

# Factsheets: The Product Information File

THE DATABOOK 2018

# PIF - 1223/2009



<b>PIF, THE COSMETIC PRODUCT INFORMATION FILE</b> .....	p. 3
PIF: Which responsibilities for whom? .....	p. 4
Products covered by the PIF .....	p. 6
PIF: which format, which language? .....	p. 7
Location and access to the PIF .....	p. 8
Information required in the PIF: Product Description .....	p. 10
Information required in the PIF: Cosmetic Product Safety Report .....	p. 11
Information required in the PIF: Manufacturing method and declar... ..	p. 14
Information required in the PIF: Evidence of the claimed effect .....	p. 15
Information required in the PIF: Animal testing data .....	p. 16
PIF: who may be safety assessor? .....	p. 17
PIF updating .....	p. 18
Public access to PIF information .....	p. 19
PIF retention period .....	p. 21

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# PIF, the cosmetic Product Information File

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On July 11, 2013, Regulation 1223/2009, known as the Cosmetics Regulation, completely replaced the former Directive that had governed cosmetic products since 1976. Recast of a text that had been subject to numerous amendments and technical adaptations over the years, this Regulation has not made any fundamental changes in the general principles. But it has reinforced the notion of a Product Information File (PIF), codified and structured around the Cosmetic Product Safety Report (CPSR). This Databook proposes a series of practical zooms, to ensure that your PIFs comply with current regulations.

## PIF: WHICH RESPONSIBILITIES FOR WHOM?

The PIF (Product Information File), within the meaning of Cosmetics Regulation 1223/2009, involves obligations for three main actors: the Responsible Person, the safety assessor, the distributor.

### Duties of the Responsible Person

- Ensure that a cosmetic product placed on the EU market is safe for human health under normal or reasonably foreseeable conditions of use
- Maintain specific information on the product that he places on the market, as specified under Article 11 of EU Cosmetic legislation PIF: *“When a cosmetic product is placed on the market, the Responsible Person shall keep a product information file for it”*
- Be in a position to demonstrate upon request that the product he has placed on the market meets the requirements laid down by the EU cosmetics legislation  
cf. Art 5.3: *“Responsible Persons shall cooperate with these authorities, at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular, Responsible Persons shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in a language which can be easily understood by that authority”*
- Ensure that the Cosmetic Product Safety Assessment has been performed by a safety assessor, i.e. a person with appropriate qualifications and expertise
- Keep the product’s safety assessment as well as the data upon which it is based as part of a “Cosmetic Product Safety Report” in the PIF and update it in view of additional relevant information generated subsequent to placing the product on the market  
cf. Art. 10.1.c: *“The Responsible Person shall ensure that the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market”*
- Ensure that he has a PIF available in order to answer the enquiries made by the competent authority where the PIF is kept and to bring evidence that the product is in compliance with the Regulation
- Be the first point of contact for the enforcement authorities should there be any enquiry on the product he has placed on the market

#### Note

- The Responsible Person may, by written mandate, designate a person established within the Community as the Responsible Person who shall accept in writing
- The Responsible Person can outsource tasks for collating and storing the PIF, but the overall responsibility always lies with the Responsible Person placing the product on the market
- The Responsible Person has not necessarily to prepare the PIF on his/her own. He/She can draw upon several sources of expertise to fulfill the PIF requirements: in-house support from Research & Development, safety, quality assurance departments; literature review; data from suppliers, third party experts and consultants; trade associations and competent authority advice and support

### Duties of the distributor

- Collaborate with the Responsible Person and the national competent authorities whenever necessary to ensure compliance with the Regulation - See: **Distributors of cosmetics: a focus on your obligations**

### Duties of the safety assessor

- Assess the safety of the cosmetic product before it is placed on the market
- Depending on his contractual agreement with the Responsible Person, the safety assessor may also have to:

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