

Introduction to the problems surrounding garment textiles

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Garment textiles may contain a number of chemical substances. The dyes, auxiliaries and finishing agents ensure colour fastness during washing, a stable shape or a wrinkle-free garment. In addition, biocidal products (e.g. insecticides, acaricides or antimicrobially active substances for protection of fibrous or polymerised materials) can be used. These substances are subject to the biocidal legislation and can, depending on the hazard posed by them and by the extent of contact with the skin of the wearer, pose a health risk if they have not been tested or if they are used inappropriately.

In the past there have been frequent reports in the media about health hazards linked to garment textiles. Consumer organisations called for the full declaration of all textile finishing agents. Already in 1993 a parliamentary inquiry was submitted to the Bundestag on the "Use of harmful substances in textiles", and the Enquete Commission of the 12th German Bundestag on the "Protection of Man and the Environment" has addressed this issue.

The Federal Institute for Risk Assessment (BfR) has for a long time worked to identify potential health risks arising from dyes, auxiliaries, and finishing agents for consumer products made from textiles or leather, or from textile manufacturing processes, and to identify solutions to specific problems. It receives support from a committee of the BfR Consumer Goods Commission, the *"Committee for Textiles and Leather"*. The committee continues the work of the former *"Textiles Working Group"* which was called into life in 1992 at what was then the Federal Health Office. The committee brings together scientists from universities and research institutions, the supervisory authorities of the federal and state authorities, consumer protection organisations, the textile and garment industries, and test laboratories.

The following introduction to the problems surrounding garment textiles is mainly based on the results of the former Textiles Working Group. It gives an overview of its assessments and recommendations and also takes into account the latest changes in the legal provisions such as the ban on certain organotin and perfluorinated compounds. A new addition are scientific opinions on the use of antimony compounds in polyester garment textiles and on the (nano) silver finishing of textiles. In addition, the introduction contains market surveillance statistics on the exceedance of limit values for banned azo dyes and provides new insights from experimental studies on the sensitisation potential of certain disperse dyes. Last but not least, the introduction contains a description of the BfR model for exposure estimation for dyes and other substances in garment textiles which can be released from the garments during wear and thus absorbed through the skin.

1 Legal foundations

Under the Textile Labelling Regulation (EU) No 1007/2011, information need only be provided in the case of garment textiles about textile fibres but not about any auxiliaries used. Garments, including the impregnating agents and other finishing agents used in their manufacturing, are Commodities within the intendment of the German Food and Feed Code (LFGB). § 30 of this Code prohibits the manufacturing or treatment of commodities in such a way that they could harm human health. Compliance with the legal provisions is primarily the responsibility of manufacturers. The federal states, in turn, are responsible for monitoring compliance with the legal provisions. However, as the legislation does not envisage any marketing authorisation or mandatory reporting for these consumer products, the public agencies often do not have comprehensive information on these products.



According to the Biocidal Products Regulation (EU) No 528/2012, biocidal products used here, notably of *Product-type 9* (protection agents for fibres, leather, rubber and polymerised materials) and of *Product-type 18* (insecticides, acaricides and products against other arthropods) are subject to an evaluation and approval of their active ingredient substances at the European level and, subsequently, to a national product authorization procedure which includes the evaluation of proposed uses. In an interim phase, biocidal products have to be registered in Germany in accordance with the national Biocide Notification Ordinance. The new Biocidal Products Regulation (EU) No 528/2012 also applies to imported articles that are treated with pesticides.

In Germany, the use of certain substances for the manufacturing of consumer products made from textiles or leather is regulated, for example, by the European Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and by national legal provisions such as the German Commodity Ordinance (BedGqstV) and the German Chemicals Prohibition Ordinance (ChemVerbotsV). These provisions foresee, for example, a ban on the use of certain flame retardants. In addition, azo dyes, which can be cleaved into one of the carcinogenic amines listed there, may not exceed 30 mg per kilogram of textile in products made from leather or textiles which come into direct and prolonged contact with the human skin or mucosa. According to Annex 9 of the BedGgstV, textiles whose intended use involves contact with the skin, which have been given a finish and which contain more than 0.15 % free formaldehyde should be labelled as follows, "Contains formaldehyde. It is recommended that this garment be washed before wearing for the first time to improve skin tolerance". The ChemVerbotsV stipulates that products containing more than 5 mg of pentachlorophenol per kilogram of textile may not be placed on the market. Hence, in the area of garment textiles there are only detailed legal provisions for some substances which are deemed to be harmful. Unlike cosmetics products and food contact materials, there is no standardised and comprehensive product-specific regulation for products made of leather or textiles.

The European Product Safety Directive 2001/95/EC contains general safety requirements to be met by products, including garment textiles. Amongst other things it envisages consideration of use by consumers under reasonably foreseeable conditions even if not intended for them, the labelling of the product and extensive information for consumers as well as the possibility of withdrawal or recall to avoid any product-related hazards. In Germany this Directive has been transposed into national law through the Product Safety Act (ProdSG).

2 Committee for Textiles and Leather (formerly "Textiles Working Group")

The concern that garment textiles could lead to health hazards for consumers prompted the setting up of a *"Textiles Working Group"* in 1992 within the then Federal Health Office (BGA). This working group was initially continued in the Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV). Its tasks are now carried out by a committee of the Consumer Goods Commission of the BfR, the *"Committee for Textiles and Leather"*. This committee includes, among other professions, scientists from universities and research institutions, representatives of monitoring federal and state authorities, representatives of consumer protection organisations as well as textile and garment industry representatives and employees of test laboratories. Particular attention is paid to consumer exposure to substances released from products. Given the large number of dyes, auxiliaries and finishing agents for textiles, the following topics were given priority:



- Principles for the toxicological testing of textile dyes and textile auxiliaries for garments
- Exposure assessment
- Allergic reactions
- Mutagenic and carcinogenic substances
- Dye accelerators
- Flame retardants
- Dioxins
- Fluorine surfactants
- Detergent residues and whitening agents
- Anti-bacterial finish
- Functional clothes
- Nano-finish

3 Auxiliaries and finishing agents for garment textiles

The German Catalogue of Textile Auxiliaries 2008/09 contains 5,800 preparations of auxiliaries and finishing agents for textiles; only some of them are used in the manufacturing process of garment textiles [1]. According to information from industry, these preparations contain a total of 400–600 ingredients which can be classified in various categories (Table 1). This list does not yet contain any dyes.

Name	Chemistry	Comments
Agents for improving crum-	N-methylol derivatives (formaldehyde)	Shape stability, "high grade finishing"
pling and wrinkling behaviour		
Catalysts for crumpling and	Dialkylated tin derivatives	
wrinkling-free finish		
Gripping agents	e.g. polymers	Up to 20 % of textile product weight
Flame retardants	e.g. organophosphates	Protective clothing
Anti-microbially active agents	Biocides	Footbed, socks (sanitised)
Phagodeterrents	Permethrin	Preservation (transport, storage of
_		uniforms)
Waterproofing agents	Paraffins, fluoropolymers	Water, oil and dirt repellent
Anti-felting finish	Polymers	Wool
Conditioning agents	Oils, greases	Surface enhancement
Lustering finishing agents	Waxes, paraffins	
Coating agents	Polymers	

Table 1: Some categories of auxiliaries and finishing agents for garment textiles without reference to dyeing

3.1 Formaldehyde

Amongst the textile auxiliaries, finishing agents to improve crease and shrinking behaviour play an important role (high grade finish to improve dimensional stability). The applications for the use of such finishing agents include fibres on a cellulose basis (cotton and viscose) and their blends with synthetic fibres. The residues of finishing agents in garment textiles may account for up to 8 % of the textile product weight. Mainly used are N-methylol compounds, which are produced by the reaction of formaldehyde with urea and melamine derivatives (self-cross-linking agents, resin formers), and of cyclic urea derivatives (reactant cross-linking agents). Reactant cross-linking agents lead to a cross-linking of cellulose fibres, whereas self-cross-linking agents form synthetic resins which are deposited in micellar spaces.



The health requirement for high-grade finish is a low quantity of free and cleavable formaldehyde [2].

According to the Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, formaldehyde is classified as a hazardous substance with carcinogenic properties of Category 2. The International Association for Research and Cancer (IARC) of the World Health Organisation (WHO) in 2006 classified formaldehyde as a human carcinogen. This was prompted by epidemiological studies among industrial workers in the USA in whom there was an increased incidence of nasopharyngeal cancer after inhalative exposure to formaldehyde. In terms of the carcinogenic effect of the substance, the BfR has derived an indoor concentration of 0.1 ppm as a *"safe level"* which is sufficient for the protection of the entire population [3].

For consumers there is no risk of being exposed via respiratory air to problematic formaldehyde concentrations in garment textiles. However, in case of skin contact, formaldehyde must be regarded as an important contact allergen. It is not possible to state a threshold value for sensitisation and triggering of allergy that would be applicable to everyone. In 1989 what was the Federal Health Office at the time conducted a survey amongst the dermatological departments of German university hospitals in order to ascertain the importance of allergic reactions to formaldehyde in garment textiles. The survey came to the conclusion that allergic reactions to formaldehyde in garment textiles had not been of any relevance in previous years. This situation has remained unchanged up to now. This is also confirmed by the results of a research project conducted by the Information Network of Departments of Dermatology (IVDK). The conclusion there is that formaldehyde is not an allergen in the private sector and that formaldehyde-containing resins in garment textiles no longer play a role as allergens.

