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

THE ABS CAPACITY DEVELOPMENT INITIATIVE

Schweizerische Eidgenossenschaft
Confédération suisse
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Swiss Confederation

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

WEBINAR

REGULATION (EC) No 1223/2009 on cosmetic products and Cosmetic Raw materials

This webinar is offered free of charge, courtesy of the SECO-funded and GIZ-implemented ABS Compliant Biotrade in South(ern) Africa (ABioSA) project

Date: 11 August 2021
Time: 10:00- 12:00

LISAM SYSTEMS
Enabling full compliance.

The ABS Initiative is funded by

Federal Ministry
for Economic Cooperation
and Development

NORWEGIAN MINISTRY
OF FOREIGN AFFAIRS

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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

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About Lisam

Founded in 1999, Lisam Systems is a global provider of Environmental, Health and Safety (EH&S) compliance management software solutions and services, operating from 18 offices worldwide.

- **Over 20 years of experience in the chemical compliance market**

Our Values:

- **Think Ahead**
- **Be Passionate**
- **Strive for Excellence**
- **Foster Knowledge**
- **Value Customers**

About Lisam

We have a **local support team**: with GHS expertise (globally), technical expertise and product expertise (waste, cosmetics (including Safety Assessments for the EU), industrial chemicals, gas, retail products, biocides) and **18 offices globally** enabling us to provide you with **up-to-date regulatory advice and software support:**

- REACH Registration
- REACH Only Representative (OR) services
- REACH Volume Tracking - EU Volume Tracking
- EU Poison center Notification
- Legal entity
- EU regulatory assessments
- EU COSMETIC Regulatory compliance – Safety As - sessments, RP

Project background

Indigenous ingredients

(Raw materials

e.g. vegetable oils, essential oils)

- **REGULATION EC 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH); and Product readiness;**
- **REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP); and**

Cosmetic products

(Finished products

e.g. face cream/body lotion etc)

- **REGULATION (EC) NO 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products**

Project Background

To provide small and medium sized enterprises(SMEs) and indigenous peoples and local communities (IPLCs) **with technical assistance** to ensure greater sector compliance with EU regulations for REACH, CLP, Cosmetics and where possible novel foods for primary ABioSA indigenous ingredients. The oils included in the project:

6 Vegetable oils

1. *Sclerocarya birrea* (Marula oil) – refined and crude
2. *Adansonia digitata* (Baobab oil) – refined and crude
3. *Schinziophyton rautanenii* (Manketti/Mongongo oil) – refined and crude
4. *Citrullus lanatus* (Kalahari melon oil) – refined and crude
5. *Ximenia Americana* and *X. Caffra* (Sour Plum oil) – refined and crude
6. *Trichilia emetica* – (Mafura oil and butter) – refined and crude

5 Essential oils

1. *Lippia javanica, L. rehmani and L. scaberrima* (Lippia oil)
2. *Pelargonium radens*, *P. capitatum* and *P. graveolens*, resulting in the hybrid Pelargonium var Rose (Rose geranium oil)
3. *Helichrysum splendidum / odoratissimum* etc. (Helichrysum oil)
4. *Agathosma betulina* and *Agathosma crenulata* (Buchu oil)
5. *Eriocephalus species, E. punctulatus* and *E. africanus*, *E. comosum* and *E. racemosus* (Cape chamomile oil)

LISAM SYSTEMS
Enabling full compliance.

Product Information Files and details required to complete

Regulatory Requirements

EU Regulation for cosmetic products (EC 1223/2009)

Requires a product Information File (PIF) for all cosmetic finished products made available on the EEC market

22.12.2009 EN Official Journal of the European Union L 342/59

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 30 November 2009

on cosmetic products

(recast)

(Text with EEA relevance)

Regulatory Requirements

Definition of a Cosmetic Product:

"any substance or mixture **intended to be placed in contact** with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity **with a view exclusively or mainly** to **cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours**"

Key aspects of the definition: the application site and the principle intended function

A product may have a **principle purpose and a secondary purpose** and this may not exclude it from being a cosmetic product e.g. toothpaste (keeps teeth clean and healthy but is not a medicinal product if the product is not presented as such). The product may also be a medicinal product, medical device, biocide, toy, food or chemical. Articles are not cosmetic products (e.g. cosmetic wipes (tissue is NOT cosmetic, lotion is), clothing with a releasing substance (the material is NOT a cosmetic, but the substance is)) – the General Product Safety directive (GPSD) will apply.

- Tattoos are NOT cosmetics
- Nutro-cosmetics are NOT cosmetics
- Body Paint IS a cosmetic
- Leave-on hand sanitiser is NOT a COSMETIC (main purpose is to sanitise) = biocidal product

Regulatory Requirements

Definition of a Cosmetic Product:

If a product does fall in both cosmetics and medicine, the Medicinal Products Directive (Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001) will apply:

> The Medicinal Products Directive defines a medicinal product as "**any substance or combination of substances presented as having properties for treating or preventing disease in human beings**" ("definition by virtue of presentation") i.e. a product may be considered as medicinal product if it is presented either for treating or preventing disease

The following considerations need to be taken into account when deciding which regulation the product falls under:

- Claims and context of the claims
- How a product appears to the public
- The packaging and labelling
- The promotional material, advertisements, target market

Regulatory Requirements

Purpose of the PIF

To ensure that all the supporting documentation is made available to support the assessment of human safety risk assessment of the cosmetic product for the foreseeable use/s of the product and is kept updated at all times. The document must be made available to the authorities within 48 hours.

Safety Assessor

Required to perform the Safety Assessment that forms part of the PIF. The Safety Assessor does not have to be domicile in the EEC, but needs to be suitably qualified as per EU regulations (a person that possesses as university qualification in pharmacy, toxicology, medicine or a similar discipline, or a defined by the member state e.g. France)

Regulatory Requirements

Responsible Person (RP)

Defined as a legal or natural person within the EEC that is responsible to ensure compliance in accordance with the cosmetic regulation

Default RP is the manufacturer of the product (established within the EEC).

