

IKW Working Group »Baby Cosmetics«\*

## Children's and Baby Cosmetics – Product Safety Information

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### Introduction

**C**osmetic products are regulated in the European Union by the EC Cosmetics Directive and in Germany by the Food and Commodities Act as well as the German Cosmetics Regulations. These legal regulations already include several requirements meant to ensure the safety specifically of those cosmetic products intended for babies and small children. These include for example special regulations on ingredients (usage bans and restrictions) as well as usage information and warnings. The special responsibility of the cosmetic industry for this target group is reflected, however, also in a number of additional voluntary measures taken during the development and manufacture of products and including compatibility testing of the finished product.

cluding evaluations by the SCCNFP (Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, the scientific advisory committee of the European Commission), is mandatory. Besides the toxicological profile and skin and mucous membrane irritation potential, important selection criteria include especially the microbiological quality and the purity of raw materials. Raw materials must be tested for a number of possible contaminants such as heavy metals or pesticide residues. These kinds of unwanted substances can only be tolerated in extremely low, non-toxic trace concentrations. Continual and rigorous raw material analyses are essential to ensure a constant high quality of finished products.

Subsequently, the safety of the finished product is assessed on the basis of the toxicological evaluation of the raw materials. In addition to physico-chemical parameters such as the pH and viscosity, this assessment takes into account especially the intended and foreseeable use. If the user can be exposed to the ingredients by other routes, such as foods containing certain preservatives, the overall exposure level is always taken into account.

The anatomy and physiology of the skin of babies differ significantly from that of the skin of adults only during the first few weeks after birth. At this time, restrictions on certain products or ingredients are possible but not always necessary. Dermatologically, the skin of small children can already be assessed as basically the same as that of adults. Therefore, there is currently no broad consensus on a scientifically sound definition or

### ■ Safety Assessment

Cosmetic products must be safe for all consumer groups unless the user group is clearly defined by a special presentation of the product. Therefore, products are safe for the elderly and chronically ill, for pregnant and nursing women as well as naturally also for children and adolescents. It must be assumed that especially cosmetics for cleansing the skin and hair as well as skincare products are widely used by all consumer groups. Normal safety assessments of cosmetic products therefore usually cover also the consumer group »Children«. Separate safety assessments might be required only if special active ingredients are contained in the product.

The performance, positioning and claims of a cosmetic product can selectively address or exclude certain consumer groups. A safety assessment must take this into account. For instance, the latest amendment to European cosmetics legislation (7<sup>th</sup> Amendment to the EC Cosmetics Directive) expressly stipulates that a special evaluation must be performed, for instance, for cosmetic products intended for children under three years of age. The latest scientific findings relevant for children relating to all aspects of safety and compatibility are always taken into account in the formulation of cosmetic products for children. Raw materials are chosen especially carefully. Compliance with all legal regulations on materials as well as further recommendations, in-

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separation of age groups for babies and small children for the safety assessment of cosmetic products.

### ■ Microbiology

With respect to the microbiological specifications, IKW recommends that its member companies comply with a particularly low limit value of not more than 100 colony forming units (CFU) per gram or millilitre of product. In addition, it recommends testing of all products for the absence of specific pathogenic microorganisms. In its »Notes of Guidance for Testing of Cosmetic Ingredients for Their Safety Evaluation«, the SCCNFP recommends the same limit value specifically for all products that are intended for children under the age of three.

### ■ Manufacture

Cosmetic products are manufactured in accordance with §§ 5b and 5c of the German Cosmetics Regulations according to the principles of »Good Manufacturing Practice« (Cosmetics GMP). IKW has provided its member companies with comprehensive guidelines on this. The requirements of Cosmetics GMP cover the entire production process from raw materials through intermediate products to quality control of finished products and include additionally technical and building requirements, aspects of industrial hygiene as well as employee training and comprehensive documentation. The requirements of cosmetics GMP are of the utmost importance for children's and especially baby products.

### ■ Skin compatibility

Especially good skin compatibility is of fundamental importance for products that are intended for use on infants and small children. The aim is to develop particularly mild products for sensitive baby skin. Raw materials are selected with appropriate care. To determine the skin and mucous membrane irritation potential, a variety of in vitro studies (e.g. HET-CAM test, RBC test) are already per-

formed during the development phase. After non-toxicity of the formulation is confirmed, the finished cosmetic product is subjected to further comprehensive studies for final control of the local compatibility at the site of application (e.g. on the face, in the eye region or on the hair). Patch tests on the (if applicable, scarified) skin of adults are used to check the skin compatibility of the market product. If applicable, the eye compatibility can also be determined in special tests in humans under ophthalmologic control. In addition, clinical studies can be performed on children under dermatological and paediatric control. In this case, special emphasis is placed also on the subjective assessment of the product properties by parents and medical professionals.

### ■ Raw Materials

#### Colouring Agents

Besides fragrance, colour is one of the most important sensory perceptions. Much like fragrances, colours can help communicate different messages. Only colouring agents that are expressly approved in cosmetics legislation may be used in cosmetic products. The use of colourants in cosmetic products for children has been reduced to a minimum by manufacturers. If the individual usage restrictions specified in cosmetics legislation and the purity criteria are complied with, these colourants are also safe for use in products for babies and small children. Colouring agents in cosmetic products hardly play a role in possible sensitizing or allergenic effects. Many of the colouring agents incorporated in personal care products are also approved for use in foods and pharmaceutical preparations.

