COMPLIANCE

Product Information File

Regulatory documents and information needed to create a PIF

ABioSA GUIDE

SEPTEMBER 2021

This guide establishes a basic guideline to be followed for cosmetic products intended to be made available on the EU market; it includes an outline of the documents required to create a Product Information File (PIF), and aims to summarise the key regulatory points of the PIF creation process. This guide covers compliance for both the ingredient and final product stages covered by EC Regulation 1223/2009.

forestry, fisheries & the environment
Department:
Forestry, Fisheries and the Environment
REPUBLIC OF SOUTH AFRICA

THE ABS CAPACITY DEVELOPMENT INITIATIVE

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Economic Affairs SECO

Contents

This guide is part of a series of knowledge products produced by ABioSA. These knowledge products and other biotrade resources can be found at www.abs-biotrade.info/projects/abiosa/resources

A glossary of biotrade terms can be found at www.abs-biotrade.info/resources

Lisam was commissioned by the project ABioSA to develop and publish this guide. ABioSA is funded by the Swiss State Secretariat for Economic Affairs (SECO), integrated in the governance structure of the ABS Initiative, and implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH. Although every effort has been made to provide complete and accurate information, GIZ, SECO and Lisam make no representations or warranties, express or implied, as to its accuracy at the time of use.

Adrie El Mohamadi
Component Manager
The ABS Capacity Development Initiative
(ABS Compliant Biotrade in Southern Africa)
Center for Cooperation with the Private Sector (CCPS)

Deutsche Gesellschaft für
Internationale Zusammenarbeit (GIZ) GmbH
+27 12 423 7955 | +27 82 902 4083
adrie.elmohamadi@giz.de
www.giz.de & www.abs-biotrade.info

The ABS Initiative is funded by

Federal Ministry for Economic Cooperation and Development

Norwegian Ministry of Foreign Affairs

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Economic Affairs SECO

and implemented by

giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Glossary

General

- **ASTM** - The American Society for Testing and Materials, an international standards organisation that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems and services
- **CEN** - European Committee for Standardization (*Comité Européen de Normalisation*)
- **CMR** - Carcinogenicity, mutagenicity and toxicity to reproduction
- **CosIng** - European Commission database with information on cosmetic ingredients
- **Cosmetics Europe - The Personal Care Association (formerly COLIPA)** - The voluntary association represents the interests of companies from the cosmetics sector
- **CPSR** - Cosmetic Product Safety Report
- **CPNP** - Cosmetic Products Notification Panel
- **EC** - European Council
- **ECVAM** - European Centre for the Validation of Alternative Methods
- **EEC** - European Economic Community
- **EFFA** - European Flavour & Fragrance Association
- **EFfCI** - European Federation for Cosmetic Ingredients
- **EINICS** - European Inventory of Existing Chemical Substances. The EINICS number is a registry number given to each chemical substance commercially available in the EU between 1 January 1971 and 18 September 1981. The inventory was created by Directive 67/548/EEC concerning the labelling of dangerous substances. The EINICS number/s must appear on the label and the packaging of dangerous substances.
- **Endemism** - A state of a species being indigenous to a single defined geographic location
- **EPAA** - European Partnership for Alternative Approaches to Animal Testing
- **GIZ** - Deutsche Gesellschaft für Internationale Zusammenarbeit (German Society for International Cooperation)
- **GLP** - Good Laboratory Practices is a quality system concerned with the organisational processes and conditions under which non-clinical health and environmental studies are managed
- **GMP** - Good Manufacturing Processes is a quality system concerned with ensuring that products are consistently produced and controlled according to quality standards
- **IFRA** - International Fragrance Association
- **INCI** - International Nomenclature Cosmetic Ingredient
- **OECD** - Organisation for Economic Co-operation and Development
- **PIF** - Product Information File
- **RP** - The Responsible Person is a legal person of the European member states that takes responsibility for many facets of cosmetic product deployment
- **SDS** - Safety Data Sheet
- **SUEs** - Serious Undesirable Effects
- **TDS** - Technical Data Sheet

Terms taken from the EC Regulation 1223/2009 glossary

- **CAS number** - Unique numerical identifiers for chemical entities
- **Colourants** - Substances which are mainly intended to colour the cosmetic product
- **Cosmetic product** - This is any substance or mixture intended to be placed in contact with the external parts of the human body (skin, nails, etc.), or with the teeth and the oral cavity, with the main purpose of:
  - Cleaning
  - Perfuming
  - Changing their appearance
  - Protection