3.2 Glyoxal

As a consequence of the on-going discussions about the health hazards posed by formaldehyde, substitute substances were tested as technological alternatives. One of these substitute substances are synthetic resins on the basis of other aldehydes such as glyoxal. Glyoxal-containing reactant-type resin is used to give a shrink-proof finish to some viscose and cotton fabrics (cotton velvet, viscose velvet) in a manner similar to the above-mentioned formaldehyde-based synthetic resins. However, glyoxal-based cross-linking agents are rarely used.

Under the Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, glyoxal is classified as genotoxic (GHS category 3), harmful by inhalation, irritating to skin and very irritating to eyes, In addition, it can cause allergic skin reactions. In terms of its chemical structure, reactivity, molecular size and due to its toxicity, glyoxal is very similar to formaldehyde. Despite its sensitising potential, there have not been any reports of textile-related allergic reactions to glyoxal in contrast to formaldehyde.

Following reports of the release of, in some cases, considerable amounts of glyoxal from certain garment textiles, the subject was discussed by the *"Textiles Working Group"*. According to information from the textile industry, the use of glyoxal-containing cross-linking agents, which had led to the considerable release rates, is no longer considered to be state of art in Germany. The release of glyoxal from garment textiles can be assessed by analogy with formaldehyde.



3.3 Flame retardants

In contrast to many other textile auxiliaries and finishing agents, where only small quantities remain on the garment, a flame-retardant coating may account for up to 20 % of product weight. In Germany textiles with a flame-retardant finish are used, amongst other things, for protective clothing at workplaces with a particularly high fire hazard. Curtains and uphol-stered furniture in public areas and car interior furnishings may also be treated with flame retardants. There are flame-retardant modified polyester fibres which involve practically no exposure of users to flame retardants. There are also permanent flame retardants made of fibre-active compounds where exposure is assumed to be minor. Some substances involving health risks are also used as semi-permanent flame retardants. Under the REACH regulation and the national BedGgstV, tri-(2,3-dibromo-propyl)-phosphate (TRIS), tris-(aziridinyl)-phosphine oxide (TEPA) and polybrominated biphenyls (PBB) are banned. Considerable exposure is to be expected when wearing garments with a non-permanent finish. According to the information available to BfR only salts with low skin absorption are used in Germany. They include, for instance, ammonium sulphate, amidosulphonic acid and borax (sodium borate).

Antimony compounds continue to play an important role. They are used in flame-retardant finishes of textiles and in the manufacture of polyester fibres on the basis of polyethylene terephthalate (PET) as a catalyst for the polymerisation of PET (see Item 3.4).

For textile toys, a flammability test is contained in the European Standard DIN EN 71-2 regarding the safety of toys. The European Standard DIN EN 14878 lays down the requirements for the burning behaviour of children's nightwear. A balance needs to be struck here between keeping flammability as low as possible (as a way of protecting children in case of contact with open fire) and toxicological safety in case of finishes containing flame retardants.

In the opinion of the BfR, no flame retardants should be used in the private sphere for textiles (garments, home textiles and toys). If they are used nevertheless, such products should at least be labelled accordingly.

3.4. Antimony Compounds

In the synthesis of polyester fibres, antimony trioxide (Sb_2O_3) is used as a catalyst. An exposure of users can happen primarily through skin contact with garment items when wearing polyester textiles. An additional exposure is possible by oral uptake and by inhalation of material abrasion.

Information on the exposure to polyester-fibre textiles is contained, for example, in a study of the Danish Environmental Protection Agency [4]. The overall contents of antimony trioxide in the textiles were between 7 and 200 ppm, out of which up to 10 % of the contained antimony could be extracted with sweat simulans. To estimate dermal absorption of antimony from wearing such textiles, a dermal uptake of 0.1 % antimony has been derived from studies on the dermal absorption of various metals [4]. A model calculation based on these data shows that only 1 % of the tolerable daily intake (TDI) for antimony (6 μ g Sb₂O₃ per kg bodyweight and day) derived by the WHO is reached when polyester textiles are worn, even when conservative assumptions are made.

A study has been conducted in Germany on the overall antimony content and the antimony quantities released by extraction with a sweat test solution in 433 samples of polyester gar-



ment textiles available in the German market. Underwear, middlewear, outerwear, bathing togs and other textiles were tested. In each case, the textile samples consisted of mixed-fibre materials with different PET fibre proportions and textiles made from pure PET fibre material. The measured overall contents for antimony amounted, for all types of clothing, to 87–147 mg of antimony per kg of textile. The maximum value was 270 mg of antimony per kg of textile (middle wear made of 100 % PET material). Taking into account all types of garments, the textiles released an average of 0.33–4.57 mg of antimony per kg from PET fibre materials in sweat simulans. The maximum release was 22.9 mg of antimony per kg (bathing togs made of 100 % PET material). This means that the limit value for extractable antimony (using an acidic synthetic sweat solution in accordance with ISO 105-E04, test solution II) of 30 mg/kg (30 ppm) for garment textiles, which were certified in accordance with OEKO-TEX[®] Standard 100, was not reached.

Scientific articles published in the 1990s speculated about a connection between the use of antimony trioxide as a flame retardant in mattresses and cot death. However, it was not possible to prove the existence of such a connection in a scientifically plausible manner. According to the current scientific knowledge, there are therefore no health risks if the products are used in an intended manner.

3.5 Dye accelerators (carriers)

Dye accelerators (carriers) are organic solvents which are used as auxiliaries in the dyeing of chemical fibres (polyester, acetate, polyacryl nitrile, polyamide) with disperse dyes. They enable the dyes to penetrate the fibres more quickly. For polyester (polyethylene glycol te-rephthalate) which is the most important chemical fibre for the garment industry in terms of volume, dyeing with disperse dyes is of major relevance. It is either done with the aid of carriers at 95 °C or under high-temperature conditions (HT) at 130 °C. In principle, carriers are not needed for HT dyeing; nevertheless, they are used in small quantities as levelling agents to achieve uniform dyeing. Carriers are also used for dyeing polyester-blend fabrics as temperatures have to be limited to 110–115 °C because of the wool component.

Depending on the substance and dyeing system, the residual content after dyeing is between 5 and 37 g/kg fibre (0.5-3.7 %). If dyeing is done in accordance with the state-of-the-art technology, the carrier content is below 0.2 %, otherwise levels of up to 2.7 % on the textile cannot be ruled out. Amongst the chemicals used as carriers 1.2.4- trichlorobenzene in particular must be rejected. In Germany the view is held that the use of this substance as a carrier no longer corresponds to state of the art. The advisory panel on environmentally relevant substances of the Society of German Chemists (GDCh) already appealed to the textile industry years ago to stop using trichlorobenzenes and received undertakings to that effect. The environmental criteria for awarding the EC eco-label for bed linen and T-shirts specify that halogenated dye accelerators may no longer be used (Commission decision 96/304/EC of April 1996). The guality requirements of various organisations specify that trichlorobenzene (total limit value of chlorinated benzols and toluols under 1 mg/kg) should not be detectable either (e.g. OEKO-TEX[®] Standard 100, RAL, UZ 154 on awarding the ecolabel "Blue Angel" for textiles, TOXPROOF certificate "Pollutant Tested" of the TÜV Rheinland, Öko-Info DTB). In the opinion of the BfR, the use of 1,2,4-trichlorobenzene as a carrier for garment textiles poses health risks and should be banned throughout the EU.

In 2010, Germany submitted a dossier for the identification of 1,2,4- trichlorobenzene as a Substance of Very High Concern (SVHC) to the European Chemicals Agency (<u>http://www.echa.europa.eu/</u>).



3.6 Organotin compounds

In recent years there have been repeated reports of organotin compounds in garment textiles. "Organotin compounds" is used as a generic term for derivatives of tetravalent tin in which covalent carbon-tin bonds to one or several organic substituents exist. Derivatives with methyl, butyl, octyl and phenyl groups as substituents are of particular technological significance. The number and relation of the tin-bonded organic substituents and inorganic groups have a significant influence on the physico-chemical properties and biological effects.

The use of certain tin-organic compounds in consumer products is, due to recent scientific findings, classified as a hazard to human health. The health hazards include immunotoxicity (especially di- and trialkyl and triphenyl tin compounds), sensitisation as well as skin and eye-irritating properties (especially mixtures of mono- and dimethyl as well as mono- and dioctyl tin compounds), reproductive toxicity (especially di- [DBT] and tributyl tin [TBT]), neurotoxicity (methyl and ethyl tin compounds), and effects on the endocrine system of humans (DBT, TBT, and triphenyl tin). Since 2009, extensive Europe-wide bans exist on the use and marketing of di- and triorgano tin compounds. These have been incorporated in the Annex XVII of the REACH Regulation. As a result, no triorgano tin compounds such as TBT must be used in products anymore since 1 July 2010, if the concentration of tin in the product or in parts thereof exceeds 0.1 % by weight. Products with a higher content must no longer be placed on the market. Similar bans have been in place since 1 January 2012 for dibutyl tin compounds in products which are intended for supply to, or use by, the general public. Garment textiles are not affected by the interim exemptions for certain products still in effect until 2015. Similar usage and marketing bans have been in place since 1 January 2012 even for dioctyl tin compounds in explicitly mentioned products intended for supply to the general public. This includes textile articles intended to come into contact with the skin.

