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**Ethylhexylglycerin –
Highly Pure Quality by Patented Stabilisation**

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Ethylhexylglycerin – Highly Pure Quality by Patented Stabilisation

■ sensiva® SC 50 – a Multifunctional with Versatile Properties

sensiva® SC 50, INCI Ethylhexylglycerin, is a well-known multifunctional ingredient which is widely used all over the world. Since its introduction by schülke in the 1990ies, the use of this ingredient has increased tremendously (Fig. 1).

One of the first detected benefits of sensiva® SC 50 was its deodorant activity. Ethylhexylglycerin provides excellent antimicrobial efficacy against Gram-positive bacteria. Many of these are the microorganisms that transform sweat, an odourless natural secretion, into volatile components (e.g. short-chain fatty acids (C2-C5)) which generate axillary malodour (1). Thus,

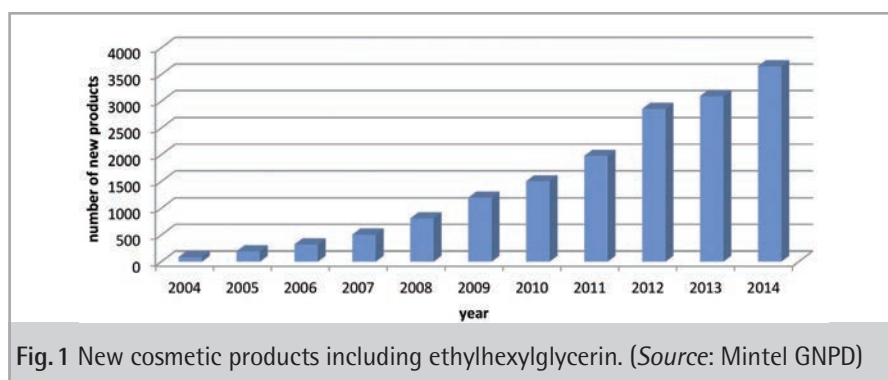


Fig. 1 New cosmetic products including ethylhexylglycerin. (Source: Mintel GNPD)

sensiva® SC 50 is used widely in deodorants and in antiperspirant/deodorants (APD). Since this initial benefit, schülke has discovered many other functions of the

versatile molecule ethylhexylglycerin. Ethylhexylglycerin, as a medium spreading emollient, improves the skin feel of skin care products. Humectants, especially the frequently favoured, low-cost glycerine, are effective moisturizers, but have the negative side effect of increasing tackiness and greasiness of the formulation on the skin. The influence of ethylhexylglycerin on the skin feel of an emulsion with high glycerine content has been tested by schülke at proDerm Institute for Applied Dermatological Research, Germany. The addition of ethylhexylglycerin reduced tackiness, greasiness, and soaping of the formulation and improved speed of absorption, as well as the overall impression of skin feel (2).

As an amphiphilic molecule, ethylhexylglycerin is surface active. This capability enables ethylhexylglycerin to boost the antimicrobial activity of preservatives or other active substances. Ethylhexylglycerin in a cosmetic leave-on formulation affects the interfacial tension at the cell membrane of microorganisms, allowing antimicrobial substances a closer contact and consequently enhancing their

Abstract

Ethylhexylglycerin is a frequently used multifunctional additive. Beside its deodorant efficacy, it is an excellent booster of many traditional preservatives and other antimicrobial substances. It was introduced into the personal care market by schülke as sensiva® SC 50; a product with outstanding quality and comprehensive safety data.

The stabilisation of ethylhexylglycerin in sensiva® SC 50 guarantees that the high purity is maintained for the entire shelf-life of the material. This stabilisation system has been patented by schülke. Unstabilised ethylhexylglycerin can form unidentified impurities with unknown toxicological profiles during storage.

To maintain the reputation of integrity and safety of ethylhexylglycerin, no material of uncertain quality or stability should be used for the formulation of personal care products, particularly as ethylhexylglycerin is most often used in leave-on cosmetics with extended skin contact.

MULTIFUNCTIONAL ADDITIVE

penetration into the cell membrane. Due to this mode of action, the antimicrobial capacity of many common preservatives, glycols, perfume actives etc. is enhanced by ethylhexylglycerin.

The concept of incorporating ethylhexylglycerin to boost antimicrobial activity is widely used to reduce required levels of traditional preservatives, like phenoxyethanol, or to formulate self-preserving products by increasing the antimicrobial effect of substances with biostatic effects. Recently schülke found that ethylhexylglycerin acts as a booster and fixative for fragrances. Depending on the perfume composition, ethylhexylglycerin can increase the scent and/or prolong the perception of the scent.

