

Evaluation of the PaO (Period After Opening)

What is the PaO? "Period after opening" (PaO) is defined as the period of time after opening the cosmetic product for which it can be used without any harm for the consumer. The stability parameters on which the determination of the PaO is based are so relative to consumer safety and not to the technical performance of the product. A cosmetic is considered "opened" when the consumer uses it for the first time.



Therefore, as regards the lifetime of a product, the PaO refers exclusively to the part relative to the use of the product by the consumer.

The final decision on the adequacy of the PaO, even though it requires an appropriate documentation, is the responsibility of the manufacturer that places the product on the market.

Since there are no official scientific methods, this causes difficulties for the person responsible for declaring that: in fact, not only there are not protocols that identify the typology of analysis more appropriate for the different products, but also there are not recognized bibliographical references with regard to the effective

correspondence between the stress artificially imposed on the product in climatic chambers (e.g.: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \text{RH} \pm 5\% \text{RH}$) and the real ageing of the product.

Therefore, for lack of provisions that set the modalities and duration of this type of test, it is necessary to rely on the knowledge of the characteristics of the product, applying more or less restrictive criteria according to the bigger or smaller risk of chemical contaminations and/or degradations.

Whoever has to determine the PaO has to base itself on quantitative and/or qualitative data, turning to personal and company experience too.

The evaluation has to take into consideration the complexity of the totality of the cosmetic products and the normal or reasonably foreseeable conditions in which the consumers use them.

Generally, the main factors that can influence the chemical and physical stability are:

1. Susceptibility to microbial contamination. From this point of view the stability after opening is principally due to the protraction of the efficacy of the preservative system after exposing to the external environment, and the risk of contamination of the product is correlated especially to the physical contact with the consumer. Some products, for their nature, are not exposed to bacterial contamination, therefore it is pointless to investigate their microbial stability e.g. products in confections that assure specific protection for the content and prevent any contamination (aerosol, confections that avoid contact between the product and the outside) and products that for their inherent characteristics are hostile to the growth of micro organisms (products with a high alcohol content, with a low presence of "free water", with a pH higher than 8 or lower than 4,5). A typology of products for which the determination of the PaO is not necessary is, obviously, the throwaway.
2. Modalities and destination of use (e.g. Is it for consumer use or for professional use? In how much time will it be reasonably consumed? Is it a rinsable product or not? How many times a day and how is it applied?)

Another aspect to evaluate is the timing of the carrying out of the controls: once the hypothetical duration of the product after opening (e.g. 6 months) and the most appropriate correspondence between the accelerated and the real ageing (e.g. 1 month= 6 months) have been set, in fact, will it be better to do a single control on term or carry out more controls spaced out (e.g once a week)? Even in this case the best approach strictly depends on the characteristics of the sample: obviously the more these characteristics are such as to make the product "at risk" the more it is opportune to carry out controls at regular intervals. Instead, for example, for a product that comes in contact every day with the outside and with the hands of the user, a test of the kind "by repeated insults", with controls to carry out ad intervals of a week one from another, is necessary and for a product with a pump container, that is used once a week (e.g. a scrub) a challenge test instead could be enough at the hypothetical time limit.

Indicative protocols The protocols suggested are intended as proposals of maxims to adapt case by case depending on the specific characteristics of the product.

It is presupposed, obviously, that since the evaluation of the security of a cosmetic product is an obligation provided for by the legislation in force from time, all the analyses for the case have been carried out to comply

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with them, and that consequently the only unknown factor can not be the security of the product in itself, but the security of the product subject to "stress for use".

All the analyses proposed are meant carried out after staying in a thermostat chamber at 40 °C with humidity equal to 75% with a daily simulation of use by expert personnel. The duration of the permanence and the frequency in the carrying out of the controls is defined time by time.