A substance or mixture intended to be used in the following ways cannot be considered a cosmetic product:
- Ingested
- Inhaled
- Injected
- Implanted

- **Distributor** - An appointed person from one of the EU member states in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the EEC market
- **End user** - Either a consumer or professional using the cosmetic product
- **Frame formulation** - A formulation which lists the category or function of ingredients and their maximum concentration in the cosmetic product
- **Hair dyes** - These products can be divided into three categories according to their colour-fastness:
  - Temporary hair dyes
  - Semi-permanent hair dyes
  - Permanent hair dyes
- **Harmonized standard** - A harmonized standard is a European standard developed by a recognised European Standards Organisation; CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonized standards to demonstrate that products, services, or processes comply with relevant EU legislation.
- **IFRA** - International Fragrance Association
- **Importer** - A person from one of the EU member states who places a cosmetic product from a third country on the EEC market
- **Making available on the market** - Any supply of a cosmetic product for distribution, consumption or use on the EEC market in the course of a commercial activity
- **Manufacturer** - A person from one of the EU member states who manufactures a cosmetic product, or has such a product designed or manufactured, and markets that cosmetic product under their name or trademark
- **Mixture** - A combination or solution composed of two or more substances
- **Nanomaterial** - An insoluble or biopersistant manufactured material with an internal or external scale of 1 to 100 nm in the cosmetic product
- **Placing on the market** - The first time a cosmetic product is made available on the EEC market
- **Preservatives** - Substances which are mainly intended to inhibit the development of micro-organisms in the cosmetic product
- **Recall** - Any measure aimed at completing the return of a cosmetic product that has already been made available to the end user
- **Serious undesirable effect** - An undesirable effect which results in serious permanent or semi-permanent health problems
- **Substance** - A chemical element and its compounds in the natural state or obtained by any manufacturing process
- **Undesirable effect** - An adverse reaction for human health attributable to the foreseeable use of a cosmetic product
- **UV-filters** - Substances which are mainly intended to protect the skin against certain UV radiation by absorbing, reflecting, or scattering UV radiation
- **Withdrawal** - Any measure aimed at ceasing the process of making the cosmetic product available on the market

Background

Europe is a world leader in the cosmetics industry, exporting to every corner of the globe. Th EU's detailed and extensive regulatory framework affords a high level of safety for cosmetic products. With 7% of plant species and one of the six floristic kingdoms being found in South Africa, it is considered the country with the second highest plant endemism (Poole, 2019). The potential to export to the EU market is considerable, and therefore compliance and safety for trade are of paramount importance. This document aims to guide the process for obtaining the correct information needed to create a Product Information File (PIF).

Information and documentation required for the PIF as per EC Regulation 1223/2009

Documentation and information are required for both the raw material level and the final cosmetic product level. Depending on the manufacturing process/characteristics of the material, differing analyses/declarations are needed.

General Information required for the PIF

a. Information on brand owner (name, address, contact details)

b. Information on manufacturer (name, address, contact details)

c. Information on EU RP (name, address, contact details)

d. Information on EU importer (name, address, contact details

e. Information on EU distributor (name, address, contact details)

f. Information on EU member state/s where the cosmetic product is to be made available

g. Information on the Safety Assessor who must comply with the prerequisite qualifications stipulated in Article 10, paragraph 2 of EC Regulation 1223/2009

Raw material information

The section covers the required analyses, identification, and declarations regarding raw materials.

1. **Identification** of all substances of all raw materials by means of:

- CAS number
- INCI name
- EC number
- EINICS number
- **Note** - Isomeric configuration must be considered

2. **Frame formulation**

- Maximum percentage of each substance that can be found in the raw material
- Intended use of the raw material as utilised in the frame formulation (e.g. viscosity control, fragrance, preservative, pH buffering, emollient, solvent, colourant, humectant, etc.)

3. **Exact compositional percentage** of each substance found in the raw material which includes:

- Preservatives
- Additives
- Manufacturing impurities (residuals, pesticides, heavy metals)

4. **Molecular weight** of each substance:

- **Note** - If the overall composition of the raw material is confidential, the molecular weight of the components must be made available to the purchaser. It can remain confidential, but this information will be used in the PIF.