- The manufacturer may designate a person established within the EEC as the RP.
- If the product is imported, each importer for the product is designated as the RP.
- The importer may designate a person established within the EEC as the RP.
- A distributor is the RP if he places a product under his name or trademark or modifies a product already paced on the market

Regulatory Requirements

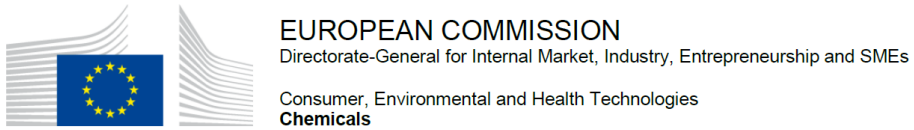
The RPs legal obligations include:

1) Ensuring the product is safe for the intended foreseeable use
2) Ensure the product is manufactured according to Good Manufacturing Principles (GMP)
3) Ensure that the cosmetic product has undergone a safety assessment prior to it being placed on the EEC market
4) Keep a Product Information File (PIF) for 10 years following the date of the last batch of the product was placed on the market

Regulatory Requirements

The RPs legal obligations include cont..

5) Ensure that all analyses of a cosmetic product are performed within the guidelines of GLP (Good Laboratory Practice) and appropriate reference standards as published bin the Official Journal of the European Union where applicable.



EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Chemicals

Version March 2016

EU LEGISLATION WITH GOOD LABORATORY PRACTICE (GLP) PROVISIONS

This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents. Only European Union legislation printed in the paper edition of the Official journal of the European Union is deemed authentic.

6) Submit information electronically to the Commission – this is done through the Cosmetic Product Notification Portal (CPNP) (See pg 40)

Regulatory Requirements

The RPs legal obligations include cont..

7) Ensure the control of prohibited and restricted substances as listed in the Annexures of the Cosmetic Regulations
    a. Prohibited substances: Annex I and II
    b. Restricted Substances Annex III
    c. Colourants: Annex IV
    d. Preservatives: Annex V
    e. UV Filters: Annex VI
    f. Assess the use of CMR substances within the requirements of the regulation
8) Notify the commission of the use of a Nanomaterials that do not conform to Annex III and used in a cosmetic product, 6 months prior to placing the product on the market
9) Define traces of prohibited substances based on being technically unavoidable within good manufacturing practice are permitted

Regulatory Requirements

The RPs legal obligations include cont..

10) Ensure that the final cosmetic product has not been tested on animals
    a. for the purposes of proving cosmetic safety or
    b. ingredients that have been used in the product for the purposes of cosmetic safety and meeting the requirements of the Cosmetic Regulation
11) Ensure the label conforms with the Regulation
12) Ensure product claims are substantiated and the evidence is provided in the PIF
13) Access to information by the public as required by the regulation
14) Ongoing market Surveillance
15) Notification to the authorities in the event of any Serious Undesirable Effects (SUEs)
16) Provide authorities as and when requested on the presence of particular substances in the product
17) Continuously update the PIF if any changes necessitate it e.g. change in raw material supplier, change in formula, updated stability

Regulatory Requirements

Labelling of a cosmetic Product

1) Name or registered name and address of the Responsible Person (RP) where the PIF can be readily accessed- to be underlined if there are several addresses
2) Country of origin for imported cosmetics
3) Regulated language/s of the member in which the product is made available to the end user
4) Nominal content (given by weight (g) or volume (ml). The net contents of a product must be labelled i.e. the net quantity of product at the time the packaging is filled with the cosmetic product
    a. Not required below 5 g or 5 ml, for single use packs such as sachets or capsules, or for free samples. If products are sold as a collection of items, this should be stated, e.g. 10 sachets
5) The "e" mark must be shown if the product is filled according to the "average fill system" which is defined in weights & measures legislation (1976) e.g. "200ml e"
6) Particular precautions for consumers to take note of must be advised (In particular the requirements in Annex III and VI of the Cosmetic Regulation 1223/2009) as a minimum and any additional precautions depending on components, sources of raw materials and potential vulnerable population exposure
7) Batch number or reference number to identify the cosmetic
8) The function of the Cosmetic Product

Regulatory Requirements

Labelling of a Cosmetic Product

9) List of ingredients as per the regulatory requirements preceded by the word “ingredients” – if too small may be on packaging or Z-label.
    a. The list of ingredients and the order and wording is supplied in the PIF.
    b. If an INCI name is not available for an ingredient, a common nomenclature name may be used
    c. Once an INCI name becomes available, the label must be updated within 12 months of the date of the INCI name being made available by the European Commission in the glossary in the Official Journal of the European Union;
10) Small packaging: information 5-8 may be provided on an enclosed or attached leaflet, label, tape, tag or cord and Figure 1 must then be included on the package

Figure 1

Regulatory Requirements

Labelling of a cosmetic Product

11) Soap bath balls and other small products where a Z label is not possible, a notice shall appear in immediate proximity to the container in which the cosmetic product is exposed for sale

12) Products packaged at point of sale:

    a. Refer to each member states for labelling requirements

13) Language prescribed by each individual member state:

    a. Comply with additional national laws in the language required

14) Specific labelling/warnings are to prevent misuse of the product:

    a. Take into into account the hazardous components and routes of exposure

    b. Safety Assessor will provide a statement the particular warnings and instructions based on additional hazards

15) NOTE: Cosmetic products and packaging should not mimic a foodstuff - refer to regulation 87/357/EEC

Regulatory Requirements

Labelling of a cosmetic Product

16) Date of minimum durability may be indicated by the appropriate symbol or the words 'best used before the end of..' and the conditions which satisfy this guarantee (where applicable). This is mandatory for products with stability tests <30 months or minimum durability <30 months. In this case the following symbol is used:

