An overview of the European Cosmetic Regulation

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GPC Global Product Compliance

COSMED THE FRENCH COSMETICS ASSOCIATION FOR SMEs

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RRMA REGULATORY REPRESENTATIVES & MANAGERS ASSOCIATION

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LOBBYING FOR COSMETIC COMPANIES

→ ANSM
→ European Commission
→ ISO, CEN , AFNOR
→ Foreign countries authorities

SHARED SERVICES

→ Regulatory watch
→ Free Sale Certificates : https://www.cosmedcvl.fr/
→ Training
→ Purchasing group
→ Events, Congress

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WORLDWIDE REGULATORY WATCH – ACCESS TO THE DATABASE

YOUR WORLDWIDE REGULATORY MONITORING

120 Countries monitored (Europe & international).
On-line available databases 24 hours, 7 days

1500 Updated factsheets and summary tables

48h Deadline answer to your regulatory requests from a specialized team

7 days a week Email alerts at each regulatory amendment

Uptaded database - Experts assistance

CHOOSE your tailored solution

1 database France / Europe OR International
2 databases France / Europe AND International

EUROPEAN DATABASE

. French and E.U regulations
. Specificities of E.U
. Summary Tables of regulated ingredients
. Product Information File
. Assessment of ingredients
. Notification of cosmetic product
. Labelling, Claims
. Cosmetovigilance
. PAO tool
. REACH, CLP
. Actors' Obligations ...

INTERNATIONAL DATABASE

. Classification of products: cosmetics, quasi-drugs, OTC, Natural Products
. Fact sheets on regulations
. Summary tables of regulated substances
. Labelling, Claims
. Registration / Notification of products ...
. Comparative substances tables (UV filters ...)

NEW COSMED REGULATORY monitoring in english
A real asset for foreign subsidiaries and / or distributors

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INTRODUCTION

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Before 11 july 2013?

Cosmetics Directive76/768/EEC Adopted in 1976

Reasons for Recast

- Significant amendments
- Diverging transposition
- Simplifying procedures and streamlining terminology

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DEFINITIONS

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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”

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RESPONSIBLE PERSON

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Responsible person

Only cosmetic products for which a legal or natural persons designated **within the Community** as ‘responsible person’ shall be placed on the market.

Who is the responsible person?

- Manufacturer within EU
- Manufacturer outside EU –shall designate an RP within the EU
- Each Importer is RP
- Distributor is RP where he places product on the market under his name or modifies a product already on the market in such a way that compliance with the applicable requirements may be affected

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Obligations of the responsible person

1. Product classification
2. Ingredients compliance
3. GMP compliance
4. Labelling / Claims
5. Product information file including safety report
6. Notification
7. Cosmetovigilance

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Regulated substances

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Compliance with annexes of restricted and prohibited ingredients:

- ANNEX 2 : prohibited ingredients
- ANNEX 3 : ingredients with restrictions
- ANNEX 4 : authorized colorants
- ANNEX 5 : authorized preservatives
- ANNEX 6 : authorized UV filter

} Positive lists

Good manufacturing process

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GMP Good Manufacturing Practices ISO 22716 or any other equivalent standard

- Self certification
- Possibility to a third party certification (not mandatory)

Labelling

	Container	Packaging
Name or corporate name and address of the responsible person (note 1)	x	x
Country of origin if imported cosmetic products	x	x
Nominal contents (note 2)	x (exempted if lower than 5g or 5ml, free samples and single dose	x (exempted if upper to 5g or 5ml, free samples and single dose)
Date of minimum durability / PAO (note 3)	x	x
Precaution of use (note 4)	x	x
Batch number of manufacture	x (excepted in case of practical impossibility linked to the size)	x
Function of the product (excepted if it comes out of its presentation)	x	x
List of ingredients (note 4)		x

Other regulatory/voluntary mentions

- **Sunscreen labelling (EC's recommandation)**

- **Aerosols**

- **Environment**

- **Labels**

Language :

Some Member States require mandatory information in the language of their territory on :

- The function
- The content
- Use and precautions

Claims

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- **Regulation (EC) 655/2013 on cosmetic claims** sets 6 common cumulative criteria:
  - Legal compliance
  - Truthfulness
  - Evidential support
  - Honesty
  - Fairness
  - Informed decision-making

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PRODUCT INFORMATION FILE

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How to structure a PIF?