#### Preservatives

Due to the high standards for the quality of starting materials and production processes, cosmetic products leave production in a flawless state of hygiene. Although products may be nearly free of undesirable microorganisms in the unopened state, use of preservatives is often indispensable to guarantee the safe-

ty of products during their consumption because microorganisms are usually introduced by consumers themselves when using the product. Here, too, the standards specifically for products for small children are especially high. Manufacturers of cosmetic products are always required to develop formulas that intrinsically prevent growth of microorganisms. However, if use of preservatives cannot be avoided, the amount of preservatives added is limited to that absolutely necessary to ensure the safety of the product. Only those preservatives are used that have been evaluated by the SCCNFP and – taking into account the requirements of and restrictions in cosmetics legislation – are expressly approved for the preservation of cosmetic products. Additional restrictions are stipulated by the legislature specifically for products for small children.

Cosmetics legislation stipulates that cosmetic products must be labelled either with a best before date or – in accordance with the 7<sup>th</sup> Amendment to the EC Cosmetics Directive – with the durability after opening. The manufacturers of children's and baby products are aware of their responsibility to assure flawless microbiological quality until the labelled date especially for these extremely sensitive products. Once again the intended and foreseeable use of products must be taken into account.

#### UV Filters

Only UV filters expressly approved in cosmetics legislation may be used in sunscreen products. When individually specified restrictions are complied with, these filters are also safe for use in children's products. The SCCNFP confirmed in a position statement (SCCNFP/0557/02) dated February 27, 2002 that it is unnecessary to take an additional uncertainty factor into account when calculating the safety margin specifically of sunscreen products intended for use on small children of the age of one year or older. Babies and toddlers under the age of one should never be exposed to direct sunlight. The European cosmetics industry adopted a new recommendation for stating usage instructions on sunscreen products in March 2004. This includes the in-

structions for sun protection for babies and small children: »Keep babies and young children out of direct sunlight« and »Wear protective clothing and very high SPF sunscreens (higher than SPF 25) for babies and young children«.

### Perfuming

Like all other ingredients, the fragrances used in cosmetic products must be safe for the intended and foreseeable use of the products. In addition to the basic requirements of cosmetics legislation on perfuming ingredients, a large number of other recommendations such as the position statements of the SCCNFP, recommendations of the industry and national authorities and especially also the *Code of Practice* of the International Fragrance Association (IFRA) need to be taken into account. Individual labelling of 26 perfuming ingredients on the packaging of cosmetic products, which was introduced in the 7<sup>th</sup> Amendment to the EC Cosmetics Directive, clearly also demonstrates the high safety standard for fragrances.

Compared with cosmetic products for adults, baby products are only very weakly scented. However, completely unscented products are hardly accepted by the vast majority of consumers, largely because the characteristic odour of the ingredients does not correspond to their personal taste. Fragrances also have a beneficial effect on well-being. Depending on the composition, they can have a calming or stimulating effect or affect well-being in some other way. Consequently, the fragrance is an important criterion for product selection and recognition.

### Essential Oils

A number of recommendations and criteria exist for essential oils that need to be taken into account, including the *Code of Practice* of the International Fragrance Association and various position statements of the SCCNFP. Products containing essential oils must always receive special attention in any safety evaluation. In addition, the industry has a number of its own recommendations. For instance, certain essential oils like euca-

lyptus oil, menthol or tea tree oil should only be used in amounts below specified maximum concentrations, and certain essential oils should not be used at all in products intended for babies and small children.

### Surfactants

Surfactants (detergent substances) are surface-active substances that lower the surface tension of liquids. This property enables them to dissolve fats and impurities as well as to stabilize emulsions. Use of surfactant-containing cleansing products partially removes lipids from the skin's surface. Due to their surface-active properties, many pure surfactants irritate the skin and mucous membranes. By skilfully combining different surfactants, the skin-irritating effect of some substances can be clearly reduced. Skin and hair cleansing products for babies and small children are formulated with especially mild surfactant combinations. In addition, moisturizing and lipid-replenishing substances that allow quick restoration of the natural biological balance of the skin surface after cleansing are added to cosmetic products for skin and hair cleansing.

### ■ Poisoning – Foreseeable Misuse and Accidents

Poisonings with cosmetic products are extremely rare. This is shown by the annual statistics of the Federal Institute for Risk Assessment (BfR) and poison information centres. To ensure that in the event of an accident the correct medical care can be ensured immediately, European cosmetic legislation requires that the competent national authorities are provided with the necessary information on the composition of the products found on the market. The European cosmetic industry has created together with the European Association of Poison Information Centres a uniform electronic notification procedure (»SYSDECOS«) based on framework formulas. When formulating and evaluating the safety of cosmetic products for children, any foreseeable misuse of the product must be taken into account in addition to the ac-

tual intended use. To prevent cosmetic products from falling into the hands of children, manufacturers label many products with voluntary warning statements. Special bitter substances are even added to some products to prevent swallowing larger product amounts.

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