



Documentation needed to create PIF and Safety Assessment

FINISHED COSMETIC PRODUCT DOCUMENTATION

1. Qualitative and quantitative composition of the product, including chemical identity of the substances (INCI name, CAS, EINECS/ELINCS, where possible), and their intended functions
2. Name of the supplier for each ingredient and mixture used in the production of a finished cosmetic product
3. Product specification for each cosmetic product with its organoleptic properties, physical and chemical characteristics, expiry date, etc.
4. The stability of a cosmetic product under reasonably foreseeable storage conditions
5. Result of a Stability test
6. Result of a Challenge test if appropriate
7. Microbiological quality
8. Declaration from the manufacturer that the product does not contain prohibited ingredients: CMRs under Regulation 1272/2008 (if some of the raw materials contain them, provide evidence or statement from the raw material manufacturer/supplier that it is technically unavoidable), and that the proportion of impurities SVHC (Substance of Very High Concern) in the raw material is not greater than 0,1% (PUT YOUR LOGO, STAMP, DATE AND SIGNATURE)
9. Declaration of the manufacturer that the cosmetic product does not contain nanomaterial for each cosmetic product (PUT YOUR LOGO, STAMP, DATE AND SIGNATURE)
10. Declaration of the manufacturer that the finished product and the ingredients are not tested on animals (PUT YOUR LOGO, STAMP, DATE AND SIGNATURE)
11. Suggestion for label for each cosmetic product and/or primary (label) and secondary (outer packaging) artworks for each size (ml, g) of the product, and the prospectus (if there is any) (The total label size should not exceed 10 MB and the labels should be readable.)
12. If there is any claim on the packaging of the product, document/analysis report/scientific articles etc. that prove that claim

RAW MATERIAL DOCUMENTATION

13. Material Safety Data Sheet (MSDS) for each cosmetic ingredient/raw material
14. Technical Data Sheet (TDS) for each cosmetic ingredient/raw material
15. Certificate of Analysis (CofA) for each cosmetic ingredient/raw material with Microbiological quality
16. Physical and chemical characteristics of the substances/mixtures (from the raw material supplier)
17. Purity of the substances/mixtures for each ingredient (from the raw material supplier)
18. In the case of traces of prohibited substances, evidence for their technical unavoidability
19. MSDS, TDS, CofA, and IFRA certificate with the list of cosmetic allergens for perfume(s) used
20. If the product formulation contains colourants, a document that proves the purity criteria in the Directive 95/45/EC

CHARACTERISTICS OF PACKAGING MATERIAL, IN PARTICULAR PURITY AND STABILITY

21. Primary packaging specifications (for all parts in the direct contact with the product) with TDS, MSDS and CofA of packaging raw materials and declaration of conformity
22. Analytical reports

GMP DOCUMENTATION

23. Name and address of the Manufacturer
24. List of Importer(s) in the EU or intended Importer(s)
25. A description of the method of manufacturing
26. Process flow sheet for each product
27. An example of filled out manufacturing worksheet for each cosmetic product
28. Statement on compliance with the Good Manufacturing Practice (GMP) referred to in the Article 8 of REGULATION (EC) No. 1223/2009 (PUT YOUR LOGO, STAMP, DATE AND SIGNATURE)
29. GMP certification according to ISO 22716 standard (if there is no, we can send you a questionnaire to check whether you are producing in accordance with the GMP standards)