Exposure estimations by the Federal Environment Agency and the BfR [5a] show that the daily intake of organotin compounds from consumer products including textiles (T-shirts with PVC prints) can, in a *worst-case* scenario, lead to considerable exposure of consumers to specific organotin compounds. Due to the general minimisation imperative regarding the exposure to organotin compounds, such substances should therefore not be used in garment textiles.

In an older edition of the German Catalogue of Textile Auxiliaries from 2000, three textile auxiliaries are commercially available which contain organotin compounds. However, they were not used to give a biocidal finish to textiles but to provide material protection for heavy textiles like tarpaulins, marquees and tents. According to information from the manufacturers a TBT content of 0.1 % (i.e. 1 g/kg) must be achieved in order to produce an anti-microbial effect. High levels on this scale are prohibited under the current legal provisions and have not been detected up to now in the analyses of textiles undertaken by various offices. For instance, the TBT level in the padding of cycling shorts was 110 mg/kg (equivalent to 0.011 %); in a Dutch study on organotin compounds in textiles a maximum level of 13.2 mg/kg was measured [6].

In studies on the migration of TBT from textiles, 5 % TBT could be detected in the eluate of a perspiration test solution. It is, however, likely that the release decreases with repeated use which means that an average exposure of 1 % is plausible [4]. According to estimates of internal consumer exposure whilst wearing textiles of this kind, there is no health hazard. In the context the general reduction in exposure to organotin compounds, they should still not be used in textiles. The use of TBT for the biocidal finishing of garments also goes against manufacturers' recommendations and must, therefore, be interpreted as misuse.



3.7 Sunscreen filter substances

Properties of use like colour fastness or tear resistance of polyurethane and polyester fibres can be impaired through the influence of UV rays via photochemical reactions. UV absorbers which convert UV rays into longer wave rays like visible light or heat are, therefore, used to protect the fibres and dyes.

Furthermore, garment textiles are explicitly finished with UV-absorbing substances in order to reduce consumer exposure to UV rays. The UV permeability of textiles depends on fibre material, porosity, thickness of the textile surface, the dye used and colour intensity. Generally speaking, synthetic fibres like polyester absorb more UV radiation than natural fibres like cotton. The main area of use of a finishing treatment with UV-absorbing substances is, therefore, cotton textiles. The active substance is bound covalently to the fibres similar to the reactive dyes; the levels are between 0.2 and 0.8 %. In the case of viscose UV absorption can be achieved through pigmentation with titanium dioxide; UV absorbers have been developed for polyester which – similar to the disperse dyes – are applied to the tissue. At the present time special detergents are being developed to apply these active substances to garments.

In accordance with the European DIN EN 13758-1 Standard on the permeability of UV radiation, the protective properties of garment textiles against ultra-violet solar radiation are tested between 290 and 400 nm and are given as an ultraviolet protection factor UPF.

3.8 Perfluorinated polymers

Perfluorinated polymers (fluorocarbon resins) are known for their water-repellent and oilrepellent properties and are, therefore, used to finish textiles, particularly for waterproof clothing. Because of the possible residual content of perfluoro-octane sulphonate (PFOS) and perfluorooctanoic acid (PFOA) in fluoropolymers, the persistence and ubiquitous occurrence of PFOS and PFOA, this category of compounds has moved centre stage of public interest.

The marketing and use of PFOS was already restricted by a European Directive in 2006. PFOA was suggested as a SVHC substance with the relevant restrictions under REACH. In accordance with the Regulation (EU) No 757/2010 amending the Regulation (EC) No 850/2004 on persistent organic pollutants, the use of PFOS and its derivatives is forbidden as a substance in articles. Derogations exist for unintentional trace contamination when using the best available techniques. In the case of textiles, the threshold for unintentional trace contamination amounts to a PFOS share of 1 μ g/m² (corresponds to 0.1 ng/cm²) of the coated material.

According to information from trade associations neither PFOS nor PFOA is used as building blocks in the main production method today, telomerisation. Rather, perfluorinated C2 parent structures (tetrafluoroethylene) are converted to perfluoroalkyl iodides, the chain is lengthened through the addition of other tetrafluoroethylene units (telomerised) and finally converted with ethylene to perfluoroalkyl alcohols, so-called fluorotelomer alcohols (FTOH). This leads to the formation of linear chains whose length is determined by the number of parent substances added and always has an even number of C-atoms. Normally between three and six parent substances are added which means that the number of fluorinated C-atoms is as a rule between six and twelve. The terminal, fluorine-free ethyl group is then derivatised into various reactive intermediate products, e.g. into acrylates, methacrylates or polyurethanes.



A second method is electrofluorination. In this process organic parent substances are dissolved in hydrofluoric acid (HA) and the H-atoms in the substance are exchanged for fluorine by applying an electric current. The starting substances are C4 parent substances which are converted to perfluorobutanoic sulphonic acid and then used to produce other fluorine surfactants. No details are known about the method. A method involving C8 parent substances leading to the formation of PFOS and PFOA was withdrawn by the market leader on his own initiative in 2000.

Although PFOA is not used in the manufacturing process as a building block for the synthesis, different studies of consumer products show that PFOA can nevertheless occur as a contaminant.

In general, no fluorinated monomer substances are used in textile finishing but rather fluorinated polymers (also known as fluorocarbon resins) with a molecular weight (MW) of >20 kDa. The FTOH-based fluorocarbon resins used in the textile industry consist of a reactive parent structure with perfluoroalkyl monomers and alkyl monomers as the side chains. As a rule the polymer contains 20-50 % (w/w) fluorine and is commercially available as an aqueous dispersion with a polymer content of 20-30 %. Dispersion, the last step in the finishing process, is mainly applied using a foulard to the textile. Fixing is done by means of a covalent bond (cross-linking) to the fibres in a tenter at 120-180 °C. The typical amounts of polymer applied to the fibres are 0.2-0.5 % (w/w) which means that the fabric then contains 0.04-0.25 % (w/w) fluorine.

Toxicological data indicate that the fluorinated polymer is of little dermatological relevance because of the rigid binding to the fibres and also because of the high molecular weight. In the case of oral intake there is no metabolism.

According to the risk assessment of the European Food Safety Agency (EFSA) in 2008 on PFOS and PFOA, the liver is the main target organ for the toxic effect of PFOS. EFSA has derived TDI values of 0.15 µg/kg bw/d (PFOS) and 1.5 µg/kg bw/d (PFOA). In its opinion from 2008, the BfR confirmed these TDI values in principle. However, due to the species differences (the experimental animals used were monkeys, rats, and mice versus humans), the BfR regarded these values as provisional. These differences are particularly pronounced with regard to toxicokinetics (significant differences in half-life). In the BfR opinion, immunotoxicological effects in experiments with mice were pointed out, but the relevance of these effects for risk assessment could not be conclusively evaluated at that time. In the meantime, further experimental data and results from clinical studies have been published. These studies provide further indications that PFOA may impair the function of the adaptive immune system due to their effect on humoral factors. A recent study [8] suggests that such effects already occur at serum concentrations of PFOA which can be measured in the population. Confirmation and final assessment of these findings is still pending, especially of the causal relationship between exposure and the significant changes of immunological parameters.

Exposure calculations are available for PFOA in the literature which were undertaken on the basis of the maximum extractable content from treated textiles (various extraction agents) and a skin penetration rate determined *in-vitro* [9]. Based on these data the average daily uptake from garment textiles for various age groups in case of a reasonably assumed maximum exposure is far lower than the values which are assumed as threshold values for toxicological effects. The *Margin of Exposure* (MOE) is 10⁶-10⁸.

During telomerisation a mixture is formed of FTOH compounds of varying chain lengths. The most frequently found component consists of four tetrafluoroethylene units (and a terminal



ethyl unit). In line with the number of fluorinated and non-fluorinated C-atoms it is called 8:2 FTOH. Toxicological data and information about the amounts extracted from impregnated textiles (extraction agent: water or ethylacetate) are available in the literature both for the FTOH mixtures and for the individual component 8:2 FTOH [10]. These data are the basis for an exposure estimation and a risk assessment which has been published [9]. The model for exposure estimation is based on brand new textiles in which the mean contents extractable with ethylacetate are 27 ng/cm² for 8:2 FTOH at 22 ng/cm² [10]; under application conditions (i.e. after several wearing and washing cycles) approximately 10 % can reach the skin [11]. The assumed penetration rate is 0.14 % per hour (h). With an exposure of 12 h/day and a wear frequency of 365 days per year, this leads – calculated for the entire skin surface (child, adolescent, adult) – to intakes of 8:2 FTOH and total FTOH of approximately 10 ng/kg bw/day. This results in a margin of exposure (MOE) of approximately 5×10^5 [12]. Using aqueous extraction values instead, the absorbed amounts are far lower and the MOE is approximately 10^7 . The model is based on conservative assumptions.

The model calculation was also used to estimate possible exposure to PFOA. Here a conversion rate of 1 % was assumed for the conversion of FTOH to PFOA. For both carcinogenic and non-carcinogenic effects, this led to a MOE of at least 5×10^7 (extraction with ethylacetate) and 10^9 (aqueous extraction). There is a good correspondence within one order of magnitude between the modelled exposure estimation and other published data. When impregnation is carried out properly there does not seem to be any hazard for consumers because of the low migration rates. However, difficulties are encountered when converting general exposure estimates to serum values. Furthermore, there is a need to explain the relatively high PFOA serum values in humans described in the literature. A possible disproportionate accumulation, particularly at low concentrations, was discussed in the literature.