Figure 2

17) If a room temperature stability test is available for the product for >30 months stability test (room temperature) there should be an indication of period of time after opening and the following symbol is used followed by the period months and/or years:

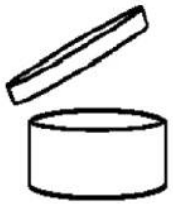
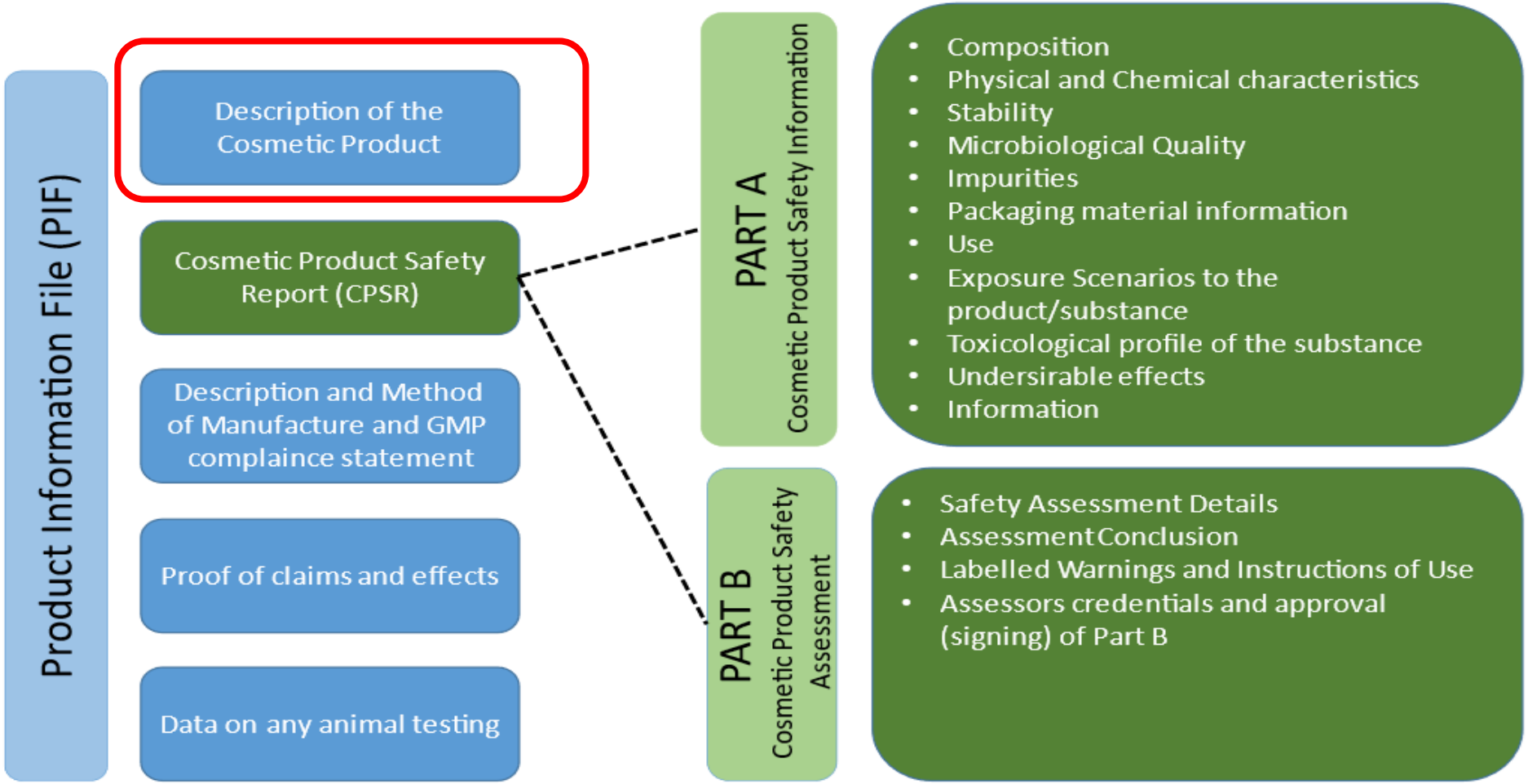