5. **Physical form/state** of each substance composing the raw material

6. **If the substance cannot be identified**, a sufficient amount of information regarding the manufacturing process of the substance must be provided in order to determine its characteristics

7. **Stability data** on the raw material and an indication as to whether a preservative has been used; storage stability data should be included

8. **Further data** on raw materials to be supplied, if applicable:

- Solubility in solvents
- Hydrophilic/hydrophobic attributes
- Log (Pow) value as defined by pH
- Boiling point and flash point
- pH value
- Density
- Auto-ignition temperature (gas)
- Presence of UV active component and UV spectrum
- Presence of nanomaterials (< 100 µm and > 50% particle distribution warrants further information that must be readily available on request)
- Proprietary chemical property must be readily available from the manufacturer on request

9. **Supporting raw material documentation**:

- Supplier SDS for all raw materials and components, where available
- TDS and/or Certificate of Analysis, including:
  - Analyses done according to GLP must be accompanied by a batch reference, alternatively, the date found on the batch certificate
  - Reference to standardised test methods (e.g., OECD, ASTM), including acceptance criteria or limits found in the method
  - The results of all the test methods performed on the batch, present in numerical form, and compared to the established acceptance criteria or limits stipulated by the product specifications. The results should be included along with the following parameters:
    - Appearance of raw material
    - Spectroscopic identity (IR, UV, NMR, MS)
    - Purity (%)
    - Solubility
    - Impurities (% composition)

        - Heavy metal content (< 10 ppm)
        - The date the tests were performed
        - Signature of the head of the laboratory performing the tests or an authorised person
        - GLP accreditation or a certified statement declaring that GLP practices are adhered to, stating where applicable the relevant test methods
    - If the supplier cannot provide the necessary test results, then an official authorised declaration on the supplier's letterhead should be provided stating that this information has been obtained, and thus the supplier conforms with the relevant EU legislation requirements; the declaration must include an indication of whether or not the results comply
    - IFRA certificate for essential oils and fragrances
    - Any other applicable test results with referenced methods obtained from testing the batch samples, completed periodically to form statistical evidence/ results
- An official authorised statement referring to the specific raw material conditions applicable for:
    - Shipping information
    - Packaging information
    - Storage condition
    - Distribution information;

10. Source information on raw material:

- **Botanical source** (plant, alga or macroscopic fungus):
    - Common name
    - Scientific classifications (sub-species, variety, species, genus, family)
    - Organoleptic, macroscopic, and microscopic evaluation
    - Morphological and anatomical description (including gender, if applicable)
    - Photograph of the specimen used
    - Information on whether it is cultivated or harvested from the wild
    - Natural habitat information
    - Geographical distribution
    - Preparation process declaration, including processes undertaken such as:
        - Collection
        - Washing
        - Drying
        - Extraction
        - Distillation
        - Purification (if possible)
        - Preservation procedures
        - Handling considerations
        - Storage conditions
        - Any applicable physical/chemical preparations
    - Description of commercial form (granules, gel, powder, etc.)
    - Description and identification of characteristic components found in the botanical
    - Known toxic compounds (% composition, CAS No)
    - Peroxide Value where applicable, and in compliance with EC Regulation 1223/2009 (present in mmol/l for batch specific oils)
    - Presence of microbiological activity, including fungi
    - Presence and identity of any possible contaminants
    - Presence and identity of preservatives and/or additives
    - The components of a raw material that is a mixture must be clearly indicated and identified, with compositional range data at a minimum
- **Animal source**:
    - Preparation process declaration - including processes undergone - such as:
        - Extraction conditions (solvent, pH, temperature)
        - Hydrolysis type (acidic, enzymatic)
        - Other applicable chemical procedures performed
        - Purification (if possible)
        - Distillation
    - Description of commercial form (granules, gel, powder, liquid, etc.);

- Description and identification of characteristic components, such as:
  - Amino acids
  - Total nitrogen content
  - Proteins
  - Polysaccharides
  - Molecular mass
  - Any other applicable information
- Physiochemical information/data
- Presence of microbiological activity, including relevant viral contamination data
- Presence and identity of any possible contaminants
- Presence and identity of preservatives and/or additives

- **Mineral source:**
  - Preparation process declaration - including processes undergone - such as:
    - Physical processes
    - Chemical processes
    - Purification (if possible)
  - Semi-quantitative analyses (% ranges)
  - Mineralogy
  - Particle size and distribution (% and dimensions)
  - Presence of microbiological activity
  - Presence and identity of any possible contaminants
  - Presence and identity of preservatives and/or additives
- **Biotechnology source**
  - Preparation process declaration
  - Description and identification of organisms involved, including:
    - Donor organisms
    - Recipient organisms
    - Modified organisms
    - Host pathogenicity toxicity
    - Metabolite identification
    - Presence and identification of toxins produced
    - Fate of viable organisms in the environment
    - Survival potential for transfer of characteristics such as natural bacteria
    - Physiochemical specifications
    - Microbiological presence/quality
    - Presence and identity of any possible contaminants
    - Presence and identity of preservatives and/or additives