3.9 Biocides

For a long time the finishing of technical textiles and material protection were to the fore in conjunction with biocidal finishing. For example, battle dress uniforms of the Bundeswehr (German Federal Armed Forces) are often finished with insecticides and / or acaricides for missions abroad in some countries. For finishes with permethrin, a coating procedure has been developed for which the active ingredient is relatively closely attached to the textile. The BfR has assessed the health risks for subjects wearing permethrin-impregnated uniforms. The assessment was based on a study of the Bundeswehr which, as part of biomonitoring study, measured the urinary excretion of permethrin metabolites over 24 hours in a cohort of soldiers following wearing of the uniforms. Assuming standard values for body weight and exposed body surface, it was possible to estimate internal and external exposures based on the collected data. According to the calculations, the daily absorption of permethrin amounted to one fifth of the ADI value [14, 15]. The skin surface-related dose was about one hundred times lower than the dose at which paraesthesia would be expected. Another active biocide ingredient which has been used in a wide range of consumer goods for over three decades is triclosan. Triclosan is predominantly used in cosmetic care products (85 %) and also in textiles (5 %), detergents with disinfectant effect and in disinfectants as well as in plastic containers and food contact materials (10 %).

Because of an increased awareness of hygiene, textiles worn next to the skin are also increasingly being given a finish with antimicrobially active substances. The application areas for textiles with an anti-microbial finish are sports and leisure wear for outdoors but also textiles for personal protection, medical products like bandages, technical textiles, curtains, carpets and mattresses. The function of the antimicrobially active substances is to counteract the development of odour by preventing the decomposition of perspiration by bacteria. The



requirements to be met by an anti-microbial finish are skin tolerance, toxicological safety and stability under conditions of use as well as a clearly proven effect in the final product. In addition, bacterial skin colonisation may not be negatively impaired by wearing garments of this kind.

The most commonly used substances are silver and silver compounds, quaternary ammonium salts, chitosan compounds, isothiazolinones and, above all, triclosan. The anti-microbial effect of these substances can be impaired by processing methods and interaction with other textile auxiliaries and dyes. An anti-microbial finish is frequently achieved by post-processing of the textiles in an application bath. In the case of synthetic fibres it is also possible to integrate the active substances prior to spinning. More recent methods are based on the permanent fixing of supramolecules (e.g. cyclodextrins) on the textile surface which in turn can bind and incorporate active substances. This technique opens up diverse opportunities for textile finishing.

Active anti-microbial substances are subject to EU legislation. In Europe, the Biocidal Products Regulation (EU) No. 528/2012 applies since 1 September 2013. According to Biocide legislation, biocidal products must go through an authorisation procedure. This authorisation procedure impacts existing as well as new future biocidal products. Active substances contained in biocidal products, which were placed on the market prior to 14 May 2000, were collected and categorised at EU-level. These substances are currently assessed with the goal of approving them under the new biocide regulation (under the old legislation, Directive 98/8/EC, active substances were included in an annex to the Directive). Approval is the precondition for the later authorisation of biocidal products. A simplified authorisation procedure is foreseen for a group of active substances (listed in Annex I of the Regulation) that are considered to have a more favourable risk profile.

Besides possible allergic reactions and a possible impairment of the skin's own bacterial population, resistance development is a problem of textiles with an antibacterial finish. The growing use of biocide substances in the home prompts fears of the selection of resistant germs. There have already been reports in the literature [16] about multiple antibiotic resistance as a consequence of the selection of triclosan, a very frequently used active substance. When it comes to the anti-microbial finish to textiles, the risks and benefits should be carefully weighed up against one another. More particularly, no triclosan should be used [17]. Active biocide substances should always be declared.

4 Dyes

Dyes are the most importance group of substances used in textiles. Textile dyes may be classified by their solubility, chemistry or the dyeing process used. When classification is based on solubility, a distinction is made between two groups: dyes which are deemed to be soluble in the application medium and not readily or insoluble pigments. It is assumed that pigments are not absorbed through the skin as long as they are not readily soluble (solubility < 1 mg/l).

When classification is by colouring groups (chromophores), i.e. from the chemical angle, a distinction is made between azo dyes, anthroquinone dyes, metal complex dyes and others.

The classification of dyes for textiles by the dyeing process is also useful from the health angle (Table 2). Water-soluble direct dyes are bound to the fibres by deposition in cavities. However this binding is not very strong which means that the colour fastness of textiles dyed in this way is only moderate. As a rule, however water-soluble direct dyes are generally cha-



racterised by low absorption through the skin. Water-soluble reactive dyes, in contrast, are firmly bound to the fibre by means of a covalent bond which means that there is no significant exposure of the consumer as long as dyeing and after-treatment have been performed properly. Disperse dyes are lipophilic substances which are dissolved in the chemical fibre. For technical reasons, only small molecules with a required water solubility of approximately 30 mg per litre are suitable. Additional organic solvents (dye accelerators, carriers) are used. If this dyeing is not done in accordance with state of the art, e.g. over-dyeing, wrong textile substrate or incomplete removal of the carriers, there may be higher exposure to dyes and carriers when wearing garments dyed in this way. Given their properties (small molecular size, high lipophilicity) and the fact that disperse dyes and carriers are lipophilic substances, some of them are easily absorbed through the skin which means that health risks cannot be ruled out.

Name	Chemistry	Dyeing principle, function			
Dye					
Reactant-type dyes	Water-soluble	Covalent binding to the fibres			
Disperse dyes	Lipophilic azo dyes	Balanced distribution, carriers, chemi- cal fibres			
Acid and base dyes		Binding via ion exchange			
Mordant agents		Fixation via chromium salts			
Direct dyes	Water-soluble	Deposition in cavities			
Vat dyes	Anthraquinones	Redox dyeing process, high degree of fastness in use			
Sulphur dyes					
Development dyes (naphthols)	Azo dyes	Diazotised amine, coupled on fibre			
Pigments	Azo dyes, anthraquinones	Not readily soluble			
Dyeing auxiliaries					
Dye accelerators (carriers)	Aromatics	Chemical fibres, disperse dyes			
Levelling agents	Surfactants	Uniform coloration			
Crease prevention agents	Polyglycol ethers				
After-treatment agents	Surfactants, resins	Colour fastness			
Binding agents	Copolymers	Pigment dyeing			
Thickening agents	Copolymers	Pigment printing			
Dispersing agents	Polymers, surfactants	Pigment dyeing			
Fixation accelerators	Oxethylates	Pigment printing			

Table 2: Dyes and auxiliaries for dyeing

Dyes are the most important group of substances used in textiles when it comes to possible health risks. In a European research project data were compiled on the mutagenic effect of 281 dyes, in some cases from unpublished information sources of the manufacturers. 14 of them were classified as mutagenic; for 25 % (71 textile dyes) the available data were not sufficient in order to assess a possible mutagenic effect. Overall the proportion of problematic substances amongst the textile dyes used is estimated to be 10 % [18].

Of the 4,000 or so dyes listed in the Colour Index, about one half are azo dyes. They are, therefore, by far the most important group of dyes. Quite a few of these azo dyes (approximately 500) are manufactured on the basis of carcinogenic amines, and some of them (approximately 150) are still commercially available today. After intake into the human body these azo compounds may be cleaved by means of reduction during metabolism and then form the corresponding aromatic amines from which they had been synthesised. Intestinal bacteria are capable of azo cleaving but the liver also produces corresponding enzymes. Furthermore, there are indications from experiments that azo cleavage may also take place during skin passage and that skin bacteria are capable of cleaving azo dyes [19]. These findings have led to the treatment of all azo dyes in line with the corresponding amine component in



occupational health and safety rules. The TRGS 614 (Technical Rules for Dangerous Substances) sets out comprehensive limitations on the use of soluble azo dyes in the application medium, which can be cleaved into carcinogenic aromatic amines.

As far as the BfR knows, around 800 dyes are used in textiles. The German industry has long since abandoned the use of azo dyes which can cleave into carcinogenic aromatic amines. However it must be assumed that problematic dyes of this nature may be contained in some imported textiles, particularly from non-EU member states. In such cases the ban on the application of such dyes specified in the Consumer Commodity Ordinance and the REACH regulation applies. This means that no textiles treated with dyes of this kind may be placed on the market if the limit values are exceeded.

As part of official monitoring of textiles in the federal states, carcinogenic aromatic amines with contents above the limit value of 30 mg/kg were detected in 15 (9.7 %) of a total of 155 textile and leather samples tested for azo dyes in 2002 [20, 49]. In a joint market-surveillance project, 359 textile and leather product samples and two dye samples were tested for aromatic amines. In nine cases (2.5 %) it was found the limit value was exceeded [21].

Limited information on the market situation is provided by RAPEX (Rapid Exchange of Information System), a rapid warning system of the EU for hazardous consumer products, with the exception of food, pharmaceuticals and medical products for which other control mechanisms exist. RAPEX permits fast information exchange between the member states and the EU Commission about measures such as withdrawal or recall measures of products posing a serious health and safety risk for consumers. An assessment of the weekly reports recent RAPEX warnings on chemical risks in garments, textiles and fashion articles in the time period 2008-2011 showed a total of 112 reports on banned azo dyes (Disperse Yellow 23, Disperse Orange 37/76) and cleavable amines such as aniline, benzidine, *o*-toluidine, 3,3'-dimethoxybenzidine, 3,3'-dimethylbenzidine, 4,4'-methylenedianiline, 4,4'oxydianiline, 4-amino azobenzene, 4-aminobiphenyl, 4-chloro-*o*-toluidine and 4-methyl-*m*phenylenediamine.

