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### Physico-chemical tests



#### Our services in the field of chemical and physico-chemical testing include:

- ightarrow Allergenic fragrances, Majantol
- $\rightarrow$  Preservatives
- $\rightarrow$  Formaldehyde
- → Verification of cosmetic active ingredients (e.g. allantoin, bisabolol, Q10, glycerine, hyaluronic acid, zinc oxide, titanium dioxide, UV filter substances)
- $\rightarrow$  Vitamins (e.g. panthenol, tocopherol, retinol)
- $\rightarrow$  Oxidation stability (Rancimat test)
- $\rightarrow$  Fat parameters (acid value, peroxide value etc.)
- $\rightarrow$  Physical parameters such as density, pH-value, viscosity, water activity (aw) etc.
- ightarrow Surfactants: qualitative and quantitative testing of different surfactant classes

The tests ensure adherence to legal provisions and support you in the assessment of product specifications. The range of services includes also parameters that 'Stiftung Warentest', 'Ökotest' and other institutions regularly analyse in their product tests.

### Analysis of residues

The testing for certain residues and contaminants is an essential element in the assessment of the safety of cosmetics. Regulation (EC) No 1223/2009 stipulates clear requirements regarding the safety and purity of products and used raw materials.

Potential contaminants must be taken into account and assessed when compiling the safety report.

### WESSLING identifies the following residues in cosmetics and raw materials using highly sensitive measurement methods:

- $\rightarrow$  Phthalates
- ightarrow Nitrosamines, e.g. NDELA
- $\rightarrow$  Polycyclic aromatic hydrocarbons (PAH)
- → Heavy metals: determination after pressure decomposition as well as determination after artificial sweat test
- → Chromium (VI)
- $\rightarrow$  Pesticide residues
- $\rightarrow$  MOSH/MOAH: mineral oil residues
- $\rightarrow$  Solvents such as benzene, toluene etc.
- ightarrow Polycyclic musk and nitro-musk compounds
- ightarrow Asbestos (in decorative cosmetics etc.)
- ightarrow Organic halogen compounds



## Dermatological and clinical tests

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Cosmetics have to feature corresponding skin compatibility in consumers when applied. Claims regarding certain effects have to be tested and must be sufficiently proven.

## Our services in the field of dermatological tests and other analysis of cosmetics include:

- → Skin compatibility testing (epicutane test) for normal and sensitive skin (after tape stripping)
- $\rightarrow$  Eye compatibility (ophthalmologic tests)
- ightarrow Determination of sun protection factor: in vitro and in vivo
- ightarrow Water resistance of cosmetics

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- $\rightarrow$  Efficacy testing: skin hydration, wrinkle depth etc.
- ightarrow Claim support on the basis of a questionnaire evaluation



### Expert evaluation services

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Consultancy and expertise in all issues regarding cosmetics are key topics in the work of WESSLING. Only good and competent consultancy gives you the security you need in order to sell your products to consumers.

#### Our expert evaluation services:

- → Labelling expertise of your product national and international
- → Document review with regards to observance of documentation obligations as per Regulation (EC) No 1223/2009
- → Expertise of claims regarding effects as per Regulation (EU) No 655/2013 (Claims)
- $\rightarrow$  Marketability evaluations
- ightarrow Compilation of safety reports

- $\rightarrow$  Toxicological evaluations
- Compilation and legally compliant storage of product information files (PIF)
- → Notification of your product in the European Union's CPNP database
- → Legal advice and expert evaluations in all matters pertaining to Regulation (EC) No 1223/2009









### Services on site

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WESSLING supports you on site at your production facility to ensure the quality and safety of your products. Experienced colleagues lend you their competent support. Looking behind the scenes can be indispensable at times. Please do not hesitate to contact us.

### We support you swiftly and competently with the following on site services:

- → Plant hygiene: microbiological control of room and production air as well as inspection of surfaces, devices and machines
- ightarrow Personal hygiene
- ightarrow Performance of hygiene trainings

### Other services:

- ightarrow Sampling of raw materials and finished products
- → Consultancy in the event of deviations and anomalies in the production and manufacturing process
- ightarrow Process optimisation

### Nanomaterials

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WESSLING offers its customers a wide range of services in the field of particle measurement methods, especially of nanoanalysis. Nanomaterials are materials that are on a nanoscale (1-100 nm) in at least one dimension. Different sizes of a material can result in novel characteristics that are already being utilised in many cosmetic products. This includes titanium dioxide and zinc oxide as UV filters as well as micelles as an active ingredients and delivery system.

Regulation (EC) No 1223/2009 on cosmetic products stipulates explicit requirements regarding nanomaterials. These specific requirements apply to the assessment and notification. For example, insoluble nanoscale ingredients of a cosmetic product must be identified in the list of ingredients.

#### Our services in the field of nanomaterials in cosmetic products:

- ightarrow Quality analysis of raw materials on a nano- and micrometer scale
- → Comprehensive consultancy with respect to Regulation (EC) No 1223/2009 on cosmetic products regarding nanomaterials
- → Individual development and adaptation of analytical services to meet customer requirements
- ightarrow Consultancy regarding the safe use of nanomaterials





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### Nanoanalysis of micelles

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The WESSLING experts support manufacturers, the manufacturing industry and users of micelles with their analytical know-how.

Nanocarriers are systems that are used to carry active ingredients and that are not readily water- or fat-soluble. Such systems are of increasing significance in skin cleansing and moisturising care products, such as facial toner. The active ingredients systems consist of biologically degradable and easily soluble nanostructures such as micelles, liposomes, nanoemulsions and lipid nanoparticles.