11. **Microbiological analysis** results and the relevant testing method employed. This should include a description of analyses, such as:
    - Anaerobic count (cfu/g)
    - Aerobic count (cfu/g)
    - Total plate count (cfu/g)
    - P. aureginosa
    - S. aures
    - E. coli
    - C. albicans
    - Salmonella

12. **Allergen report**:
    - Essential oils
    - Fragrances
    - Any raw material containing any of the 26 allergens as found in Annex V

13. **Quality assurance protocol** or official authorised declaration given by the supplier for raw materials

Cosmetic product information

The section covers the required analyses, identification, and declarations regarding cosmetic final products.

1. **General information**:

- Brand name
- Product name
- Product code
- Formula code and name
- Use instructions
- User group/s (adult, elderly, gender, etc.)
- Foreseeable uses (leave-on, rinse off)
- Recommended warnings
- Indication on professional/consumer/ industrial use

2. **Physiochemical characteristics and test results**:

- Physical form (appearance, form, state)
- Homogeneity and stability
- pH of final formulation
- Viscosity (dynamic and kinematic)
- UVA, UVB analysis results (if a sun protection formula)
- Particle size and distribution (if in powder form)
- Description of droplet size and density (if a sprayed formulation)
- Any other applicable physiochemical properties (if relevant to the Safety Assessment)
- Challenge test results and testing method employed:
  - Challenge testing:
    - This should be done according to the ISO 11930:2019, USP <51> Antimicrobial Effectiveness Test, the PCPC preservative Challenge testing or a custom preservative Challenge testing (as per product specifications)
- Microbiological analysis results and relevant testing method employed. This should include a description of analyses, such as:
  - Anaerobic count (cfu/g)
  - Aerobic count (cfu/g)
  - Total plate count (cfu/g)
  - P. aureginosa
  - S. aures
  - E. coli
  - C. albicans
  - Salmonella
- Stability testing (UV, room temperature, 40°C), with interim reporting to predict shelf-life
  - Whether conducted in real time or under accelerated conditions, tests should be done in order to assure (SCCS, 2015):
    - Stability and physical integrity of cosmetic products under appropriate conditions of storage, transport, and use
    - Chemical stability
    - Microbiological stability
    - The compatibility between the contents and the container
  - Stability must be conducted on the test substance packaged in a container, which is the same as the container intended for storage and distribution. In addition, tests should be conducted with the test substance in glass (UV stability test).
  - Two samples - one in glass and one in the actual packaging - should be kept in the following conditions:
    - Temperature:
      - Three months at 50°C, or 6 months at 40°C
      - 30 months at room temperature (control)
      - Storage stability at refrigerator temp (control at 4°C)
    - Oxygen:
      - If applicable, sensitivity to oxygen under storage conditions should be provided

- UV radiation (photostability):
  - Cosmetics whose packaging may allow the product to be exposed to light should undergo light stability testing; the lighting used in testing should simulate the intensity to which the cosmetic will likely be exposed
  - The standard testing guideline recommends 30 hours UV light (glass)

- The following parameters must be analysed for their variation during stability/shelf-life testing, and should be recorded weekly:
  - Colour, odour, and appearance
  - Changes in the container
  - pH change
  - Viscosity
  - Weight changes
  - Microbial tests demonstrating the ability of the product to prohibit microbial growth during normal use, and other specific tests if necessary
  - Oxidation - Peroxide Value and Acid Value (for oils)
  - Packaging integrity, colour changes and functionality
  - Analytical data in relation to other parameters for specific product types
    - For long-term studies, the frequency of testing should be sufficient to establish the stability profile of the finished product. The frequency of testing in the long-term storage condition should normally be every three months over the first year, every six months over the second year, and annually thereafter, throughout the proposed shelf life.
    - At the **accelerated** storage condition, a minimum of three points are recommended, including the initial and final time points (e.g., one, two, three, and six months) from a six-month study. Where an expectation (based on development experience) exists that results from accelerated testing are likely to approach significant change criteria, increased testing should be conducted, either by adding samples at the final time point, or by including a fourth time point in the study design.

