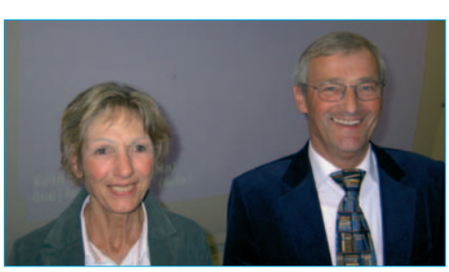
SWISS SCC Conference

»Efficacy and Safety – A Perfect Team«

Olten, Switzerland, October 2006

In October 2006 the SWISS SCC organized a conference in Olten for about 70 participants from industry, universities and authorities. Under the direction of *Catherine Schneider*, Rausch AG, aspects of ***»efficacy and safety – a perfect team«***, sitting in one boat and building a synergistic team were discussed.

As first speaker *Dr. Wolfgang Pittermann*, Düsseldorf, Germany (formerly Henkel KGaA) highlighted »percutaneous absorption: evidence and models«. Based on the substance and the test model used (also looking into history) a different penetration depth will be reached. The aim of many cosmetic developments is to transport active ingredients as safely and deeply as possible into the skin (epidermis/dermis), where they can have local but also systemic effects. In the mid of the 80s the Bovine Udder Skin model BUS was developed. Since 1993 (and in meanwhile adapted), BUS has been the valid test model used by the company Henkel in cosmetic and chemical application-field. Via BUS the penetration depth of different test substances is evaluated. According to current knowledge, the primary skin barrier »stratum corneum« is not »dead«, but in reality a very complex skin layer with dynamic depot/barrier function, where especially passive diffusion plays a role. An absolute barrier does not exist.



Picture: *Dr. Gero Feistkorn, previously Wella und Catherine Schneider, Rausch AG*

In the second presentation *Dr. Joachim Blank*, Cosmetochem, introduced the audience to the »values of plants«. Efficacy is combined with the »internal« value of a plant, mainly connected with the ingredients – therefore giving scope for messages of feeling and for marketing creativity. The »external« value is seen in the quality of a plant, *i.e.* in reproducible and standardized production. Five value levels with increasing requirements were presented: *i.e.* value level 1 as standard extract and *i.e.* value level 5 as a very specific, especially developed extract with proven activity. From a legal point of view safety documentation is mandatory. In future, *Dr. Blank* foresees an increasing demand for analytical proof of active ingredients of an extract, combined with a minimal/test dosage of single components and a stricter cosmetic GMP.

Dr. Alfred Markowetz, Procter & Gamble GmbH, concentrated on »efficacy claims on packaging«. Efficacy can be proven via technical methods, visual/sensoric evaluations and consumer use studies. In skin and hair care different efficacy test methods are used to support the claims. All technically measured values should correlate with the results of quantitative and/or quantitative consumer in use studies to be relevant for the consumer. Long term, as well as short term, effects are targeted. Publications in scientific papers and at congresses support the expected claims. Ref. the borderlines with pharmaceuticals, it must be recorded that cosmetics can have efficacy, for example in regard to an anti-dandruff shampoo or an anti-aging cream. Ref. safety tests epicutaneous tests (incl. phototoxicity/photosensitisation) are used in various levels and case numbers (*i.e.* semi-occlusive or occlusive). Authorities – as well as competition – already clearly survey the industry.

Dr. Gero Feistkorn, Mönkebude (formerly Wella) introduced the legally required behaviour in regard to consumer complaints based on 6th and 7th Amendment of the European Union Cosmetic Legislation. A legally responsible person has to judge the product/case to be improbable, questionable, probable or very probable, exactly registering symptoms and chronology. The case/product has to be registered in the product information of the company.