- Product description
  - A clear link must be established between the cosmetic product and the Product Information File
- Cosmetic Product Safety Report (CPSR)
  - Part A and B
- Manufacturing method and GMP compliance
- Evidence of the claimed effect
- Animal testing data

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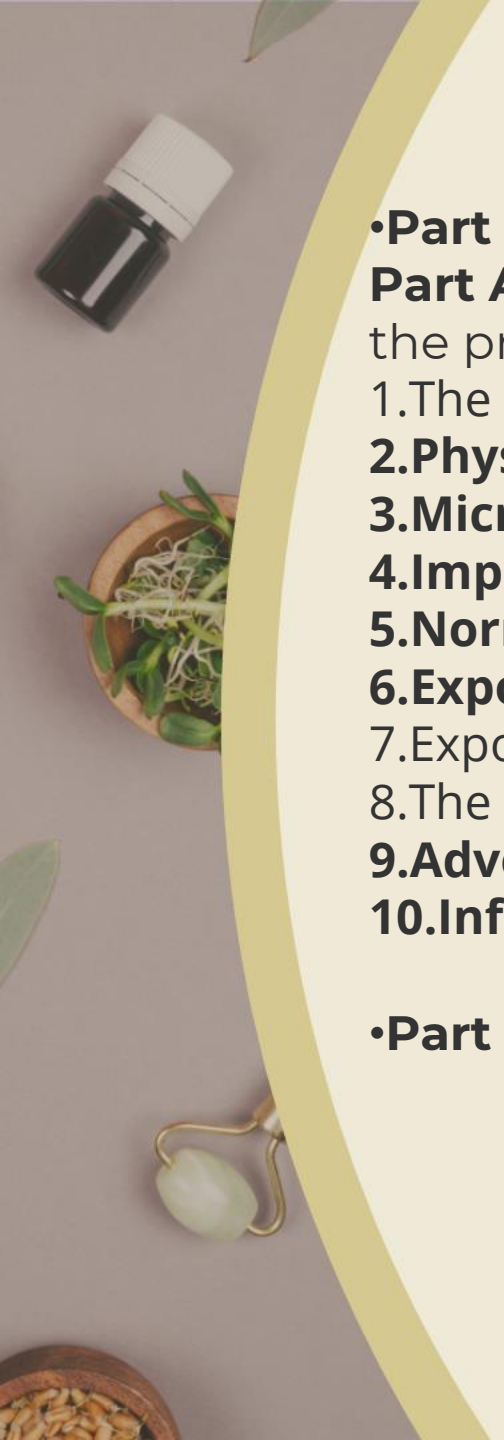

•**Part A**: Information on the safety of the cosmetic product
Part A is intended to collect the numerous data necessary for the safety assessment of the product. It contains:
1.The quantitative and qualitative **composition** of the cosmetic product
2.Physical/chemicalcharacteristics and product stability data
3.Microbiological quality
4.Impurities, traces, and information about the packaging material
5.Normal and reasonably foreseeable **use**
6.Exposure to the cosmetic product
7.Exposure to **substances**
8.The **toxicological profile** of the substances
9.Adverse reactions (ARs) and serious adverse reactions (SARs)
10.Information on the cosmetic product

•**Part B**: Cosmetic product safety assessment

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NOTIFICATION

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Prior to placing the cosmetic product on the market the responsible person shall submit, the following information to the Commission:

- the category of cosmetic product and its name or names, enabling its specific identification;
- the name and address of the responsible person
- the country of origin in the case of import;
- the Member State in which the cosmetic product is to be placed on the market;
- the contact details of a physical person to contact in the case of necessity;
- the presence of substances in the form of nanomaterials
- the name and CAS number of substances classified as CMR, of category 1A or 1B;
- the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

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IMPORTANT: reminder of security rules on ECAS password
Multiple windows/tabs

Welcome to the Cosmetic Products Notification Portal

The CPNP is the online notification system created for the implementation of Articles 13 and 16 of Regulation (EC) No 1223/2009[1] of the European Parliament and of the Council on cosmetic products.

The responsible persons and, under certain circumstances, the distributors of cosmetic products shall submit some information about the products they place or make available, or intend to place or make available, on the European market through the CPNP.

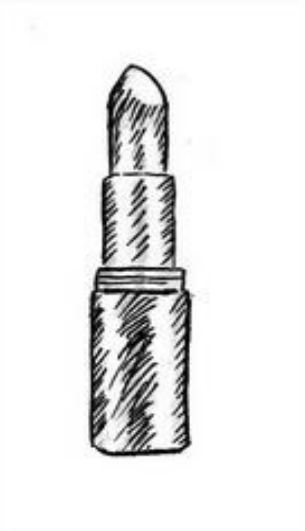
In Accordance with Article 13 of the above mentioned Regulation, the CPNP makes available some of the above mentioned information to the Competent Authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information) and to the Poison Centres or similar bodies established by Member States (for the purposes of medical treatment).