A study conducted in Japan recently investigated the presence of carcinogenic aromatic amines in commercial textile products [22]. In 10 of 86 samples (all place mats), the limit value of 30 m/kg of the REACH regulation was exceeded. Cases were the limit value was exceeded were found for benzidine (6 samples), 3,3'-dimethoxybenzidine (3 samples) and 2,4-diaminotoluene (1 sample).

5 Nano finishes in garment textiles

As a promising area for the application of nanotechnology is textile manufacturing and finishing. The term "nano" equipment covers both the application of particles (of the order of 10-100 nm) and the application of oligomeric or polymeric substances which cross-link to form a thin layer ("nano"). The particles can be of compact shape (crystalline or amorphous) or hollow bodies (globules and tubules), which in turn can contain specific active substances. Nanoparticles can be incorporated in synthetic fibers or deposited on the fibre surface (either free or bound) during the final finishing. Similarly, the deposited layers can coat the fibers in a non-covalent manner or can be covalently bounded to the fiber materials.

Nanotechnology is used to provide the fibers with new functional properties. From the variety of possible applications, however, only a few are have been realized in textile products available on the market. Examples for the use of nanoparticles are the biocidal finish of fibres by



means of silver particles as well as the sunscreen finishing with titanium dioxide or zinc oxide. A dirt-repellent effect can be achieved by surface structuring (lotus effect) with the help of silica or by a hydro- and oleophobic finishing. Especially in the latter examples, problems arise in definition of "nano" finishing and "normal" finishing.

Growing market shares show so-called Cosmeto-textiles, among these in particular women's tights. Usually, this involves the use of nanocapsules, which are filled with cosmetics and which release their content under mechanical and / or thermal stress. So far, the problem achieve a textile finish in such a way that the intended function is maintained over long-term, i.e. possibly permanent and in particular resistant to the mechanical and thermal stress of the laundry care. Another problem with the nano finishes is the preservation of the haptic properties (grip, flexibility) of the fabric. In addition, the nano finishing represents a non-negligible cost factor.

With regard to a possible hazard potential, the abrasion of nanoparticles and their uptake via inhalative and oral routes are in focus. A dermal uptake of textile material is not to be assumed due to the size of the particles. Specific legal requirements for the use of nanoparticles do not exist at present. The production and use of nanoparticles are subject to the general chemicals legislation requirements. Textiles, which are covered by the BedGgstV, have to meet the general requirements laid down there. In the Cosmeto-textiles, the provisions of the Cosmetics Regulation (EC) No 1223/2009 additionally apply to cosmetic substances.

5.1 Finish of textiles with silver and nanosilver

Apart from medical and therapeutic applications, aspects of hygiene play an increasingly important role in antimicrobial agents for textiles. For this reason, treatment of the textile fibres with silver or silver compounds is used to counteract odour development resulting from the microbial decomposition of sweat.

In general, different procedures are used as an antimicrobial finish for garment fabrics. They can take the form of fine silver threads which are woven in with the textile fibre. There are also procedures whereby elemental silver is, in a first step, applied to a polyamid thread by galvanisation. In a second step, the silver-coated thread is then spun in with a second thread made of cellulose. In another procedure, polyamide fibre is not only made to be extremely thin but also hollow. The structure of these fine polyamide hollow fibres is similar to that of tiny microscopic tubes (approximately 20 to 100 micrometers in diameter). They can be specifically equipped with additional substances such as silver. These "silver deposits" are not directly on the surface of the fibre. Another known possibility is the inclusion of metallic silver, silver zeolite or silver glass ceramic in the fibre matrix of melt-woven fibres such as polypropylene fibres, polyester fibres and polyamide fibres. In recent years, elemental silver has increasingly been used in microcrystalline form and in the form of nanoparticles for the antimicrobial finish of textiles.

If the silver salts are integrated directly into the cellulose, they are not bonded in wash-proof manner. If the antimicrobial finish is done only after manufacture of the textile is complete, the relevant substances such as silver ions and nanosilver can easily be removed through mechanical stress and washing.

The BfR has repeatedly recommended to refrain from using silver, if the same effect can be achieved with hygienic measures that are typically used in households. This also applies to the use of silver in garment textiles for healthy consumers. There are no corroborated data



that compellingly confirm the effectiveness and necessity of a broad use of silver as a surface biocide in consumer products.

The BfR is critical of the increasing use of textile finishes with antimicrobially active substances including silver. For silver, the main concern is that an increasingly uncontrolled large-scale low-dosage application of silver and nanosilver in everyday products could increase the selection of resistances to silver but also the spread of multiple resistances to antibiotics in microorganisms. Biocidal agents are a valuable resource which should be used with care in order to preserve their effectiveness in the future. The *"Committee for Textiles and Leather"* of the BfR Consumer Goods Commission has discussed the mode of actions and causes of the observed silver resistance in bacteria [23].

The effective agent in the silver finishing of textiles is not the metallic silver but rather the silver ions (Ag⁺). As is the case with metals in general, silver ions too enter the cells through the bacterial cell wall by means of active energy-dependent transport systems. However they can, also by energy-dependent means, also be exported again. The toxicity is a result of reactions of the ions with functional groups, especially with the SH groups of enzymes. This can, among other things, lead to blockages of the electron-transport chain in the mitochondrial membranes, to impairments of DNA replication and to interaction with the metabolism of other, vital elements such as sodium, magnesium or phosphorus. Overall, the picture shows a broad and rather unspecific effect of silver ions which depends on metabolic activity and which notably occurs in the exponential growth phase of bacteria. For silver, the bacteriostatic or bactericidic effect is difficult to quantify, since the availability of the agent, i.e. the Ag⁺ ions, depends, among other things, on the type of silver additive, the milieu conditions and the complexation with or adsorption to other substances. The medical application as a bactericide is therefore usually topical and in high concentrations. Many bacterial strains are known to be resistant to silver ions and they can be found, for example, in the skin flora after therapy of burn wounds with silver preparations, in photographic waste waters, in silver mines, and in the mouth flora in case of amalgam-containing fillings. Under non-selective conditions, resistances are relatively rare. However, there is a risk of resistance development, especially at low Ag⁺ concentrations (below the ppm range). In some cases, the resistances are not stable. In addition, it must be taken into consideration that epigenetic processes can be the cause of observed resistances. Due to the non-specific effect on various cell structures, the resistance mechanisms described for other antibiotics are practically impossible for silver. Rather, the silver resistance is the consequence of modified intake or excretion processes for silver ions. These genetically fixed changes are usually encoded on the DNA of plasmids and can therefore easily be transmitted to other bacteria. At present, silver resistance is not an acute problem yet. However, it is recommended that the garment industry dispenses with the use of such textile finishing agents.

6 Health aspects

6.1 Dioxin contamination

In a study conducted in the 1990 [24] the dioxin levels were determined as the sum of chlorinated dibenzodioxins and dibenzofurans in new textiles, mainly cotton products. In one of the samples the maximum levels specified in the ChemVerbotsV for this substance group were exceeded. The main share of the chlorinated benzodioxins and benzofurans found in the respective textiles consisted of higher chlorinated compounds (heptachlorinated and octachlorinated HpCDFs, HpCDDs, OCDF and above all OCDD), which have been assigned a toxicity equivalence factor of only 0.001 (compared with the toxicity equivalence factor 1 assigned to the Seveso dioxin TCDD). Although it was demonstrated that these substances are



partly transferred to the skin when wearing contaminated garments, they could only be detected in the outermost layers of the skin. From there the substances are largely eliminated via the scales of the skin. The internal exposure of the consumer wearing these garments is low and there is no health risk. However, the relatively high dioxin levels found in individual garments are technically avoidable. They are not acceptable given the overall objective of minimising dioxin exposure.

In principle there are several possible dioxin sources: organochlorine carriers, certain dyes, some pesticides and pentachlorophenol whereby mention should be made here for instance of their use in layers (substances to treat yarn, in order to improve its properties during weaving and to protect against mechanical stress) and their use as transport preservatives in tropical countries. The use of pentachlorophenol in leather, which also leads to dioxin contamination, should be mentioned too.

6.2 Allergic reactions to garment textiles

Intolerance reactions occur when wearing textiles, for example to wool. However, real allergic reactions are relatively rare [25-26, 27, 28]. In German dermatological clinics, contact allergies are attributed in around 1-2 % of the cases to textiles. There have been reports of allergic reactions to all groups of textile auxiliaries and dyes. In Germany, however, it is mainly dyes which are of relevance for textile-related contact allergies. Certain disperse dyes in particular have been identified as the trigger. In this context, skin-tight garments made of chemical fibres constitute a special hazard potential. Under the heading "stocking dye allergy", this phenomenon was described in the literature in the 1970s; in the 1990s the socalled "leggings allergy" was described. What is important is the fastness of the dye. Particularly where perspiration fastness is inadequate, the dye may leach during wear. In the case of allergy-triggering dyes, this may cause contact dermatitis.