■ Safety of Cosmetic Products

The microbial safety of cosmetic products is an important consideration. Con-

tamination must be avoided to maintain the consumers' health. On July 11th 2013 the EU Cosmetics Regulation 1223/2009 came into force. One of the objectives defined in the 3rd Recital is to strengthen »certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health« (3). This highlights the aim to ensure that products placed on the market within the European Union are safe (4). The safety requirements have been defined in Article 3 of Chapter II in far more detail than in the prior EU Cosmetics Directive 76/768/EEC. Additionally, the new regulation stipulates a greater responsibility of the manufacturer for each individual product and its ingredients (5). Detailed definitions of responsibilities are elaborated in Article 4. A cosmetic product is only permitted to be placed on the market if the responsible person has ensured

its safety by performing a safety assessment.

The contents of the safety assessment are described in Annex I. Part A lists the minimum data requirements for the safety assessment, including information on impurities and traces. Impurities are defined as unintended substances in raw materials and should be identified by their nature of origin and concentration. Traces in the finished product must be technically unavoidable and toxicologically safe in conjunction with the observance of good manufacturing practice (Cosmetic GMP) (3, 5, 6).

■ Ethylhexylglycerin – a Safe Molecule

When ethylhexylglycerin was developed as a cosmetic additive, schülke carried out comprehensive toxicological studies

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with their quality of ethylhexylglycerin (sensiva® SC 50) and registered it according to ELINCS and REACH. Ethylhexylglycerin was a »new substance« according to the former directive 67/548/EEC and is a non-Phase-In substance under REACH. Therefore, ethylhexylglycerin is not subject to pre-registration, but has the status of a NONS (Notification of New Substances).

The safety of sensiva® SC 50 is ensured by this high purity grade of ethylhexylglycerin having an extremely low impurity

profile. Due to its patented stabilisation, this purity is ensured for the entire shelf-life of the material. Beyond that, sensiva® SC 50 has been used in toxicological studies showing that no side effects coming from its few impurities are to be expected.

sensiva® SC 50-grade ethylhexylglycerin does not pose an increased risk for acquiring a contact allergy after exposure. This was proven in sensitisation assays to determine the allergic potential according to Magnusson-Kligman and a local lymph node assay (LLNA) (7).

Other qualities of ethylhexylglycerin without stabilisation are now available to the personal care market. Depending on the origin, a significant portion of unknown impurities can be present in the fresh material. Additionally, these variants may not guarantee a constant quality. Due to the ether-function, decomposition can occur in unstabilised ethylhexylglycerin. Thus, more impurities with unknown toxicological profiles can develop during storage. Against this background, it should be considered that the use of impure material could provoke an increased risk of allergies not originally triggered by the main substance, thereby potentially discrediting a valuable molecule.

■ The Issue of Ageing

Many organic substances undergo oxidative degradation reactions. Specifically, ethers have the potential of forming peroxides if exposed to air. This is also a concern for polyethers, like ethoxylated surfactants, as has been reported in the past (8, 9, 10). Several different breakdown products can be expected from primary oxidation reactions, like alcohols, ketones, aldehydes and carboxylic acids. All of these categories of substances are reactive enough to undergo secondary reactions which each other.

Additionally, 1,2-diols undergo oxidative cleavage reactions, known as glycol cleavage. This reaction is often used for structure determination of sugars. Ethylhexylglycerin is a glycerol ether which bears both functional groups, ether and diol, in the same molecule. This makes it sensitive to ageing reactions under the influence of air.

Fresh sensiva® SC 50 shows a purity of more than 99%, which is exceptionally high for cosmetic raw materials. To keep this purity for the entire shelf-life, schülke has developed a protection technology utilizing stabilisers, like antioxidants (11).