According to Article 16 of the above mentioned Regulation, the CPNP makes available the information related to nanomaterials to the European Commission who might request the Scientific Committee on Consumer Safety to perform a risk assessment in case of concerns regarding the safety of a nanomaterial.

[1]OJ L342, 22.12.2009, p.59

Products

Add a new product



Notify a single component product

Notify a multi-component product

Do not show again

Products

Add a new product

** Only product/component name and language are required when saving as draft

* Required fields for notification

Save as draft | Notify | Cancel

General information | Product details

Industry Reference

** **Product Name:**

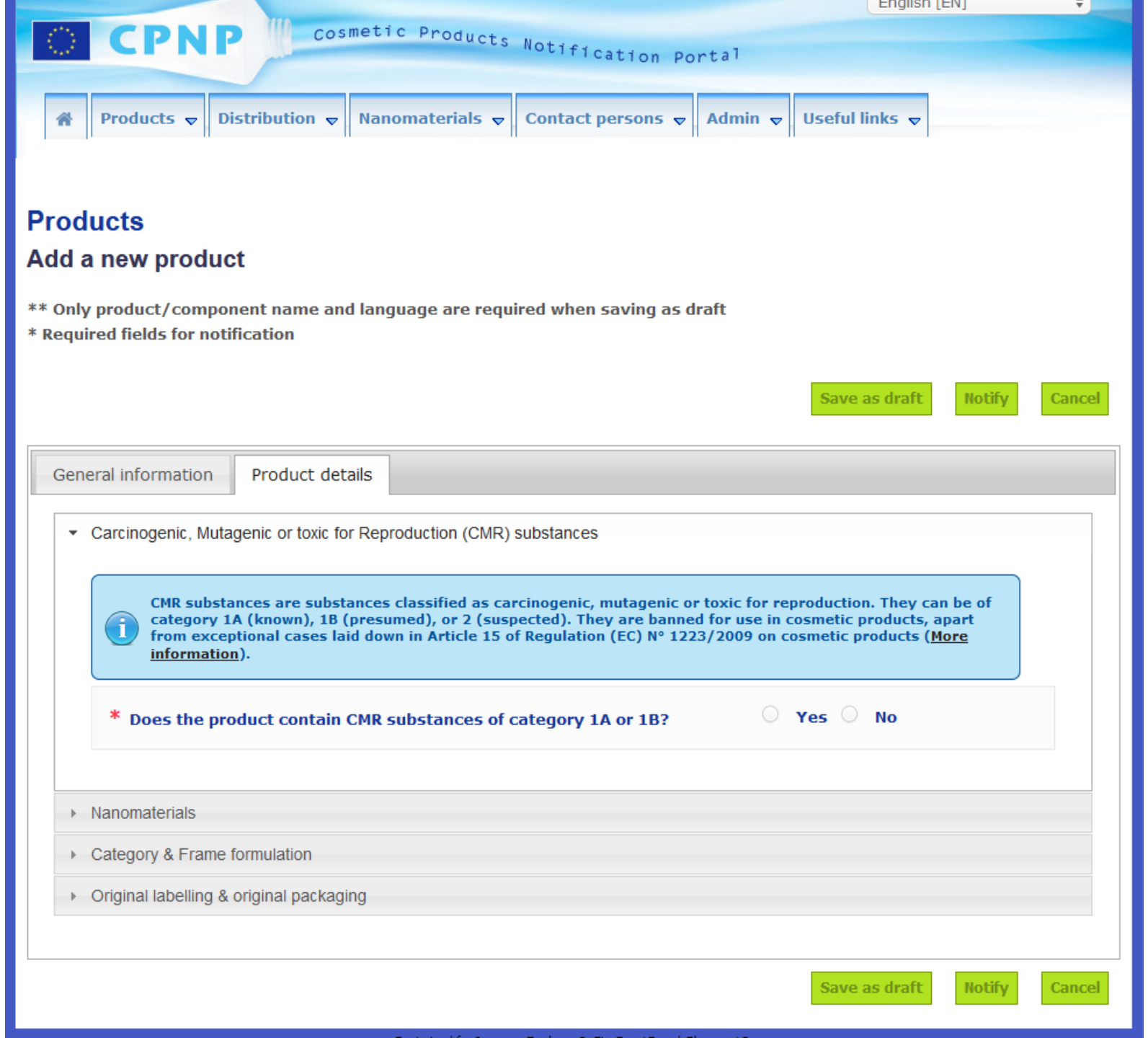
** **Language:** Select a language +

Shades (if applicable):