In connection with textile-induced contact dermatitis, 49 dyes are described as contact allergens, and about two-thirds of them are disperse dyes [29, 30, 31, 32, 33]. After evaluation of the literature on this subject and discussions within the Textiles Working Group, the BgVV identified eight dyes at that time which should no longer be used in textiles (Table 3

Colour Index Name	Number
Disperse Blue 1	64500
Disperse Blue 35	-
Disperse Blue 106	-
Disperse Blue 124	-
Disperse Yellow 3	11855
Disperse Orange 3	11005
Disperse Orange 37/76	-
Disperse Red 1	11110

Table 3:	Potentially	, sensitisina	dves	which	should	no lon	aer be	used i	n textiles
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Since then further research findings have become available on contact allergies caused by disperse dyes in textiles. Within the framework of a co-operation project of the *Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers* (ETAD) with dermatologists, patients with a textile-induced allergic skin reaction underwent a patch test for twelve disperse dyes. The textiles suspected as being the triggers of the skin reaction were then analysed. In the case of the textiles they were mainly jackets and trousers made of cellulose acetate (CA), in some cases with blends of other fibres (CA blend) or polyester (PES), polyester/cotton blends or elastane/polyamide blend. The colour fastness was between 1 and 5.



In 22 out of 27 textile samples a total of 35 different disperse dyes were detected. Nine of them are known contact allergens. The disperse dyes with allergenic potential which were detected most frequently were: Blue 106 (9 samples), Yellow 3 (8 samples), Red 1 (5 samples), Blue 102 (4 samples), Blue 124, Orange 37/76 and Brown 1 (3 samples respectively). Six allergising disperse dyes were detected in CA textiles, four in the CA blend textiles and two in PES textiles. Only Blue 106 was present in all four substance categories. Orange 37/76 could only be detected in PES. There were correlations between analytical detection in the textile and a positive patch test for the disperse dyes Blue 106 (8 cases), Blue 124 (4 cases), Yellow 3 (1 case), Brown 1 and Red 1 (1 case respectively) [34, 35]. All the above dyes are contained in the list of allergenic disperse dyes of the Ökotex Standard 100 and other eco-labels.

It is not possible to make reliable epidemiological statements on the incidence of dyeinduced contact allergies on the basis of the available scientific reports. Also the importance of individual dyes is very hard to assess because as a rule only a few selected dyes have been examined by epicutaneous testing in the clinical trials performed. There are frequent reports of cross-reactions with other dyes and also with p-phenylene diamine. One possible explanation is that cleavage products of some azo dyes (aromatic amines) may be structurally related to p-phenylene diamine (DB 124, DB 106, DO 3, see Figure 1).

Figure 1: Structural formulae of Disperse Orange 3 and p-phenylene diamine



Abb. 1: Strukturformeln von Dispersionsorange 3 und p-Phenylendiamin

In 2007, a research project on the skin-sensitising effect of dyes in garments was initiated as part of the action plan against allergies of the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV). The subsequent project, drafted by the BfR, on the "Testing of textile dyes for skin-sensitising potency in the lymph node assay" was carried out by a group of the Institute for Clinical Pharmacology and Toxicology at the Charité-Universitätsmedizin Berlin. In this research project, the sensitisation potential of eight disperse dyes (Table 3) and some dye-cleavage products was investigated using a modified local lymph node assay (LLNA) in mice and by non-animal testing using the loose-fit co-culture-based sensitisation assay (LCSA) on human cells [50, 36]. A ranking of the disperse dyes according to their sensitisation potential yielded similar results for both methods (Figure 2). These results are in agreement with human data [36]. Contradictory ranking assignments such as for DB1 and DG 3 (Figure 2) are probably attributable to metabolic differences in the skin cells of mice and man. The LCSA thus provides a human cell-based *in vitro* testing system with which the hazard potential of dyes and their degradation products can be determined in relation to their capacity to trigger contact allergies.



Figure 2: Ranking of the eight disperse dyes according to their sensitisation potential, which was determined by the modified local lymph node assay (LLNA) and the *in-vitro* sensitisation assay (LCSA). The sensitisation potential is shown in descending order from top to bottom [36].



In the LLNA in mice, the blue disperse dyes DB 106 and DB 124 in particular have been shown to be substances with a strong allergenic potential. These substances were already effective at a concentration of 0.0003 % and are therefore >1000-fold more potent than the other tested compounds [36, 23.] The use of these two highly potent sensitising disperse dyes in garment textiles is therefore inacceptable in the opinion of the BfR.

The EU Commission is, in accordance with Article 25 of Textile Labelling Regulation (EU) No 1007/2011 is invited carry out a study to evaluate whether there is a causal link between allergic reactions and chemical substances or mixtures used in textile products. On the basis of that study, the Commission will, where appropriate, submit legislative proposals in the context of existing Union legislation.

6.3 Detergent residues and additives

Data on detergent residues on textiles are available in particular from the commercial sector. When examining complaints, the frequency of which is given as approximately 1:107, it was shown that the residual contents of surfactants do not exceed 100 ppm in most cases whilst organic and inorganic encrustations are mainly below 1 % (10,000 ppm). The pH values in the majority of the samples examined were between pH 6 and pH 8; pH 10 was not exceeded. From wash experiments with branded detergents in household washing machines it can be determined that residual contents of soaps and surfactants of > 1,000 ppm are to be expected depending on the type of fabric and the composition of the detergent. Residual zeolite contents (phosphate substitutes) were found in one case of almost 37,000 ppm. Also after the switch to phosphate substitutes, there were not any signs from the environmental medical angle of a health threat to consumers from detergent residues in textiles aside from individual cases of intolerance reactions.

For the purposes of the ecological optimisation of household laundry (energy and water savings) water consumption was reduced by 50 % in modern household washing machines. The German associations of detergent and washing machine manufacturing industries (IKW and ZVEI) set up, in the second half of the 1990s, a working group called "Dermatological Aspects of Washing" to collect the latest data on detergent residues and their dermatological relevance.



Besides the primary wash effect, i.e. dirt removal, secondary wash effects increasingly play a role like preventing discoloration, bleeding or encrustations on the fabric or washing machine parts. As a rule, these effects are achieved by applying corresponding additives. Encrustations and greying are prevented by the use of polymers like polycarboxylates which disperse calcium and magnesium compounds. Other polymers are applied as a protective coating to fibres and remain on the textile after washing. To inhibit colour carryover polyvinyl polypyrrolidones (PVPPs) are used which complex anionic azo dyes. "Colour care" additives fix the dyes in the fabric. These are special additives which contain a cationic polymer amongst other things. It forms a water-insoluble complex with the anionic dye molecules on the fabric.

Fragrances are also of importance; they are added to detergents, softening agents and ironing aids. Allergic reactions are possible. It is estimated that 10 % of patients with contact eczemas and between 1 and 2 % of the total population react positively in patch tests to fragrances [37a]. The Scientific Committee on Cosmetics and Non-Food Products of the EU (SCCNFP) is of the opinion that the same requirements should apply to perfumes in detergents and household chemicals that apply to cosmetics [38]. The SCCNFP has listed perfume ingredients with a known allergenic effect [37] and also a number of fragrances which must not be contained in cosmetics [51]. The Regulation on Detergents (EC) No 648/2004 envisages the mandatory declaration of allergenic fragrances in detergents from a concentration of 0.01 % upwards.

The use of nitromusk compounds and polycyclic musk compounds is viewed critically from the ecological and toxicological angle. Musk xylene has not been used in any new products since 1994 because of a voluntary undertaking by the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW) in Germany. It is gradually being replaced in products which were already on the market prior to 1994. Major constraints on the use of musk ambrette had already been imposed in 1983 by IFRA (*International Fragrance Association*). The other nitromusk compounds have not been subject so far to any constraints on use in detergents; however in some cases manufacturers are voluntarily refraining from using them.

In detergents, the addition of substances with antibacterial or disinfectant effects is a major trend. Products of this kind are covered by the European Detergent Regulation No 648/2004. Sanitary cleaning agents, which are used like softening agents after washing and are not rinsed out, are enriched with a concentration of around 7 % benzalkoniuim chloride. Benzalkonium chloride has a sensitising potential. The use of isothiazolinones for the preservation of liquid starch must also be viewed as problematic as these substances are contact allergens and skin contact must be assumed.

7 Approaches to the estimation of exposure to textile chemicals

7.1. Release of textile dyes

One essential component of any risk assessment is exposure. According to current findings, it is almost impossible to indicate a specific value for textile dyes because the degree of release may vary considerably. In the case of dyes it depends on which dye category, dye content (colour intensity) and fastness are examined on the respective textile substrate. It is also necessary to consider the conditions of wear and dermal absorption.

In order to obtain insight into the release of dyes from textiles, various research was undertaken only recently by both industry and research institutes with a view to creating a database for generally accepted models on the migration of substances from textiles. Textiles and clothing are also one main area of the programme launched by the European Commis-



sion: "EIS-ChemRisks" – (*European Information System on "Risks from chemicals released from consumer products / articles"*).

Until only recently there was only one reliable database on exposure to dyes from textiles, namely a study by the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) [39]. This project determined the release of dyes from garments by keeping 500 cm² of dyed textile samples in test solutions prepared according to DIN 54020 (Determination of sweat fastness of dyes and prints) at 37 °C for four hours. Dermal exposure (external exposure) to dyes during the wearing of textiles was estimated from the amount of dye released. Textiles with varying specific weights and dye content were examined. Between 0.1 and 300 µg dye were extracted from 500 cm² of textile sample. For textiles with a high degree of colour fastness releases of < 1 µg per simulated wear event were obtained. When related to the surface area examined or to an equal area of exposed skin, this would mean a surface dose of $< 2 \text{ ng/cm}^2$. The highest release rate measured was 0.4 mg per simulated wear event. In this case 0.18 % of the dye was released (migration factor 0.18 %) on the basis of which a surface-related dose of 0.7 μ g per cm² can be calculated. However, it must be borne in mind in this assessment that under practical conditions, the release rates will be lower after repeated washing. On the other hand, the samples consisted of textiles which had been dyed using the latest technologies available and there may be higher release rates from poorly dyed textiles. Furthermore, the mechanical effects which result from the wearing of garments were not considered.