Figure 3

Product Information File Requirements



Regulatory Requirements

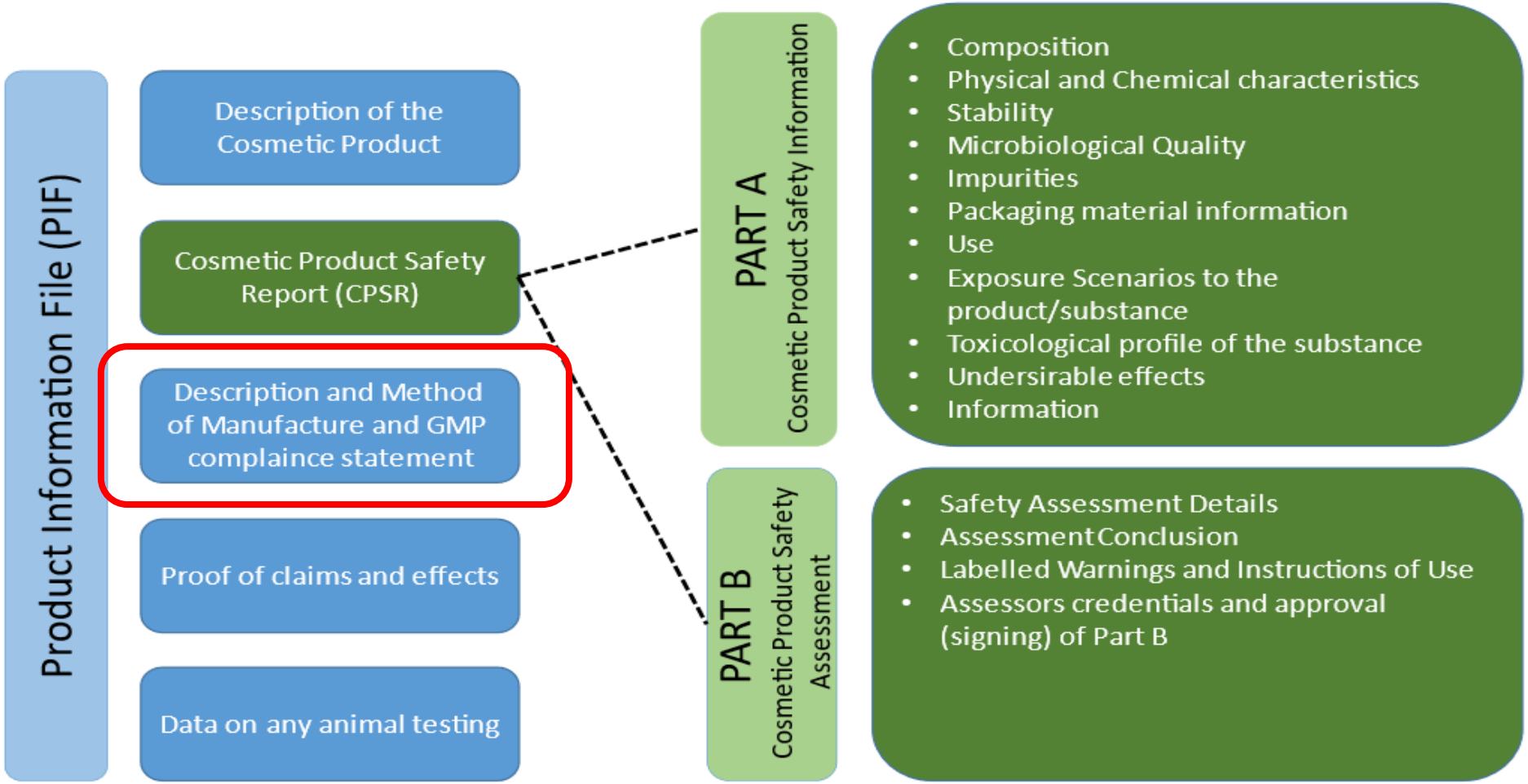
Description of Product

1) According to the COLIPA and SCCS Notes of Guidance 10th revision the following categories apply: https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_224

Product type	Estimated daily amount applied q_x (g/d)	Relative daily amount applied[1] q_x (mg/kg bw/d)	Retention factor[2] F_{ret}	Calculated daily exposure $E_{product}$ (g/d)	Calculated relative daily exposure[1] $E_{product}$ (mg/kg bw/d)
Bathing, showering					
Shower gel	18.67	279.20	0.01	**0.19**	**2.79**
Hair care					
Shampoo	10.46	150.49	0.01	**0.11**	**1.51**
Hair styling products	4.00	57.40	0.10	**0.40**	**5.74**
Skin care					
Body lotion	7.82	123.20	1.00	**7.82**	**123.20**
Face cream	1.54	24.14	1.00	**1.54**	**24.14**
Hand cream	2.16	32.70	1.00	**2.16**	**32.70**
Make-up					
Liquid foundation	0.51	7.90	1.00	**0.51**	**7.90**
Lipstick, lip salve	0.057	0.90	1.00	**0.057**	**0.90**
Deodorant					
Deodorant non-spray	1.50	22.08	1.00	**1.50**	**22.08**
Deodorant spray	0.69	10.00	1.00	**0.69**	**10.00**
Oral hygiene					
Toothpaste (adult)	2.75	43.29	0.05	**0.138**	**2.16**
Mouthwash	21.62	325.40	0.10	**2.16**	**32.54**

Product type	Estimated daily amount applied q_x (g/d)	Relative daily amount applied q_x (mg/kg bw/d)	Retention factor[1] F_{ret}	Calculated daily exposure $E_{product}$ (g/d)	Calculated relative daily exposure $E_{product}$ (mg/kg bw/d)
Hair care					
Hair conditioner[2]	3.92	-	0.01	**0.04**	**0.67**
Semi-permanent hair dyes (and lotions)[2]	35 ml (per application)	-	0.01	**Not calculated[3]**	-
Oxidative/permanent hair dyes[2]	100 ml (per application)	-	0.01	**Not calculated[3]**	-
Make-up					
Make-up remover[2]	5.00	-	0.10	**0.50**	**8.33**
Eye shadow[2]	0.02	-	1.00	**0.02**	**0.33**
Mascara[2]	0.025	-	1.00	**0.025**	**0.42**
Eyeliner[2]	0.005	-	1.00	**0.005**	**0.08**
Deodorant					
Deodorant aerosol spray (ethanol-based)[4]	1.43	20.63	1.00	**1.43**	**20.63**

Product Information File



Regulatory Requirements

GMP (Good Manufacturing Practice)

ISBN 978-0-626-35441-1

SANS 22716:2011
Edition 1
ISO 22716:2007
Edition 1

SOUTH AFRICAN NATIONAL STANDARD

Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

This national standard is the identical implementation of ISO 22716:2007 (corrected version 2008), and is adopted with the permission of the International Organization for Standardization.

