Shelf life and preservation

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Along with the latest amendment of the German Cosmetic Decree (KVO) a new regulation becomes effective. Products with a shelf life of more than 30 months or more have to be labeled with the symbol of an open jar together with the date indicating how long the product may be safely used after opening. The author takes the opportunity to have a closer look at the connections between preservation and shelf life of cosmetic products.

According to the German Cosmetic Decree (KVO) products with a shelf life of 30 months and more are not obliged to label a sell-by date. The legislator however demands for the above mentioned additional declaration to avoid problems arising with the extended storage of products.

The shelf life of a product depends on a multitude of different factors. For instance, chemical reactions with other components may transform the substances contained. One of the most simple but also one of the most frequent is the reaction of lipids (triglycerides) and oils with water during which among other substances fatty acids are released from triglycerides. The short-chain fatty acids will be noticed by their characteristic smell. Another reaction may be the attack of unsaturated fatty acids by atmospheric oxygen. During this process tiny amounts of very foul-smelling aldehydes are generated which we recognize as “rancidity”. Contamination with bacteria, fungi or mould also generates substances which subsequently are noticed by smell, color or the accumulation of microorganisms.

A typical physical process is the instability of an emulsion which means that the product breaks down into an oily and lipid phase (“creaming”). This physical instability may be caused by extended shelf life, high or very low temperatures as well as by the above mentioned change of the product composition.

From the chemical point of view **anhydrous oils**, lipid pastes or oleogels would be the easiest solution as a chemical reaction with water is impossible and the chemical attack by atmospheric oxygen could easily be prevented with antioxidants. Microbiological changes also are ruled out as microorganisms can not exist without water. Unfortunately these products rather fail to meet the consumers’ acceptance although they are an ideal solution as far as the physiological aspect is concerned. Water containing systems though are widely accepted as they easily spread and are well absorbed. However they contain a considerably higher number of non-physiological additives. One of the most difficult tasks besides the chemical and physical stability is to guarantee the sterility of aqueous systems without affecting the tolerance of the product. The opportunities offered here will be described in the following overview.

Most frequently **chemical preservatives** are added. Which substances now under which conditions and what percentage of concentration may maximally be added is stated in the German Cosmetic Decree (KVO) with the objective of avoiding any possible health risks combined with the application of cosmetic products. In spite of all the precautions, every now and then sensitizations will develop, especially if the skin barrier is damaged which already applies in case of dehydrated skin. Therefore, the alternatives of preservatives especially in aqueous products play a significant role.

A simple alternative at first sight is the **sterile manufacturing.** In this process sterile substances have to be mixed and bottled in sterile conditions and locations which is a rather complicated process, pretty expensive and limited to products which will be used shortly after opening. That is the reason why this process is primarily used for pharmaceutical products. Ampoule products yet may be heat-sterilized after the bottling process. This is a rather frequently applied procedure however it is limited to solutions containing heat-resistant components as for instance emulsions of oils as described above may be chemically and physically modified by effect of heat.

W/O emulsion and alcohol

A traditional way to avoid preservatives it the hot bottling of **water into oil emulsions (W/O)**. It bases on the fact that the outer phase has an oily consistency which impedes the

germs to penetrate to the water droplets in the emulsion. These products however only have limited shelf lives as in practical use this principle does not provide product safety. Also the packaging plays a major role. Dispensers with a second bottom part and aluminum tubes which can only be emptied on one end offer relatively safe conditions. All in all the field of application of this procedure is limited to a small spectrum of products only as well as to some cold cream types.
Still a more frequent procedure however is adding **alcohol** which, starting from a concentration of more than ten percent in the aqueous phase has biostatic effects. According to the German Cosmetic Decree (KVO) alcohol does not rank among the preservatives, has no sensitizing effects, it even pertains to the food sector.
Alcohol though has the disadvantage of dehydrating the skin in higher concentrations, a fact which does not involve negative effects on oily skin and even for “normal” skin; only concentrations of more than twenty percent are relevant.

Physiological concepts

There are additional substances containing alcoholic hydroxyl groups which have the same effects on germs as alcohol. The human glycerol, all the different glycols as for instance propylene glycol, butandiol, pentandiol and hexandiol, sugar substitutes like sorbitol and the monosaccharides (e.g. glucose) belong to this group. Compared with alcohol they have the advantage of retaining water and supporting the natural moisturizing factor (NMF). Products with these substances are easily compatible with the physiology of the skin and have no sensitizing effects. Their effect on the skin hydration can be measured with the help of corneometry. The compounds mentioned above could not gain broad acceptance in the cosmetic industry as the raw material costs of the preservatives used in quantities of a per thousand or ppm ratio are considerably lower.

All natural

Other conceptions use the germ inhibiting or germ eliminating effect of **natural substances** as e.g. farnesol which is a terpene derivative with a light lily of the valley scent and is used in deodorants. Specific glycerol esters as for instance glycerol monolaurate and diglycerol monocaprinate may have supportive effects in this case particularly if the pH value of the product rather is in the acidic range. Vitamin E may also be helpful however it has a negative side effect. Its anti-oxidative effect may be completely reversed in a higher dosage which means that it even reduces the shelf life of the product in certain circumstances.
Many fragrances like rose oil or rose water have germ inhibiting effects. Compared with synthetic preservatives however they do not offer any advantages as the effective components partly are very similar to synthetic ones and may cause the same allergic reactions. An additional disadvantage of the fragrances is their content of a variety of different components which can hardly be labeled in detail.

Suggestions for the storage of the products

The shelf life generally refers to a normal room temperature of 20°C.
Lower temperatures may considerably prolong the shelf life. The storage at 10°C (refrigerator) even may **double** the actual shelf life. However the storage temperature should not fall below 10°C due to the risk of substance crystallization and consequently the risk of product instability – in extreme cases there might be ice formation in case of temperatures below the freezing point (freezing compartment).
Storage temperatures of 30°C may cut the shelf life **in half**, 40°C even to a quarter and 50°C may reduce the shelf life to an eighth of the normal value. Hence a cosmetic product should never be stored in the car’s glove compartment.

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