Dr. Gerd Mildau, CVUA Karlsruhe (Authority of chemical and veterinary substances, Karlsruhe, Germany) emphasized the »examples of the borderline« from the authority's cosmetic survey point of view in D and EU. Especially the borderlines between cosmetics, pharmaceuticals, medical products, biocides and consumer commodities were highlighted. (see also http://ec.europa.eu/enterprise/cosmetics/doc/guidance_doc_cosm-medicinal.pdf and http://ec.europa.eu/enterprise/cosmetics/doc/manual_borderlines_v20.pdf). For cosmetics, the cosmetic use has to be predominant, but, secondarily, a cosmetic can also be used for non cosmetic purposes (*i.e.* pharmaceutical). In case of doubt, the product is a pharmaceutical. Functional-pharmaceuticals and presentation-pharmaceuticals are differentiated, the classification as presentation-pharmaceutical takes into consideration

Picture: *Participants concentrating on their papers*

all kinds of claims, independent of being registered as a pharmaceutical/having efficacy results. Functional-pharmaceuticals significantly influence body function (Judgement EuGH 1991), cosmetics – with same active principals – do not demonstrate a significant pharmacological efficacy. A decision tree helps to place the product into the correct category. Tooth whitening products or sport ointments were mentioned as examples of borderline cosmetic/medical products. Depending on the claim and quantity of the active ingredient(s), they will be categorized differently. The main purpose is decisive in classifying a product as a cosmetic or a biocide. Regarding the differentiation between consumer commodities and cosmetics a 'nail within seconds' adhesive tape is a commodity, whereas a UV hardening gel is a cosmetic.

Dr. Christoph Ort, EAWAG (water research institute university Zürich ETH) and BAFU (authority for environment, sector water) shared his knowledge of the BAFU project »strategy MicroPoll – micropollution of a drainage plant in a suburban area« with the audience. Household products, such as washing agents, cosmetics, perfumes or toilet cleaning products as well as oral or topical pharmaceuticals (via secretion) will reach waste water. To counteract the water load, models of cleaning waste water and step-wise cleaning models are judged. Scenarios and criteria to evaluate the influence of substances to the environment were demonstrated. Centralised solutions (*i.e.* elimination at the source/ban) can be seen along with decentralised solutions (*i.e.* treatment of waste water of certain emitters, *i.e.* hospitals). Substances in the hormonal sector, fragrances and special medicaments are judged to be critical. Storage, enriching and/or elimination processes have to be evaluated incl. *i.e.* oxygenation of the waste water. Chemical analytical investigations of single ingredients/groups, ecotoxicological methods, bio-tests and bio-indicators/aquatic creatures serve the control of success. The interdisciplinary cooperation of chemists, ecotoxicologists, and engineers in science, authority and production/manufacturing industry have to be actively involved to find a consensus (see also www.eawag.ch).

In the final presentation of the day *Dr. Cornelius Nussbaumer*, Luzi AG, emphasized »safety aspects of fragrances«. The target of IFRA (International Fragrance Association, www.ifraorg.org), founded 1973 in Geneva, is the safe use of odoriferous substances in consumer products. This target is/will be reached by establishing standards based on toxicological qualities of fragrances and conditions for use (exposure) as well as risk assessment by an independent expert panel (REXPAN) of the Research Institute of Fragrance Material (RIFM – www.rifm.org). The IFRA 40th Amendment will include 4 new standards and enlarging from 2 to 11 product categories. The QRA (quantitative risk assessment) will be used to evaluate sensitisation – nevertheless the acceptance of authorities and customers have to be awaited.

Summarizing, it was shown, that synergy is a key issue in a team. The safety is mandatory for cosmetics, but the efficacy, based on new active principals/ingredients, new test models or new claims, is becoming more and more important. In this context new challenges arise along the borderlines of other sectors such as pharmacy, medical products, biocide and commodities. As well as in regard to environmental aspects, which have to be increasingly taken into consideration.

Dr. Marion Fröschle

SWISS Society of Cosmetic Chemists SCC
PO Box 235
9425 Thal, Switzerland
Email: mail@swissscc.ch
Website: www.swissscc.ch