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SABS

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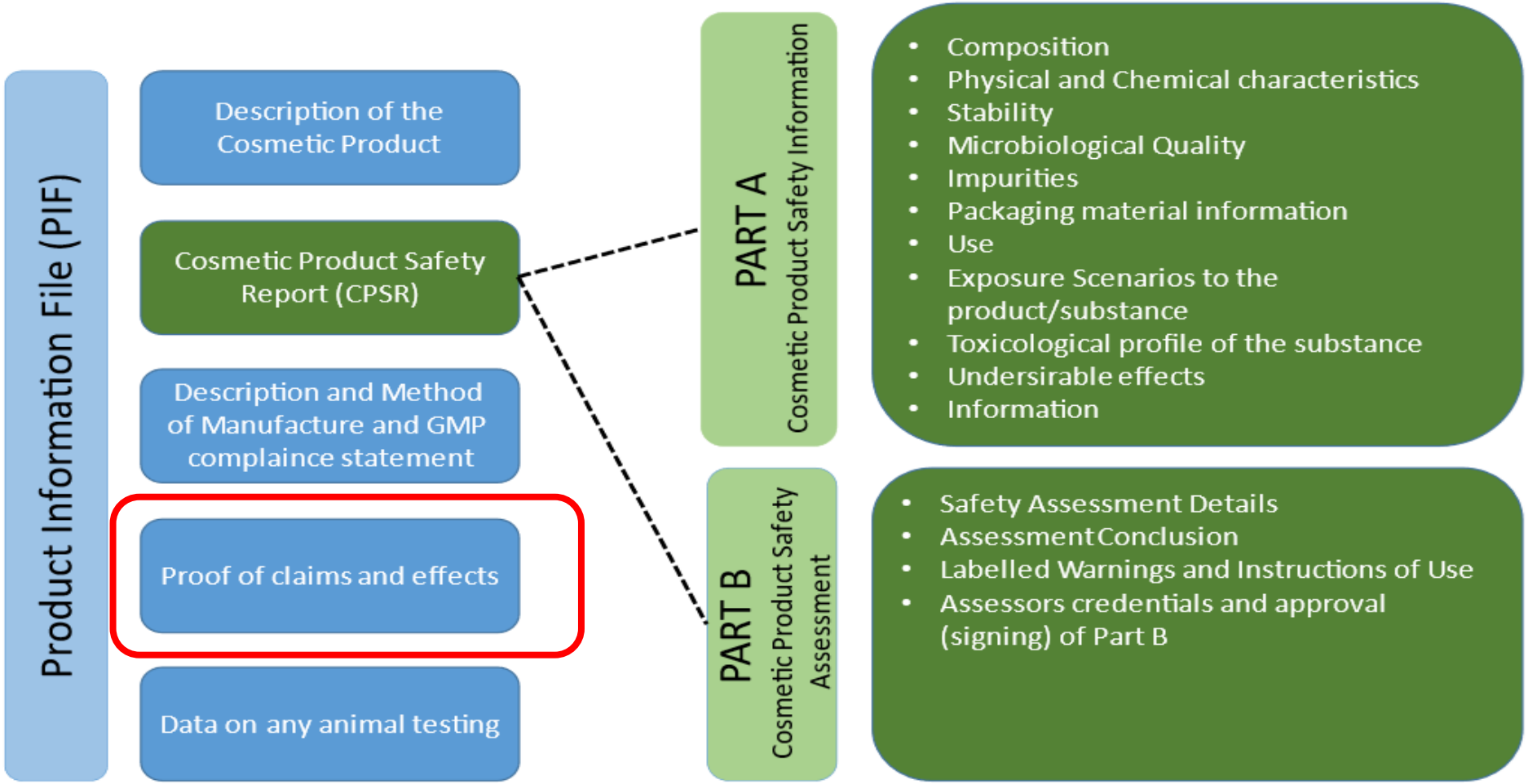


