Product Information File (PIF)

Folder structure according to EU Regulation (EC) 1223/2009 Art. 11

The Product Information File (PIF) must be maintained for every cosmetic product and kept for at least 10 years after the last date the product was placed on the market. It must be available to the competent authority upon request.

Product name: _____ **Version:** _____

▶ 01 Product Information

- Product name and intended use
- Qualitative and quantitative composition (INCI list)
- Physico-chemical specifications
- Packaging material and compatibility

▶ 02 Safety Assessment

- Safety assessment according to Annex I EU Reg. 1223/2009
- Safety Data Sheets (SDS) per raw material
- Allergen declaration and threshold analysis
- CMR substance analysis (Carcinogenic/Mutagenic/Reprotoxic)
- Nanomaterial assessment (if applicable)

▶ 03 Stability and Shelf Life

- Stability tests (temperature, light, time)
- Minimum durability date (BBD) — justification
- Period After Opening (PAO) — justification

▶ 04 Raw Material Master Data

- Certificates of Analysis (CoA) per raw material batch
- Supplier certificates (GMP, Organic, etc.)
- Toxicological dossiers (if CMR substances)
- COSING references and EU conformity

▶ 05 Tests and Inspections

- Skin compatibility tests
- Microbiological tests
- Efficacy tests (if claims are made)
- Photostability (if UV filters)

▶ 06 Manufacturing and GMP

- Manufacturing process description
- GMP checklist according to ISO 22716
- Batch-related mixing protocols
- Quality control results
- CAPA reports for deviations

▶ 07 Labelling and Compliance

- Label design according to Art. 19 EU Reg. 1223/2009
- Warnings and usage instructions
- CPNP notification number (Cosmetic Products Notification Portal)
- Allergen labelling

▶ 08 Company and Responsibility

- Responsible person (name, qualification, address)
- Country and address of manufacture
- Importer data (if applicable)

▶ 09 Audit Archive

- Authority inspections and protocols
- Customer complaints and resolutions
- Documentation updates (changelog)

PIF Document Checklist

	Date	Notes
Product Information		
☐ Product name and intended purpose		
☐ INCI list (sorted by concentration)		
☐ Physico-chemical specifications		
Safety		
☐ Safety assessment (Annex I)		
☐ Safety Data Sheets for all raw materials		
☐ Allergen analysis		
☐ CMR substance analysis		
Stability		
☐ Stability test reports		
☐ BBD justification		
☐ PAO justification		
Raw Materials		
☐ Certificates of Analysis (CoA)		
☐ Supplier certificates		
☐ Toxicological dossiers (if CMR)		
Tests and Quality		
☐ Skin compatibility tests		
☐ Microbiological testing		
☐ Efficacy tests (if claims are made)		
Manufacturing		
☐ Manufacturing process description		
☐ GMP checklist (ISO 22716)		
☐ Mixing protocols (min. 3 batches)		
☐ QC results		

Labelling and Notification

☐	Label design (Art. 19 EU Reg.)		
☐	Warnings		
☐	CPNP notification number		
☐	Company master data		

Completeness Check

- ☐ All mandatory documents available and current
- ☐ PIF accessible to authorities at any time
- ☐ Last update documented

Responsible Person:

Name, Date, Signature

Reviewed by:

Name, Date, Signature