As incompatibilities with the skin, such as irritations and sensitization, are the most threatening side effects of the use of cosmetic products, stability of the raw materials, as well as finished prod-

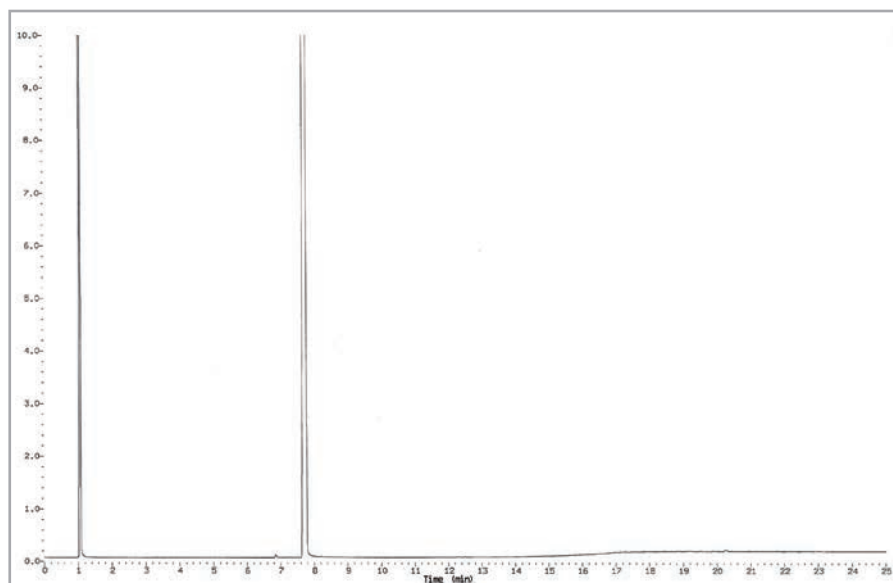


Fig.2 Gas chromatogram of fresh ethylhexylglycerin.

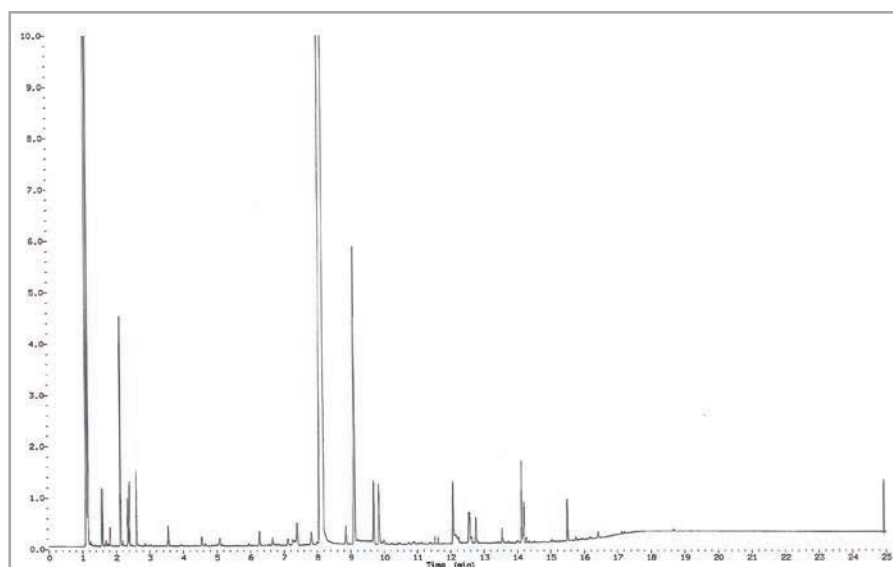


Fig.3 Gas chromatogram of aged, unstabilized ethylhexylglycerin.

ucts, is of essential importance. Fig. 2 shows a gas chromatogram of freshly distilled ethylhexylglycerin. Aside from the main peak, there are just a few very small signals that represent by-products and impurities in an amount of less than 200 ppm each. Due to the stabilisation technology, sensiva® SC 50 retains this low impurity profile for its entire shelf-life of three years.

Fig. 3 shows the chromatogram of aged, unstabilised ethylhexylglycerin. Many additional peaks can be seen, representing unknown degradation products with an amount of up to 2.5%. The well-defined material has changed to a complex mixture of potentially critical substances.

■ Conclusion

Ethylhexylglycerin becomes a very stable molecule when it is stabilised with tocopherol. The safety of sensiva® SC 50, the stabilised quality of ethylhexylglycerin, has been tested and proven in comprehensive toxicity studies by schülke. The constant purity guarantees that no degradation products develop during storage for a minimum of three years. Unstabilised, aged ethylhexylglycerin shows many breakdown products that can develop during storage. Unidentified impurities with unknown toxicological profile can negatively influence the safety of the product.

The use of ethylhexylglycerin in cosmetic products is increasing steadily, resulting in a higher exposure to consumers. To insure the safety of the consumer, it is of prime importance to verify the quality of ethylhexylglycerin and to ensure the stability over the entire shelf-life of the finished product. This is guaranteed by the use of sensiva® SC 50 with schülke's patented stabilisation system.

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