Product Information File

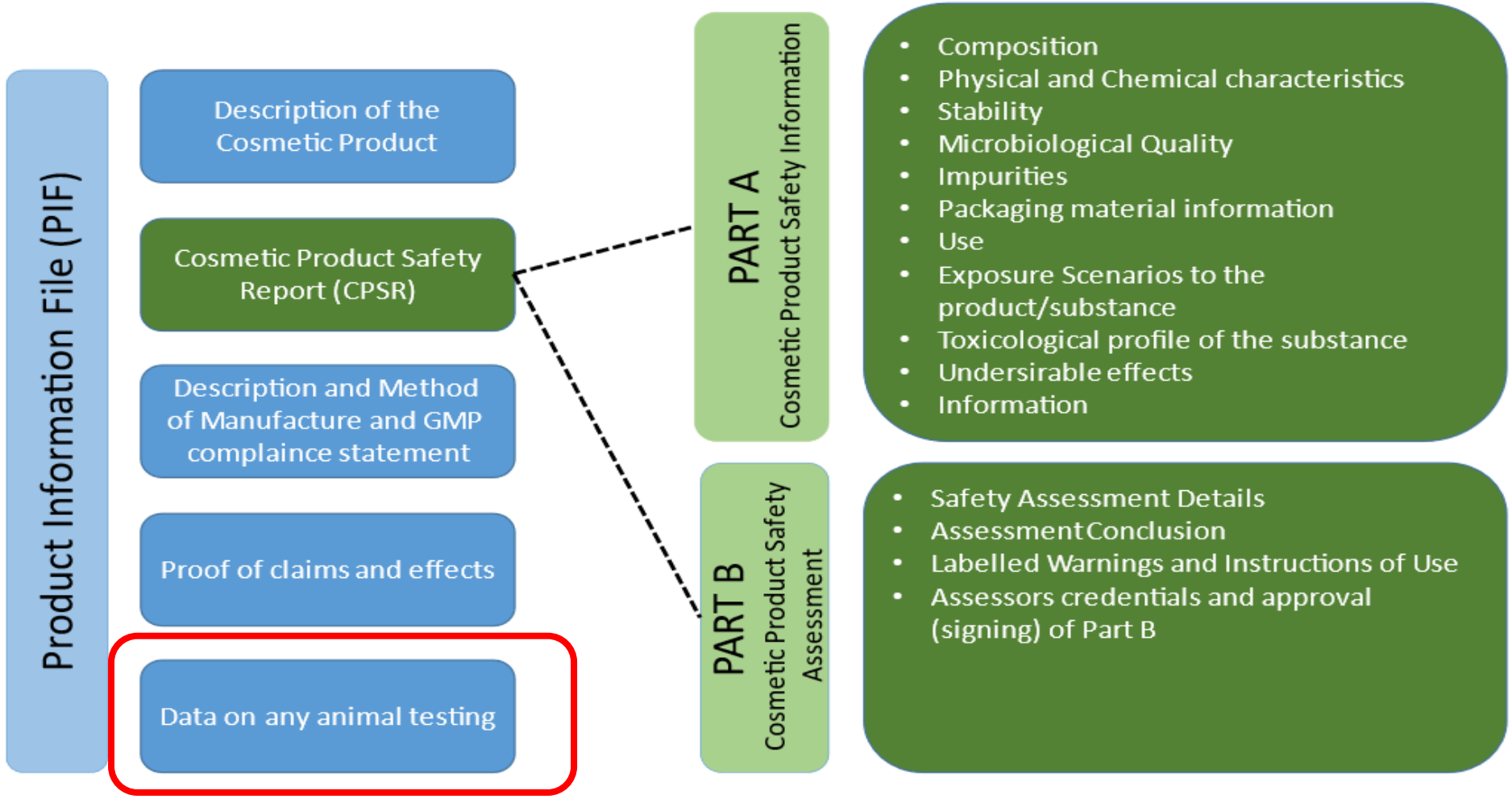
Cosmetic Product Claims

- ***Legal compliance*** is assumed and may not be stated e.g. does not contain hydroquinone (which is banned in the EU)
- ***Truthfulness*** – claims are not made falsely e.g. if it contains a specific ingredient then it should, claims on ingredients cannot be translated to the product unless proven scientifically using approved teat methods for the product e.g. moisturising, this product is 100% natural without an appropriate assessment
- Claims should be supported by ***appropriate supporting evidence***
- Claims ***cannot denigrate opposition and ingredients*** that may be legally included in a cosmetic e.g. this product does not contain parabens
- Claims should be ***clearly understood*** by the end user
- Tests should be conducted on human volunteers following ***ethical guidelines*** and products tested should have a ***safety assessment prior to human trials***

Refer to Technical document on cosmetic claims (3 July 2017), compiled by the EU Sub-working group