* **Is the product specifically intended for children under 3 years of age?** Yes No

* **Responsible person**

* **Contact person**


English [EN]
CPNP
Cosmetic Products Notification Portal
Products
Distribution
Nanomaterials
Contact persons
Admin
Useful links
Products
Add a new product
** Only product/component name and language are required when saving as draft
* Required fields for notification
Save as draft
Notify
Cancel
General information
Product details
Carcinogenic, Mutagenic or toxic for Reproduction (CMR) substances
CMR substances are substances classified as carcinogenic, mutagenic or toxic for reproduction. They can be of category 1A (known), 1B (presumed), or 2 (suspected). They are banned for use in cosmetic products, apart from exceptional cases laid down in Article 15 of Regulation (EC) N° 1223/2009 on cosmetic products (More information).
* Does the product contain CMR substances of category 1A or 1B?
Yes
No
Nanomaterials
Category & Frame formulation
Original labelling & original packaging
Save as draft
Notify
Cancel

COSMETOVIGILANCE

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1/ **Mandatory notification** to the concerned Member State's competent authorities and provide:

- All **serious undesirable** effects known to them;
- The name of the cosmetic product concerned (for its identification);
- The corrective measures they have taken, if any

2/ **Mandatory cosmetovigilance process** by registering all events that occur during the marketing.

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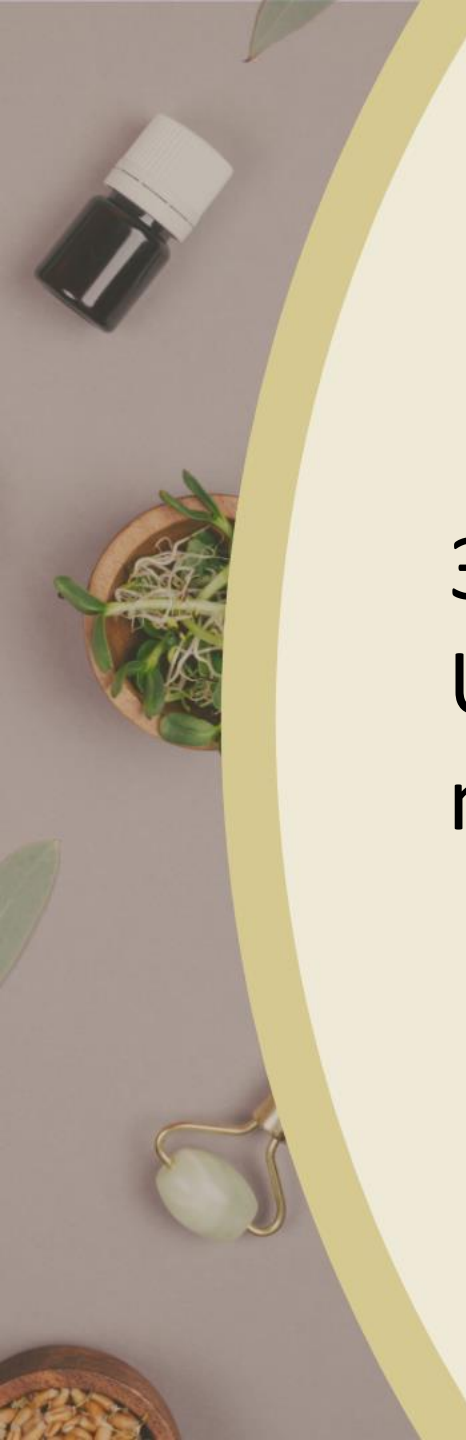

3/ **Mandatory reporting** : all available data on UE and SUE relating to the cosmetic product must be reported. This includes statistical data.

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OBLIGATIONS OF THE DISTRIBUTOR

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- Verify labelling is compliant
- Language requirements
- Date of minimum durability
- Shall not make non-conforming product available
- Respect Storage and transport conditions
- Where a product presents a risk, inform the RP and the CA where the product is made available (CPNP)
- Report serious undesirable effects

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CONCLUSION

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STEP 1: RP designation

STEP 2: Product Classification

STEP 3: PIF

STEP 4: Product Description
Safety Report → Safety Information
Safety Assessment

GMP
Method of Manufacture
Proof of effect claimed
Data on animal testing
Labelling → Container & Packaging

STEP 5: EU Notification

STEP 6: EU Market

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Thank you for your attention

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