



Annel

STABILITY OF COSMETIC PRODUCTS

EU & UK REGULATIONS



Introduction

One of the most important factors determining the quality of a product is its stability. Product duration is also one of the essential elements required for the safety assessment (**the Cosmetic Product Safety Report, Annex I to Regulation (EC) No 1223/2009**).

According to Article 3 of Regulation (EC) No 1223/2009:

“A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use”

Stability of the cosmetic product affects its safety during the use by the consumer. Last but not least, stability plays a key role by impacting the effectiveness of a product.

The meaning of the term “stability“:

In a general sense, the duration of cosmetic products refers to their **physicochemical or microbiological stability**. In this guide, we took a look at the basics of the “physicochemical stability” issue, providing a brief explanation of the parameters required for the preparation of CPSR and proper safety assessment.

Physicochemical stability can be described by using three main parameters: **shelf life, PAO, and compatibility with packaging**.

The shelf-life aka duration time or expiry date means the determined period under which a cosmetic product is safe for use.

The PAO means the period from the first opening of a product under which a cosmetic product is safe for use.

The compatibility with packaging enables demonstrating that a product is stable over time and there are no interactions between the product and packaging. The compatibility test is mandatory for every kind of cosmetic product.

Shelf life vs. PAO

There are two options on how to inform the consumers about the product's duration time.

Option 1

For products with a minimum durability of **less than 30 months**, it is mandatory to place the shelf-life on the label by using the only acceptable phrase “**best used before the end of**”. Acceptable forms of the expiry date are **DD MM YYYY or MM YYYY**, in this specific order.

Alternatively, the **hourglass symbol** can be used instead of the “best used before the end of” phrase.

Option 2

For products with a minimum durability of above 30 months, the expiry date with the phrase “best used before the end of” is acceptable but not mandatory. Instead, there is an obligation for the manufacturer to determine the Period After Opening (PAO) parameter. The PAO means the period from the first opening of a product under which a cosmetic product is safe for use. For products with a minimum durability of above 30 months is mandatory to place the PAO information on the label. The acceptable form is in this case an “open jar” symbol followed by the period in months or years.

Note

The determination and labelling of PAO are acceptable but not mandatory for products with a minimum durability of less than 30 months.

Usually, stability testing is performed aiming to establish both shelf life and PAO parameters at the same time. In addition, the most reliable is testing that meets the requirements of ISO standards*.

So make sure to discuss all the experimental details while outsourcing the analysis.

Is the determination of shelf-life or PAO mandatory for all types of products?

There are some products that do not deteriorate during normal use, and for those products, the determination of shelf-life or PAO is not relevant.

These products are:

- **single-use products;**
- products packed in a packaging that **does not allow physical opening, contact with an external environment and contamination** during use (e.g. pressurized containers, aerosols, air-less packaging);
- products with **high alcohol content** (> 20%).

The Purposes of Stability Testing

Physicochemical testing

the correct product duration
“Shelf-Life”

the duration after opening
“PAO”, Period After Opening

the stability in final packaging
“Compatibility Test”



always mandatory

Microbiological testing

Antimicrobial Efficacy
of Preservatives/
Preservatives Efficacy
Test (PET)
“Challenge Test”

“Shelf -Life” - is it mandatory to determine?

Yes

Product with the Shelf-Life
 ≤ 30 months

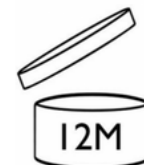
- **expiry date must be displayed;**
- the expiry date should be preceded by a phrase "**best used before the end of**";
- the phrase can be replaced by the "**hourglass symbol**";



- the expiry date should be in **DD MM YYYY** or **MM YYYY** form;
- in this case determination of **PAO** is **not mandatory** but acceptable;

Product with the Shelf-Life
 > 30 months

- in this case determination of **PAO** is **mandatory**;
- **PAO** is represented by the open jar symbol with a written number of months or years;



- in this case placing **the expiry date** on packaging is **not mandatory** but acceptable;

“Shelf -Life” - is it mandatory to determine?

No

Case 1: Single-use product

Case 2: Products packed in a packaging that does not allow contamination during use (e.g. pressurized containers)

Case 3: Products with high alcohol content (> 20%)

All tests should be performed using the testing methods, which are accepted by the EU and UK authorities, ISO standards.

ISO/TR 18811:2018 Cosmetics- Guidelines on the stability testing of cosmetic products

ISO/TR 13097:2013 Guidelines for the characterization of dispersion stability

ISO 11930:2019 Cosmetics- Microbiology- Evaluation of the antimicrobial protection of a cosmetic product

ISO 29621:2017 Cosmetics- Microbiology- Guidelines for the risk assessment and identification of microbiologically low-risk products