https://ec.europa.eu/docsroom/documents/24847

Product Information File



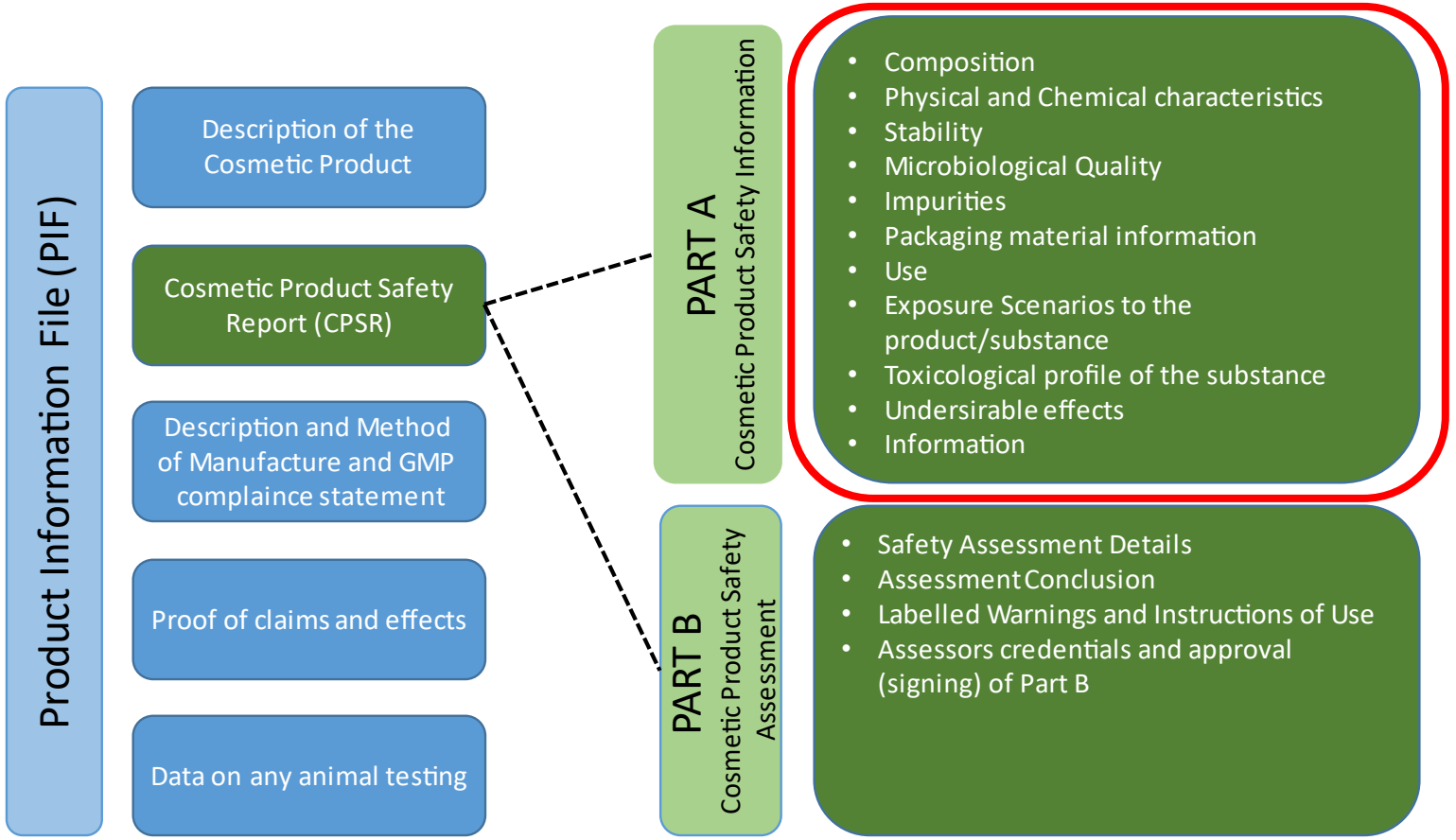
Product Information File

Animal Testing

- Prohibited for cosmetic product and ingredients where animal testing was conducted to meet the regulatory requirements for cosmetics
- Animal testing ban on finished cosmetic products applies since 11 September 2004
- Animal testing ban on ingredients or combination of ingredients applies since 11 March 2009.
- New ingredients developed for use in a cosmetic product safety data needs to be derived from non-animal alternative methods (OECD methods and approved by the SCCS). The EU reports annually on alternative test method development and validation –validated OECD test methods
- Pre-existing data prior to the deadline for an existing cosmetic ingredient can still be used
- Animal test data relating to chemical substances developed for uses other than cosmetics (e.g. food, medicines, biocides, etc.) can be used as supporting data of an ingredient intended to be used in a cosmetic product

Product Information File

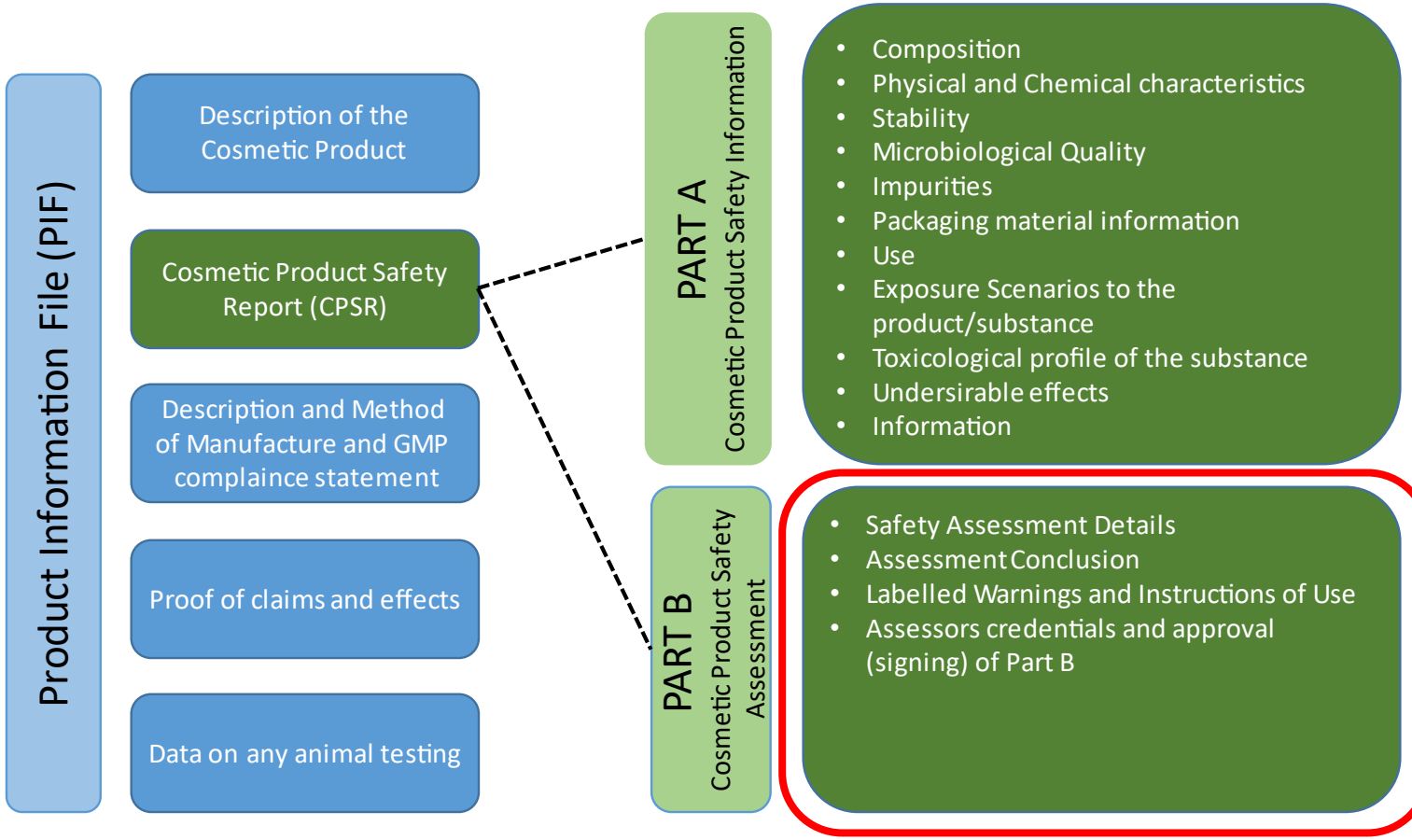
SAFETY ASSESSMENT PROCESS for CPSR



Collect Data from suppliers, validated scientific data, tests using validated test methods as required by regulation

Product Information File

SAFETY ASSESSMENT PROCESS for CPSR



Safety Assessor conducts Safety Assessment based on relevant toxicological and exposure data in accordance with regulations and guidelines

HAZARD ≠ RISK

Hazard:

- Potential to cause harm based on properties of chemical (Toxicological, Physical, Chemical, tests)

Risk:

- Probability to cause harm relating to exposure (length of time and concentration/amount)

What do we need to know in order to conduct a RISK ASSESSMENT on a chemical component in a cosmetic product?

1) A complete component profile of the chemicals in a raw material with as little uncertainty as possible;
    a. If you do not understand with confidence all the components of a raw material (in this project an essential oil or vegetable oil) and do not understand the safe level of the chemical component for an application e.g. a FACE CREAM, safety cannot be determined;
2) Possible contaminants:
    a. Heavy metals and pesticides (often as a result of the inherent nature of the product e.g. Natural) to solvents that were used for the extraction to contaminants related to packaging as well as storage conditions (oxidation, microbiological degradation etc)

WHY do we need the CONFIDENCE in the analyses of a chemical?