3. Good Manufacturing Process (Article 8)

- The manufacturer must adhere to GMP for the cosmetic product to be considered safe
- They must provide a GMP certificate/GMP accreditation or an authorised, official statement declaring that GMP has been followed
- Manufacturing and sanitisation procedures must be in place

4. Packaging information

- A food grade certificate is required for each separate component of the packaging (e.g., nozzle, cap, bottle). If none can be provided, then a standardised leach test can be conducted for each of the components, as per food safety regulations (Europe, 2019):
  - All specific items or materials (depending on what is supplied) should be described with their general chemical composition
  - All those components/materials which are potentially capable of transferring chemical substances to the cosmetics formulation should be identified

- Having identified those packaging components/materials which could potentially impact on the safety of the cosmetic product, adequate information needs to be communicated about them to allow the Safety Assessor to evaluate their impact (if any) on the safety of the cosmetic formulation. The actions recommended for this approach are described below (see the flowchart on page 15 of the 13 June 2019 Cosmetics Europe Advisory Document, available **here**).

- If possible, the supplier declares and documents compliance with food contact legislation/standards
- Where food contact compliance cannot be claimed, the supplier must provide relevant information for the safety evaluation of the packaging by other means
- The manufacturer of the cosmetic product should perform a leach test to determine if there are any hazardous components that leach into the product from the packaging, including:
  - Exact description or photograph of all labels and wording to be present on the cosmetic product
  - Photographs of all packaging parts
  - Net weight/volume, as defined by the relevant EU Regulation, present with e-mark if applicable, as per EC Regulation 76/21
  - Volume of packaging (when empty)

5. Non-animal testing declaration

- An official, authorised declaration that no testing has been done on animals for the cosmetic product or the ingredients composing it

6. Advertising, labelling, presentation, and claims

- All test results for claims supported by market information, scientifically recognised analyses or clinical trials must be provided for the cosmetic product/formulation, and must have been conducted according to best practice guidelines (GLP) and standards as required by the EU
- Artwork of the label
- Keep a market surveillance report and report any severe undesirable incidences (SUEs), and report these to the relevant authorities immediately

References

(EPA), U. S. E. P. A., 2017. *LIQUID-SOLID PARTITIONING AS A FUNCTION OF EXTRACT pH USING A PARALLEL BATCH ,* s.l.: United States Environmental Protection Agency (EPA).

Europe, C., 2019. *INFORMATION EXCHANGE ON COSMETIC PACKAGING MATERIALS ALONG THE VALUE CHAIN IN THE CONTEXT OF THE EU COSMETICS REGULATION EC 1223/2009,* s.l.: Cosmetics Europe.

Poole, C., 2019. *National Biodiversity Assessment 2018: Facts Findings and Messages,* s.l.: South African National Biodiversity Institute.

SCCS, 2015. *THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTSAND THEIR SAFETY EVALUATION, 9th revision,* s.l.: EU Commision.

SCCS, 2021. *THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 11TH REVISION,* s.l.: s.n.

Union, C. o. t. E., 1979. *The approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC,* s.l.: s.n.

Union, C. o. t. E., 1987. *Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers,* s.l.: s.n.

Union, C. o. t. E., 2009. *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products,* s.l.: s.n.

Union, C. o. t. E., 2013. *COMMISSION IMPLEMENTING DECISION of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of theCouncil on cosmetic products,* s.l.: Official journal of theEuropean Communities.

Disclaimer:

This report has been compiled specifically for the use of the individual and/or entity to whom it has been addressed. If you are not the individual or entity to whom it has been addressed, you are not entitled to act in accordance with any of the advice and/or views which have been provided herein, without the authorisation of LISAM. Notwithstanding the aforegoing, this report is confidential, and has been compiled based on the facts and circumstances based on information gathered from third parties and provided as a summary to the entity to whom it is addressed, and no third party may make use of any view or advice, as provided herein, without the authorisation of LISAM.

Lisam Systems and Lisam South Africa liability will be limited to the repair of the Report supplied that does not comply in any way. No further damage claims or liability will be recognised. Lisam Systems and Lisam South Africa will not be liable for any direct or indirect damages to the customer or user of the supplied documents. Considering the nature of the services provided, the Lisam Report is subject to a best endeavours' obligation.

The Company undertakes to provide its services in accordance with standard professional practice complying with norms and other established standards, under the terms and conditions of the agreement between the parties, as well as in compliance with the legal and regulatory provisions that apply. Neither the Company, nor any of its directors or employees are liable nor responsible with regard to the services rendered to customers or third-parties, which is based on information supplied by the Customer or individuals that is not clear, is wrong, incomplete, misleading or false. The Company is neither an insurer, nor a guarantor, and declines to accept any liability in this respect. Customers seeking a guarantee against loss and damage must obtain appropriate insurance cover.