The results of a research project supported by the Federal Ministry for Health entitled "Development of practice-oriented models of exposure to chemical substances from textiles" address the issue of the impact of wearing garment textiles on the release of dyes [40]. A wear simulator has been developed by the German Wool Research Institute in Aachen (DWI) which was used to examine the release of textile dyes and auxiliaries from textiles under simulated conditions of use. In the wear simulator dynamic processes (friction) were found to have a considerable effect on migration. In a dynamic skin model (1 h, 37 °C) using an alkaline perspiration solution, a migration factor of 0.26 % corresponding to a surface related dose of 1.1 µg per cm² skin was determined for Palatinenechtmarineblau [40]. In other tests dyed textiles were examined in the wear simulator over a 28-day cycle. Various fibres (wool, cotton, polyamide, acetate) and different dyes (direct dyes and disperse dyes) were compared with and without the addition of textile auxiliaries. In addition, colour fastness was tested according to DIN 54020. It was shown that the colour fastness of the various types of fibre was dependent on the dyes applied. The volume of dye released during the simulation of wear conditions did not, however, correlate with colour fastness. Rather, the combination of fibre type, dye and test conditions, including the pH value of the elution solution, had a major impact on migration. The migration rate during the first wash cycle for the dye AB158 from wool with acid elution was 0.8 %. By contrast, it was 8 % for the dye DB 116 from cotton. Under alkaline elution conditions, the eluatable proportions were lower. During the last wash cycle only 0.2 up to 0.5 % of the originally applied amounts of dye were released. Dye migration can be reduced through the subsequent treatment of textiles and the use of textile auxiliaries [41].

Another ETAD project sought to determine average exposure to disperse dyes from dyed garments for a typical period of use (50 wash / wear cycles) [42]. In a first extraction, depending on colour intensity, up to 0.43 % of the textile dye migrated to the extraction medium. On this basis, an area dose of up to 0.28 µg per cm² was calculated. After five wash cycles the release rates were reduced to about one-third of the initial level. Mean external exposure rates from < 0.005 up to 0.067 µg per cm² were calculated from all migration results for the test period. Assuming an exposed surface of 1 m² and a bodyweight of 70 kg,



mean external exposure rates of < 0.71 to 9.7 μ g per kilogram bodyweight can be established. In the case of contact allergies, however, it must be assumed that the decisive factor for risk assessment is not average but peak exposure [43, 44].

In the case of skin penetration it must be borne in mind firstly that there are major differences between dyes and secondly that the penetration rate depends on the concentration. For instance no skin penetration could be demonstrated in an *in vitro* experiment with pig skin and a dose of 0.2 μ g per cm² whereas at a higher specific dose of 4.2 μ g per cm, skin penetration could be measured [45, 46]. From these results it can be concluded that internal exposure to disperse dyes is low in the case of perspiration-resistant dyed textiles. However, when wearing garments whose dye is not perspiration resistant, there may be internal exposure, the level of which will again depend on the ability of the respective dyes to penetrate the skin.

Based on the sparse migration data available, it can be concluded by way of summary that the external exposure of consumers to dyes from textiles coloured in accordance with state of the art (fastness between 4-5 and 2-3) is between 1 ng and 1 μ g per cm² referred to the skin area involved. Where poor dyeing techniques have been used, release rates may however be considerably higher. However, no figures are available on this. In a dose range of 1 μ g per cm², allergic reactions to potent allergens like cathone or chromium (VI) cannot be ruled out. For disperse dyes whose sensitising potential is probably much lower, there are not enough quantitative data for a sound risk assessment or the determination of "practically safe surface doses".

The database for textile auxiliaries is even worse.

7.2 Release of substances from textiles (Migration)

General comments on migration measurement

Based on the data compiled by the Working Group Textiles, it was observed that elution is suitable as a simple and practice-driven method for the measurement of dye migration. It supplies values comparable with other methods but it would have to be standardised in terms of sample preparation, elution agent, pH, liquor ratio, temperature, time and mechanical influences (shaking, stirring). There are no comparable studies for auxiliaries or finishing agents. However, for reasons of simplicity, the Working Group Textiles recommends the same methodology. The BfR proposes the following procedure [11]:

- 0.5 g unwashed textile fabric is shaken in 25 ml synthetic perspiration (liquor ratio 1:50) for 60 minutes at 40 °C with 90 revolutions per minute.
- > According to DIN 54020 both acidic and alkaline perspiration solutions are used.
- The release is quantified with a suitable analytical method and related to 1 g or 1 cm² fabric.
- > The higher value is included in the exposure assessment.

This measurement of initial migration helps to estimate the amount of substances released during the first wear of 16 hours from the examined textile. If textiles, as is frequently the case today, are washed prior to wearing, then the value for the first migration will be lower.

The release of substances from textiles changes in the course of wear. Three main results can be derived from the DWI and ETAD studies:



- 1. The migration values vary considerably depending on the type of fibre, the dye used, the amount applied, colour intensity, extraction agent and after-treatment.
- 2. Despite the major differences exposure can be estimated in standard procedures whereby a distinction can be made between textile dyes and auxiliaries.
- 3. The migration rate after 28 hours simulated wash /wear cycles is less than 10 % of the value measured for the first migration.

Very few data are available on migration of textile auxiliaries. Here a distinction must be made between auxiliaries which are added during the production of the textile liquor but which are not meant to remain on the textile and finishing agents which are applied to the textile in line with correct use. The first group includes very hydrophilic substances like surfactants. These are almost completely dissolved during the production process or at the latest during washing of the textile which means that we can assume a low migration rate of any residues. Less hydrophilic substances with a specific fibre affinity are, however, also used. For an ingredient of a water repellent, a migration rate of 1.9 % was determined in experiments. The second group includes hydrophobic substances which are not readily soluble in perspiration. In corresponding studies possible migration almost always remained below the detection level. For levelling agents rates were measured for the first migration of between 0.1 and 0.2 %.

7.3 Exposure assessment models

The basis for the assessment of exposure to textiles are firstly migration data. Secondly, data on the skin penetration of the substances involved are also necessary. In practice, however, given the lack of experimental data for migration and skin penetration, corresponding assessments must be undertaken. As a rule, however, data are available on the levels of substances in textiles.

Based on the studies evaluated the "*Working Group Textiles*" recommends the following default values as worst case assumptions when no measurement results are available [11] (Table 4). These default values are based on experimental data determined by way of example for the initial estimation of possible exposure.

Table 4:	Recommended	default values a	as the worst-cas	e assumption i	f no other	values are	available
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Substance category	Migration rate	Penetration rate
Dye	0.5 %	1 % */**
Hydrophilic textile auxiliary	2 %	5 % *
Hydrophobic textile auxiliary	0.1 %	50 % *

* Exception molecular weight >700 or log Pow <-1 or >6

** A penetration rate of 2 % is used to calculate exposure in perspiration zones

Important parameters which can influence exposure are the area weight of the textile, the size of the exposed skin area, bodyweight, individual wear conditions and washing processes. Exposure calculations are based on the following assumptions:

- Area weight of the textile 100 g/m²
- Exposed skin area 1 m²
- Bodyweight 60 kg

7.3.1 The BfR exposure assessment model



It makes sense when estimating exposure to distinguish between acute exposure whilst wearing new textiles with a possibly higher migration rate and chronic exposure during the duration of use. This differentiation not only refers to the release scenario as confirmed by experimental data from the tests with simulated wash / wear cycles but also to toxicity. The data on first migration are used to estimate acute exposure and undertake a risk assessment of acute intoxications and allergic reactions. To determine mean chronic exposure and for the risk assessment of sub-chronic and chronic toxicity, one-tenth of the first migration value can be used alternatively, since results from complicated measurements under simulated wear conditions are not normally available. In both instances this is a worst-case estimate.

This procedure is illustrated below using a simple example for a dye (dye content 1 %). According to the above assumptions, the following applies:

Exposed area	Surface weight	Dye content	Migration share
1 m ²	100 g/m²	10 g/kg	0.5/100

This leads to an external individual dose of 5 mg. The following exposure scenarios can be considered for a person with a body weight of 60 kg:

Scenario A: Acute exposure

External body dose	5 mg / 60 kg	= 83 µg/kg bodyweight
Internal body dose (penetration rate 1 %)	0.01×83 µg/kg	= 0.83 µg/kg bodyweight
External surface dose (exposed area 1 m ²)	5 mg / 1 m ²	= 0.5 µg/cm ² body area

Scenario B: Mean chronic exposure

External body dose	$0.1 \times 5 \text{ mg} / 60 \text{ kg} = 8.3 \mu \text{g/kg bodyweight}$
Internal body dose (penetration rate 1 %)	0.01×8.3 µg/kg = 83 ng/kg bodyweight
External surface dose (exposed area 1 m ²)	$0.1 \times 5 \text{ mg} / 1 \text{ m}^2 = 0.05 \mu\text{g/cm}^2 \text{ body area}$

Special exposure calculations

The assumptions in the exposure model described are only applicable to textiles which were dyed in line with the latest technologies available. In the case of textiles which were not produced using the latest technologies available, there may be higher migration rates and, by extension, higher exposure. If data on individual parameters are available in the case to be considered, the corresponding calculation model can be adjusted. This will lead to a more realistic estimate of exposure. A corresponding correction can be undertaken of the following parameters:

- Exposure area particularly for textiles which only come into contact with specific parts of the body
- Surface weight
- Migration rate after experimental determination
- Penetration rate after experimental determination
- Wear behaviour
- Bodyweight, e.g. in order to estimate the exposure for children
- Consideration of perspiration zones, e.g. in sportswear. Here however for the dyes a worst case skin penetration rate of 2 % can be used and, if appropriate, a correspondingly smaller relevant body area.



