



COSMETIC REGULATION **(EC) N° 1223/2009**

MAKING SAFETY ASSESSMENTS SEAMLESS

SGS

Regulation 1223/2009 requires all cosmetic products to undergo a safety assessment, in the form of a cosmetic product safety report (CPSR), prior to being placed on the EU market.

To help you achieve compliance, SGS can check and review the data required to complete a CPSR. Our advice can also help you to anticipate issues, identify data gaps and define a test plan to ensure quick, and successful, completion of the CPSR.

WHAT IS A COSMETIC PRODUCT SAFETY REPORT?

Cosmetic products destined for distribution and/or sale in EU markets must comply with the requirements of Regulation (EC) No 1223/2009, including the cosmetic product safety report (CPSR).

The CPSR is an independent cosmetic safety assessor's opinion. Before a product can go to market, an assessor must declare that the product is safe in normal and foreseeable use, and complies with the requirements of Regulation (EC) No 1223/2009.

A CPSR is in two parts:

- Part A – Cosmetic product safety information.
Part A gathers all the data required for a safety assessment and consists of ten sections.
- Part B – Cosmetic product safety assessment.
Part B is a cosmetic safety assessor's opinion on the safety of a product and consists of four sections.

Strict data requirements and lengthy testing periods mean you will need to plan ahead to ensure that you have all the information at the right time to complete the CPSR and get product(s) to customers and consumers.

As examples:

- Stability/accelerated ageing tests under the cosmetics regulation take three months. The regulation requires proof that products and their packaging retain their quality over the designated use period. This includes simulating different storage conditions, transport scenarios and usage.
- Preservatives are commonly used in cosmetics to inhibit the growth of microorganisms. Antimicrobial Efficacy Testing (Challenge Test) is carried out to determine how well the preservative works in maintaining product integrity. This information is a mandatory requirement of the cosmetics regulation and normally takes.



GET SET FOR CPSR, PLAN TESTING PROGRAMMES WELL IN ADVANCE

TWO ROUTES TO APPROVAL

ROUTE 1: YOU HAVE ALL RELEVANT DATA AVAILABLE

SGS will check and review it, conduct the cosmetic product safety assessment and issue the final CPSR.

Checklist:

- Product name
- Product description (e.g. physical state, colour, intended use)
- Product photo
- Label artwork for the finished product
- Product formulation:
 - Unique internal formulation reference; ingredient list with CAS no. & composition %
 - Intended function of each ingredient
 - Ingredient material safety data sheets (MSDS)
 - IFRA certification and (SCCNFP nominated) allergen report
 - Microbial / preservative efficacy test report
 - Chemical test report
 - Stability test report
- Packaging: compatibility and stability test report, and its purity supporting data
- Method of manufacture / good

ROUTE 2: YOU DON'T HAVE THE RELEVANT DATA AVAILABLE

Our cosmetic safety assessors will preview your formulation and recommend a test plan. On approval, we can conduct the necessary testing and supply the relevant data accordingly. In addition, if your manufacturer does not supply one, we can prepare a safety data sheet (SDS) for your product that complies with CLP regulations.

INFORMATION WE LOOK AT FOR A COSMETIC PRODUCT SAFETY REPORT (CPSR)

Depending on your cosmetic product, all or some of the tests listed in the table below will be needed to comply with Regulation (EC) No. 1223/2009:

