

# A very quick guide for complete newbies to what you need to do to comply with the EU Cosmetic Regulations

## Introduction

The Cosmetic Regulations are drawn up by the European Commission and are revised regularly, normally every four years. The regulations apply to all cosmetic products which are defined in a way that is pretty close to common sense. The enforcement is in the hands of national governments, and varies a little from country to country but the UK is typical in that it doesn't have any specific officials enforcing it. The job is undertaken by the normal trading standards officers who are employed by local authorities at the county council or city council level. But the reality is that the main way that regulations are enforced is through the activities of the big supermarkets and other large scale distributors of cosmetic products. Most of these have their own standards and expectations of what they expect to see. If you intend to sell your products into these kinds of outlets you will need to meet their interpretation of the cosmetic regulations.

## The PIF File

The main provision of the cosmetic regulations is that every product needs to have a Product Information File, or PIF File.

- Formulation
- Stability Data

- Micro Data
- Safety Assessment
- Claim Support Data
- Adverse Reaction Reports

## Formulation

The PIF file needs to contain the formulation of the product, This is the recipe, the way it is made, the suppliers of all the raw materials and the specification of the final product.

## Stability Data

It needs to contain any stability data you have and certainly enough to demonstrate the stability of the product. There is a generally agreed format for stability studies that you will need to satisfy the auditors of big customers.

## Micro Data

If the product is liable to microbial attack, you will need to demonstrate that it is safe from contamination. The evidence for this will almost always need to be in the form of a standard preservative efficacy test performed by a dedicated microbiological laboratory to a protocol that is recognised. The only flexibility is that the European Pharmacopoeia and the United States Pharmacopoeia ones are both equally valid.

## Safety Assessment

The most important part of the PIF file and the one that has an official format is the safety assessment, often referred to as a CPSR report. This has to be done by somebody suitably qualified. Although the actual qualifications are not too restrictive - they are effectively any science degree that involves the study of toxicology - it is wise to make sure that your assessor is somebody who understands your formulation types. In the event of a query arising on the safety of your product you need to have somebody to turn to who sounds credible. In the worst case scenario, this person could be appearing on your behalf in court.

<https://colinscosmeticconsultancy.co.uk/collections/sorting-out-regulations/products/cpsr-safety-assessment-safety-assessment-for-a-cosmetic-product>

## Claim Support Data

The other important part of the PIF file is the supporting data for any claims you are making for the product. Not all cosmetic products need to make claims - for example you can sell a soap bar with just that statement that it is a soap bar and the consumer will understand fully what is being offered. And obvious claims such as 'this shampoo will wash your hair' do not need to be substantiated. Other claims, such as moisturises the skin for 24 hours, will need to be backed up with data held in the PIF file.

## Adverse Reactions Reports

The PIF file also needs to keep records of all the adverse reactions you have received to the product. Serious adverse reactions need to be reported.

## CPNP Portal Registration

There is no approval system for cosmetics. If you have met all the legal requirements in developing and manufacturing it, you can put it on the market. However, you do need to notify the product on the CPNP portal.

It just stands for Cosmetic Product Notification Portal.

It is an online system where you apply for an account - this usually takes a few days to come through - and then you have to notify each of the products that you sell, giving some details of the formulations and uploading the artwork.

It isn't enormously difficult to register products in most cases, so long as you have all the details to hand. It is however time consuming.

<https://colinscosmeticconsultancy.co.uk/collections/sorting-out-regulations/products/cpnp-registration>