

Period after Opening (PaO) - a new requirement for cosmetic manufacturers -

Under article 6(1)(c) of the European Cosmetic Directive (76/768/EEC) it is foreseen:

„(...) Indication of the date of durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product can be used without any harm to the consumer. This information shall be indicated by the symbol given in Annex VIIIa followed by the period (in months and/or years)“.

This means in short:

- Products with a min. **durability of \leq 30 months:**
need to be labelled with „best used before the end of ...“
- Products with a min. **durability > 30 months:**
need to be labelled with a period after opening „for which the product can be used without any harm to the consumer“

A product can be seen as being harmful to the consumer when, in accordance with Article 2 of the Cosmetic Directive, it can cause damage to human health. The deterioration may be linked to:

- the deleterious effect of micro-organisms and/or
- physico-chemical degradation

that would lead to

- harm to the consumer
- the decrease of efficacy when the modification of the efficacy can affect the safety of the product , i.e. may cause damage to human health (e.g. UV protection of sun products)

A variety of relevant methods may be used to support the period indicated on a product, including those used during product development, since there is no officially sanctioned methodology that could be used. Examples of sources of information for assessing a product's PaO may include:

- microbiological challenge tests
- stability data
- analytical data (e.g. preservative analysis)
- type of packaging
- experience with similar formulations and products
- consumer habits and practice

The mention of the PaO seems not to be relevant when there is:

- no physical opening of the product as is the case for products presented in containers where there is no possibility of contact between the product in the container and the external environment (e.g. sealed pressurised containers)
- no period after opening as is the case for single-use products, which are designed to be used only once
- no risk of harm to the consumer, as there is no risk of deterioration that could lead to, in accordance with Article 2 of the Cosmetic Directive, damage to human health.

The PaO is to be mandatory on cosmetic products placed on the European Community market from 11 March 2005.

What does S&M as supplier of cosmetic preservatives recommend to its customers when it comes to PaO? Please refer to next page.

What does S&M as supplier of cosmetic preservatives recommends to its customers on PaO?

- 1) S&M recommends to avoid PaO and to label shelf life instead. The shelf life of ≤ 30 months in a closed package will be assessed by our S&M Koko Test.
- 2) You may want or may be forced by retailers to label PaO in order to avoid shelf maintenance acc. to the first-in-first-out principle or not to take back products after the best used-date. In these cases S&M recommends that the cosmetic manufacturer uses at least some of the following additional data beside the results of a S&M Koko test to assess PaO:
 - a) Experience on microbiological stability of the product during consumer use based on i.e. complaint statistics
 - b) Microbiological challenge test with product in-use for the period of time desired as PaO
 - c) Stability of preservative actives after 30 months storage
 - d) Experiences with similar products and formulations

You than should take into consideration the type of packaging of the individual product, consumer habits and practice for use and storage of the product in-use.

We at S&M can assist you with the following tests:

- S&M Koko test (microbiological challenge test) during development of a cosmetic product, in difference to the pharmaceutical tests the S&M Koko test includes already a sixfold re-challenge in opened package
- S&M Koko test (microbiological challenge test) of cosmetic products after storage (e.g. retaining samples from existing formulations) or use (products for testing must be provided by the cosmetic manufacturer)
- Analysis of preservative actives in cosmetic products (stability of the preservative actives after storage)
- Determination of germ count (after use, e.g. in samples from a panel test)

It is the responsibility of the cosmetic manufacturer to decide which PaO may be printed on the label of each cosmetic product he manufactures. It is your risk assessment to be justified in the product dossier for each of your products. S&M can help you by providing additional data but cannot claim any PaO for you.

If you have any further questions, please do not hesitate to contact us.

Yours truly,
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Special Additives International

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