1) What does CONFIDENTLY mean?
   A. The analytical profile of the oil has been done by a laboratory that works according to GLP (Good Laboratory Practice);
   B. A chemical must be extracted/manufactured stored according to GMP (Good Manufacturing Process);
   C. All possible components have been identified including contaminants;
   D. The oil stability has been proven i.e. packaging compatibility, microbiology and oxidative stability throughout the process
2) Is it safe for human consumption? Consider ROUTES OF EXPOSURE:
   A. Orally
   B. Dermal
   C. Inhalation
3) Physical/Chemical nature of components
   1) Organic/Inorganic
   2) Water Solubility
   3) Size of particle
   4) Dermal/oral/inhalable absorption %

Safety Assessment

Understanding Toxicokinetics and Toxicodynamics (Mechanisms of action) of each chemical component required:

A. Absorption
B. Distribution
C. Metabolism and
D. Elimination

NB to understand the application of the chemical and the amount of exposure per day e.g. cosmetic, food, pharmaceutical etc and type/amount

TOXICITY PROFILE

Once we understand exposure route/s we need to understand the TOXICITY PROFILE of the components:

A. Acute e.g. LD50
B. Chronic e.g. NO(A)EL (No Observable (Adverse) Effect Level or BMD (Bench Mark Dose)
    A. Long term systemic effects – Repeated dose toxicity
        i. Subacute (28 days)
        ii. Subchronic (90 days)
        iii. Chronic (85% of life)
    B. Carcinogenicity
    C. Mutagenicity (Reproductive, development)
    D. Target Organs
C. Sensitisation (EC50)
D. Skin/Eye Irritation
E. Photo-induced toxicity
F. Point of Departure (PoD) – level of proven safety

Need to find the SAFE DOSE LEVEL of the chemical component

Questions to ask during a safety assessment:

- Leave on or rinse off – duration of contact?
- Amount applied per day?
- Frequency of use per day?
- Concentration of the component in the product?
- Exposure Route – Dermal, Inhalation, Ocular, Ingestion?
- Stage of life and state of health?
- Absorption rate
- Any contaminants? (Microbiological, technically unavoidable, packaging leachables?)

Safety Assessment

Understanding the components of each Raw material

- Name of chemical (CAS, INCI)
- Concentration range (max. concentration used for tox assessment)
- Function of each component in the Raw Material (constituent, additive, contaminant)

INCI name	CAS no.	Composition function	Percentage
Linoleic Acid	60-33-3	Substance constituent	31.934000
Oleic Acid	112-80-1	Substance constituent	30.751000
Palmitic Acid	57-10-3	Substance constituent	26.880000
Stearic Acid	57-11-4	Substance constituent	3.780000
(E)-Octadec-11-ene acid	693-72-1	Substance constituent	1.875000
Erucic Acid	112-86-7	Substance constituent	0.978000
Arachidic Acid	506-30-9	Substance constituent	0.805000
Linolenic Acid	463-40-1	Substance constituent	0.442000
Tetracosanoic acid	557-59-5	Substance constituent	0.390000
cis-11,14-Eicosadienoic acid	5598-38-9	Substance constituent	0.310000
(Z)-hexadec-9-enoic acid	373-49-9	Substance constituent	0.225000
Gondoic Acid	5561-99-9	Substance constituent	0.215000
Myristic Acid	544-63-8	Substance constituent	0.210000
Heptadecanoic acid	506-12-7	Substance constituent	0.190000
cis-10-Heptadecenoic acid	29743-97-3	Substance constituent	0.120000
Elaidic acid	112-79-8	Substance constituent	0.085000
15-Tetracosenoic acid, (15Z)-	506-37-6	Substance constituent	0.060000
Pentadecanoic acid	1002-84-2	Substance constituent	0.050000
Butyric Acid	107-92-6	Substance constituent	0.035000
Lauric Acid	143-07-7	Substance constituent	0.005000
Calcium	7440-70-2	Substance constituent	0.003610
Potassium	7440-09-7	Substance constituent	0.001970

Safety Assessment

Safety Assessment: Example of a Toxicological safety Assessment for a chemical component

Tox data available

Arachidic Acid	***NOAEL, lowest***	370	mg/kg bw/day (ECHA)
	Body Weight	60	
	amount/day -product/g	8	g/day (Colipa)
	% of Ingredient in product	0,81%	
	retention	0,01	depends on exposure
	dermal absorption	50%	default is 50%
	amount available systemically	5,3667E-06	g/kg bw/day
	Margin of Safety (MoS)	68 944	must be >100

Tox data NOT available: Structural

Toxicity Threshold Calculation (TTC) for a carcinogen		
	0,0025 ug/kg bw/day	*Kroes et al 2004*
	0,15 ug/day	
bw	60	kg
amount/day/product	8	g
Retention Factor	0,01	
dermal absorption	50%	
Systemic Availability of component	0,04	g
	40000	ug
component conc threshold	0,000375%	
	0,15	ug

How to register on the Cosmetic Product Notification Portal (CPNP)

CPNP is a free online notification system for the implementation of Regulation (EC) No 1223/2009 on cosmetic products

It is the responsibility of the EU Responsible person to register the product prior to the product being placed on the market

The European Commission website provides a tutorial on how to request access to CPNP (https://webgate.ec.europa.eu/cpnp/public/tutorial.cfm)
It gives the following steps:

1. EU login account
    a. If you already have a valid EU login account
    b. If you need to create a valid EU login account
    c. If you do not remember your EU login account
2. How to be defined as an organisation or request access in SAAS
3. How to enter CPNP

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Any Questions?

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THANK YOU

for your attention.