These nanoscale structures can penetrate through the natural barrier of the outer skin surface into the deeper layers of the skin where they release their targeted effect. Micelles form in an oil-water mixture under addition of amphiphile surfactants. As of a certain concentration, surfactants form spherical structures in a solution – micelles. Their diameter is approximately between 5 and 100 nm.

#### Our services in the field of micelle analysis in cosmetic products:

- → Testing of emulsions containing micelles by way of cryo-scanning electron microscopy
- $\rightarrow\,$  Testing of size distribution and homogeneity by way of dynamic and static light scattering
- ightarrow Determination of critical micelle concentration (CMC)

### **GMP** – Good Manufacturing Practice

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#### We make your cosmetics fit for GMP.

GMP stands for 'Good Manufacturing Practice' and provides guidelines for the quality assurance of production processes and production environments also including the production of cosmetics.

It conveys the practical development and implementation of quality assurance. The requirement of a GMP compliant production of cosmetic products has been firmly established in the cosmetics industry for many years.

Regulation (EC) No 1223/2009 demands that the production of cosmetic products must be in compliance with GMP. The publication of the DIN EN ISO 22716 standard in the Official Journal of the European Union means that it can be assumed that adherence to that standard entails sufficient consideration of the principles of GMP. A declaration regarding the observance of GMP must likewise be submitted in the context of the product information file.

#### We support you in making your products fit for GMP with the following services:

- $\rightarrow$  Initial site inspection and audit of production facility
- ightarrow Assessment and audit of the existing GMP concept
- $\rightarrow$  Consultancy regarding any questions about GMP-compliant manufacturing
- $\rightarrow$  Consultancy regarding DIN EN ISO 22716
- $\rightarrow$  Employee trainings







PLASTIC IDENTIFICATION BY WAY OF INFRARED SPECTROSCOPY

HEAVY METALS

such as arsenic, lead, cadmium, antimony, nickel, mercury ...

# **BISPHENOL A**



POTENTIAL CONTAMINANTS IN PACKAGING

## Analysis of cosmetic product packaging

#### General requirements regarding packaging

Packaging primarily serves to protect the cosmetic product. It has to be designed in a way so as to exclude the undesired migration of substances from the packaging into the product, that is, the packaging having a negative impact on the contents. This means that the correct choice of packaging for a given cosmetic product plays a key role both in the design of new products and the potential change of packaging for already existing cosmetic products. Interaction between the packaging and the cosmetic product cannot be fully excluded. For example, the migration of formaldehyde from certain plastics (POM) is a known issue. This must be taken into adequate consideration when assessing the safety of packaging.

#### Packaging and safety report

Regulation (EC) No 1223/2009 on cosmetic products explicitly stipulates that the packaging must be taken into consideration in the compilation of the safety report (Annex I). Potential contamination, traces of banned substances as well as the relevant characteristics of the packaging, in particular purity and stability, must be included. Uniform and comprehensive provisions regarding specific limit values, groups of substances etc. are not available, which is why regulations from the field of foodstuff packaging are often used in assessments.

The experts at WESSLING support you in a competent and targeted manner both in the selection and implementation of potential test parameters for the packaging of your cosmetic product and in the subsequent evaluation of test results.

#### Our range of services regarding analysis of packaging:

- ightarrow Overall migration testing
- → Specific migration testing, e.g. for formaldehyde, bisphenol A, phthalates, heavy metals, BHT, special plastic additives
- → Testing regarding olfactory/optical spoiling of the cosmetic product due to the packaging (sensory testing)
- ightarrow Testing for potential contaminants in the packaging, e.g. phthalates
- → Bisphenol A
- $\rightarrow$  Nonylphenols and nonoxynols
- $\rightarrow$  Polycyclic aromatic hydrocarbons (PAH)
- $\rightarrow$  Heavy metals such as arsenic, lead, cadmium, antimony, nickel, mercury etc.
- $\rightarrow$  Plastic identification by way of infrared spectroscopy
- $\rightarrow$  Testing of wooden packaging for formaldehyde, wood preservatives etc.
- ightarrow Comprehensive other special tests upon request





# REACH, CLP and dangerous goods legislation

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The European chemicals regulation REACH and other legal provisions governing chemicals, for example, the CLP Regulation (EC) No 1272/2008 (Classification, Labelling and Packaging of Substances and Mixtures) and the dangerous goods legislation, confront manufacturers of cosmetic products with a host of new requirements. Cosmetic products are in part exempt from the REACH regulation. Even so, a wide range of tasks must be fulfilled along the supply chain, for manufacturers are held responsible for the safe use of chemicals.

WESSLING supports you with a team of experts in the field of REACH regulation and legal provisions governing chemicals. This includes the assessment of the role within the supply chain and the resulting obligations. The WESSLING experts deal with it all for you in a tailored manner, from the legal requirements regarding the import and production of raw materials and the potentially resulting registration obligations, the labelling as per chemicals legislation, to the demands resulting from the dangerous goods legislation.

# Test seal

You are planning on obtaining national or international quality standard certification for your company? Or you want to obtain certification of your product with an approved seal?

We support and advise you, carry out the necessary analysis and internal preliminary audits and thereby offer you a complete solution from a single source.

Moreover, you secure competitive advantages by obtaining our independent WESSLING test seal for your products.









Place your trust in the know-how of the WESSLING experts for the entire production chain of your cosmetic products.































# Cosmetics know-how, throughout Germany and internationally – from a single source.

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**WESSLING** is an international and independent laboratory, testing and consulting company represented at 26 locations in Europe and China. The family-owned company enjoys an excellent reputation among national and international customers since 1983. 1,400 employees work with great expertise on the continuous improvement of quality and safety, and of environmental and health protection. We examine, analyse and assess, we plan and implement projects – for the sustainable improvement of the quality of life.





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