#	TEST PARAMETERS	DETAILS	PRODUCTS CONCERNED
1	Quantitative and qualitative composition of the cosmetic product (= product formulation) and its intended use	Chemical name, INCI name, CAS number, EINECS/ELINCs or EC number where possible, and the weight percentage in the formulation.	All cosmetic products.
2	Physical characteristics of the cosmetic product (raw ingredients and finished product)	e.g. pH, viscosity, specific gravity	All cosmetic products.
3	Chemical characteristics of the cosmetic product (raw ingredients and finished products)	e.g. heavy metals, nitrosamines, phthalates, 1,4-dioxane, allergens, preservatives	All cosmetic products.
3a	Heavy metal analysis	Six heavy metal contaminations: lead, cadmium, mercury, arsenic, antimony, nickel (soluble).	All cosmetic products.
3b	Nitrosamines analysis	N-nitrosodiethanolamine (NDELA)	Amine containing formulation.
3c	Phthalates analysis	DBP, DEHP, BBP, DMEP, DnPP, DiPP, PiPP	Nail products, including solvent based nail polishes and nail glues.
3d	1,4-dioxane analysis		Rinse-off products with surfactants and products containing raw materials (like PEG-40) which undergo chemical process ethoxylation during manufacturing.
4	Stability of the cosmetic product (under reasonably foreseeable storage conditions) [Methods: Colipa (now Cosmetics Europe) and CTFA (now Personal Care Products Council)]	Normally accelerated stability study is a 12 week test at 40°C. Additional conditions are also recommended, if applicable: 4°C, 20°C daylight, 20°C dark, 30°C and 75% relative humidity could include a number of freeze thaw cycles. Testing needs to be conducted in the packaging that the product is going to be sold in. The test assesses some of the following depending on the type of product: appearance, colour, fragrance/odour, pack performance and dispensing quality. It could include pH and viscosity. Stability test helps define the expiry date of the product and it serves as a reference data for estimation of the period for safe use after opening (Period After Opening).	All cosmetic products.
5a	Microbiological quality [Methods: European pharmacopoeia method EuP Ch.2.6.12 & 2.6.13; or the following ISO methods: ISO 21149 -Aerobic mesophilic bacteria; ISO 16212-Yeast and mold; ISO 21150-Escherichia coli; ISO 22718-Staphylococcus aureus; ISO 18416 -Candida albicans ISO 22717-Pseudomonas aeruginosa]	This test determines the acceptable microbiological specifications of the raw materials and finished product. This would include a specification for bacteria, yeast and mould.	All cosmetic products. SCCS's Notes of Guidance differentiate: <ul style="list-style-type: none"> • Category 1 is for products specifically intended for children under three years, or for products that will be used in the eye area and on the mucous membranes • Category 2 is for all other products

#	TEST PARAMETERS	DETAILS	PRODUCTS CONCERNED
5b	Antimicrobial Effectiveness Testing (Challenge Test) [Methods: European pharmacopoeia method EuP Ch.5.1.3 or ISO 11930 method]	The cosmetic safety assessor advises if a preservation test is required.	All cosmetic products except: 1. Solid products such as solid soaps 2. Products with a high alcohol content (more than 20%) such as eau de toilettes, perfume) 3. Products containing a high content of solvents and no water such as nail polishes 4. Products which are dispensed without coming into contact with the air such as aerosols and single use products 5. One-off products such as temporary tattoos
6	Impurities (=unintended substances in raw materials), traces (=small quantities of unintended substances in the finished product), information about packaging material	Characteristics, purity and stability of the packaging. Evaluation of the possibility of substances migrating from the packaging into the product / potential effect on human health.	All cosmetic products.

OTHER CONSIDERATIONS

- Claims: such as 'paraben free' or 'free from formaldehyde' content
- Labelling: warnings for certain ingredients, instructions of use
- Suitability of packaging: potential migration of heavy metals - lead, cadmium, chromium VI, mercury – must be considered, in accordance with EU Directive 94/62/EC
- Common criteria for the justification of claims used in relation to cosmetic products, in accordance with EU Regulation 655/2013
- Notification on Europe's electronic Cosmetic Product Notification Portal (CPNP)

ACHIEVE EU COMPLIANCE

At SGS, we offer comprehensive compliance services to certify that your cosmetic products can be sold in Europe, including:

- Regulatory compliance
- Formulation and label artwork/pack copy review
- Laboratory testing
- Safety assessments
- Preparation of Product Information File (PIF)
- Notification on the CPNP
- ISO 22716 GMP audits, pre-shipment Inspections
- Trainings or seminars

We have a network of highly skilled safety assessors experienced in conducting Cosmetic Safety Assessments in accordance with the EU cosmetic regulation. Our fully equipped, state of the art facilities (in Europe, Asia and the USA) offer full testing for compliance to the EU cosmetic regulation.

For more information contact your local SGS representative, or our global team consumer.products@sgs.com and visit www.sgs.com/cosmetics

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