7.3.2 Estimation of consumer exposure according to REACH

Estimation of consumer exposure using the REACH method is conducted in accordance with the "Guidance on information requirements and chemical safety assessment – Chapter R.15: Consumer Exposure Estimation" [47]. Section R.15.3.2.2.2 describes a scenario for the estimation of dermal absorption of a non-volatile substance which is released from a product during the time of skin contact and which comes into contact with the exposed skin area. According to the REACH exposure model, the external area dose L_{der} (mg/cm²) can be calculated as follows:

$$L_{der} = \frac{Q_{prod}}{A_{skin}} \cdot Fc_{prod} \cdot Fc_{migr} \cdot T_{contact} .$$

As parameters, the product weight Q_{prod} (g), the exposed skin area A_{skin} (cm²), substance content in the product Fc_{prod} (mg g⁻¹), the migration rate and / or the migrating share of the substance content Fc_{migr} (mg mg⁻¹ h⁻¹) per time unit as well as the duration of skin contact $T_{contact}$ (h) are included in the calculation. The quotient of Q_{prod} and A_{skin} represents the weight per area. The external body dose D_{der} (mg kg⁻¹ body weight d⁻¹) for *n* wearing events per day results from the given body weight BW (kg) in accordance with

$$D_{der} = rac{L_{der} \cdot A_{skin} \cdot n}{BW}$$
 .

8 Results of the test programme of the German industry for the toxicological assessment of textile chemicals based on the BfR exposure assessment model

The "*Textiles Working Group*" has drawn up principles for toxicological and allergological testing [48]. On that basis the German industry ran a test programme in which the manufacturers of textile auxiliaries and textile dyes examined the safety of their textiles finished, processed and dyed in this way.

In the opinion of the BfR, information on mutagenic, carcinogenic and sensitising properties should be available for each substance as a matter of principle. The scale of testing should, however, be oriented towards expected exposure. No substances were tested with a molecular weight of more than 700, a water-octanol partition coefficient log $P_{ow} < -1$ or > 6 or which had been proven to be not bioavailable.

8.1 Tests on the mutagenicity and sensitising properties of textile auxiliaries

The following representatives of large volume ingredients of textile auxiliaries were examined toxicologically from four textile auxiliary groups: levelling agents (benzyl trimethyl ammonium chloride, dimethyl benzyl-C₁₂₋₁₈-alkyl ammonium chloride (benzalkonium chloride)), crease prevention agents (sulphated fatty acid dialkylamide), anti-electrostatic agents (di-n-butyl phosphate, alkyl polyglycol ether phosphoric acid ester), water repellents (aluminium oxy-chloride). Given their high molecular weight no priority for toxicological testing was attributed to 16 textile auxiliary groups. Data were already available for two groups (conditioning agents, softening agents). The residual contents of these textile auxiliaries after the first wash were in the range of < 0.1 % up to 3.7 %. Migration in the synthetic perspiration solution (DIN 54020) was maximum 1.9 % (aluminium oxychloride). All substances tested negative for mutagenicity in the Ames test and in the micronucleus test. The sensitising effect of



benzalkonium chloride is known from positive results from studies in test cohorts and in especially exposed groups. The other substances were not found to be sensitising in animal tests (Magnusson-Kligmann test). For benzalkonium chloride a residual content of 1.4 % and migration of 0.1 % for methodological reasons prior to the first wash were observed. As a rule two to three industrial washes after use of this substance are customary which means that the residual content and migration from textiles should be lower under real conditions [49].

8.2 Dye mutagenicity tests

The test programme did not include pigments or reactive dyes which are not assumed to involve major consumer exposure. Naphthol dyes were not included either because of their partition coefficient (log $P_{OW} > 6$). Nor were direct dyes with a molecular weight of more than 700 or a partition coefficient log P_{OW} > -1. In the other dye categories it was assumed that at a fastness < 4 relevant migration and, by extension, possible exposure > 1 µg per kilogram bodyweight and day cannot be ruled out. A need for action was, therefore, identified for certain disperse dyes, particularly when used for polyamide and polyacetate, that are also used because of their market importance and for which relevant consumer exposure can be assumed. A total of ten disperse dyes were examined for mutagenicity and sensitising potential. The dyes C.I. Disperse Orange 30, Red 73, Red 167, Red 82, Orange 49, Red 54, Blue 79. Blue 73 and Red 11 were positive in the Ames test but negative in the micronucleus test. A further mutagenicity test was negative for Orange 30, Red 54, Blue 79, Blue 73 (tested in the HPRT test) and for Red 11 (UDS test). For Red 73, Red 167 and Red 82 it is assumed that they do not have any mutagenic potential either because of their structural similarities to non-mutagenic dyes. Orange 49 did not undergo any further testing as this dye is no longer important. Yellow 211 was negative in all three test systems [49].

8.3 Tests on the sensitising properties of dyes

Studies on the skin penetration of Disperse Orange 30 and Disperse Red 82 were conducted *in vitro* with human skin and pig skin as part of the testing programme of the German industry. For application amounts of 10 µL saturated, synthetic perspiration solution per cm², the absorption rate was below the detection limit of 0.001 µg/cm²/h. Application amounts of 200 µL saturated, synthetic perspiration solution per cm² led in the case of Disperse Orange 30 to absorption rates of 0.004 µg/cm²/h and total uptake of 0.16 µg/cm² in 48 hours (human skin) and 0.022 µg/cm²/h and total intake of 0.86 µg/cm² in 48 hours (pig skin). In the case of Disperse Red 82, penetration of this amount also remained below the detection limit. In the case of tests on skin penetration from acetone excretions, the absorption rate was below the detection limit (Disperse Orange 30: < 0.05 µg/cm², equivalent to 8 % at a dose of 0.6 µg/cm² and 0.8 % at 6.0 µg/cm²; Disperse Red 82: < 0.02 µg/cm² equivalent to 33 % at a dose of 0.06 µg/cm² and 3.3 % at 0.6 µg/cm²) when human skin was used. When using pig skin, absorption over 48 hours depending on the receptor liquid was maximum 54 % (0.007 µg/cm²/h at a dose of 0.6 µg/cm²) for Disperse Orange 30 und 79 % (0.002 µg/cm²/h) for Disperse Red 82 [52].

A test for skin sensitising properties (Magnusson-Kligmann test) showed that Disperse Orange 30 and Disperse Red 82 were sensitising. These dyes were then examined in the Local Lymph Node Assay. In this test system, the proliferation of T-lymphocytes in the lymph nodes of mice is determined after the dermal application of a test substance by means of the incorporation of radiolabelled thymidine. In the case of both dyes, the lymphocyte proliferation was not elevated after the application of concentrations of up to 30 %. It can be assumed that Disperse Orange 30 and Disperse Red 82 also have a weak sensitising potential. There



is no need, therefore, to assume a risk to consumers through textiles coloured with these dyes [53, 54].

10 Summary

- No systemic toxic effects from chemical substances are expected from the wearing of textiles (exception contact allergies).
- There are only health risks from textile dyes in the case of poorly dyed, non-colour fast products. Given that everyone has close skin contact with textiles 24 hours a day, the documented cases of contact allergies triggered by textiles are rare. Textile-related contact allergies probably account for around 1-2 % of cases.
- When garment textiles are worn with disperse dyes with a sensitising potential, there is a risk of a contact allergy when perspiration resistance is < 4 and there is intensive skin contact, particularly in perspiration zones. Another risk factor is already damaged skin with an inadequate barrier function.</p>
- On precautionary grounds the following dyes should no longer be used in textiles: Disperse Blue 1, Disperse Blue 35, Disperse Blue 106, Disperse Blue 124, Disperse Yellow 3, Disperse Orange 3, Disperse Orange 37/76 und Disperse Red 1. Other dyes with allergenic potential have since been identified and should at least be declared.
- Certain azo dyes that can be cleaved into carcinogenic aromatic amines have been banned EU-wide. It can be assumed that these dyes are occasionally still present, particularly in imported textiles.
- The use of 1,2,4-trichlorobenzene as a dye accelerator (carrier) in textiles is not safe and should be banned in the opinion of the BfR.
- > There are hardly any data on exposure to textile auxiliaries.
- Exposure to dyes, related to skin area, is between 1 ng and 1 µg pro cm² depending on colour fastness.
- > Exposure to dyes can be estimated using suitable models.
- The risk assessment for finishing with fluorine polymers revealed that there is no worrying exposure to fluorine surfactants from textiles.
- When it comes to the anti-microbial finishing of textiles, the risks and benefits should be carefully weighed up against one another. The BfR recommends in particular that triclosan should not be used. Active biocidal substances should always be declared.

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