Textiles — Cosmetotextiles

ICS 61.020; 71.100.70; 97.160



National foreword

This Published Document is the UK implementation of CEN/TR 15917:2009.

The UK participation in its preparation was entrusted to Technical Committee TCI/80, Chemical testing of textiles.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 November 2009.

© BSI 2009

ISBN 978 0 580 65117 5

Amendments/corrigenda issued since publication

Date	Comments

TECHNICAL REPORT RAPPORT TECHNIQUE TECHNISCHER BERICHT

CEN/TR 15917

September 2009

ICS 61.020; 71.100.70; 97.160

English Version

Textiles - Cosmetotextiles

Textiles - Cosmétotextiles

Textilien - Cosmeto-Textilien

This Technical Report was approved by CEN on 3 August 2009. It has been drawn up by the Technical Committee CEN/TC 248.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents Page

Forewo	ord	3
Introdu	ction	4
1	Scope	5
2	Normative references	
_		
3	Terms and definitions	
4	Characteristics	
4.1	General	
4.2	General aspects	
4.2.1	Introduction	
4.2.2	Recommendations	
4.3	Safety evaluation	
4.3.1	Introduction	
4.3.2	Risk in relation to the cosmetotextile	
4.3.3	Requirements for a cosmetic dossier	
4.3.4	Notification of the cosmetic product of cosmetotextiles to national poison centres	
4.4	Claimed effects	
4.4.1	Introduction	
4.4.2	Methodology	
4.4.3 4.5	Examples (non-exhaustive list, without hierarchy in the listed methods)	
4.5 4.5.1	Care resistance	
4.5.1 4.5.2	Introduction	
4.5.2 4.5.3	Methodology	
4.5.3 4.5.4	Calculation	
4.5.4	Test report	
4.5.6	Examples of extraction and chemical analyses	
4.6	Labelling	
4.6.1	Introduction	
4.6.2	Product labelling	
4.6.3	Marketing labelling requirements	
	A (informative) Regulations	
A.1	Cosmetics regulations	
A.2	Textile regulations	
Annex	B (informative) Guidelines	20

Foreword

This document (CEN/TR 15917:2009) has been prepared by Technical Committee CEN/TC 248 "Textiles and texile products", the secretariat of which is held by BSI.

Introduction

Recently, new textile products have appeared on the European market. They associate textile supports and cosmetic products, for example:

- slimming preparations: pantyhose, underwear, trousers;
- moisturizing preparations: pantyhose, underwear, T-shirts;
- refreshing preparations: houselinen (bedsheets.).

CEN/TC 248 WG25 has worked on this combination between textiles and cosmetic products. This new class of product has been given the name: cosmetotextiles.

An indication that the European Commission will treat the cosmetic part of a cosmetotextile analogous to cosmetic products is given in the "Manual of the scope of application of the European Cosmetics Directive 76/768/EEC". As a consequence, Article 2 of the European Cosmetics Directive 76/768/EEC gains also central importance for the cosmetic part of cosmetotextiles, stating that a cosmetic product should not cause damage to human health.

European Cosmetics Directive 76/768/EEC, Article 2 states:

"A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market".

Cosmetic products are regulated within the European Cosmetics Directive (76/768/EEC) at present in accordance with the 7th amendment. Although the complete cosmetotextile product does not need to conform to the directive, the cosmetic products of a cosmetotextile will need to fulfil the terms of the European Cosmetics Directive if they are to be marketed in Europe.

1 Scope

This Technical report specifies general characteristics of cosmetotextiles and describes their recommended properties.

Five parts have been established as follows:

- general aspects;
- safety evaluation;
- claimed effects;
- care resistance;
- labelling.

These five characteristics are developed in Clause 4.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

prEN ISO 3175-1, Textiles - Dry-cleaning and finishing - Part 1: Method for assessing the cleanability of textiles and garments (ISO 3175-1:1998)

EN ISO 3758, Textiles - Care labelling code using symbols (ISO 3758:2005)

EN ISO 6330, Textiles - Domestic washing and drying procedures for textile testing (ISO 6330:2000)

EN ISO 22716, Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices (ISO 22716:2007)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

textile

flexible material comprising a network of natural, man-made fibres often referred to as yarn

NOTE Yarn is produced by spinning raw wool fibres, linen, cotton, or other material on a spinning machine. Textile fabrics are formed by weaving, knitting, or non-woven processes.

3.2

cosmetic product

substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively, or mainly, to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition". [In accordance with article 1 of the European Cosmetics Directive 76/768/EEC]

CEN/TR 15917:2009 (E)

3.3

cosmetotextile

textile consumer article containing a durable cosmetic product which is released over time

NOTE Disposable products (e.g. wipes) are not considered as cosmetotextiles.

3.4

binder

material used to bind together two or more other materials (for example textiles and microcapsules). Its two principal properties are adhesion and cohesion

3.5

microcapsule

small particle with a wall that contains the cosmetic product. Most microcapsules have diameters of a few micrometers

3.6

cosmetic effects

effects that are in line with the general definition of a cosmetic product as mentioned in the European Cosmetics Directive (76/768/EEC)

3.7

cosmetic claim

information, made available to the consumer and/or market, on the contents (properties, effects, etc.) of the cosmetic product or its constituents as well as the cosmetotextile

NOTE See also Guidelines for the Evaluation of the Efficacy of Cosmetic Products, COLIPA, Annex B.

3.8

claim substantiation

process of proving the effects claimed to be generated by the cosmetotextile, e.g. via a scientifically sound method, published data or consumer testing

NOTE This is obligatory in accordance with various laws including the European Cosmetics Directive (76/768/EEC).

3.9

care resistance

cosmetotextile property which characterizes the quantity of the cosmetic product remaining after a given number of care cycles

NOTE "Care resistance" should not be confused with "durability of the cosmetic effect".

3.10

durability of the cosmetic effect

number of care and use cycles during which this (these) effect(s) can be measured and/or noticed by the user

NOTE 1 This information is relevant for marketing claims. It should not be confused with the date of minimum durability of the cosmetic product (shelf life) which in accordance with the European Cosmetics Directive should be indicated by the words: "best used before the end of ...".

NOTE 2 "Durability of the cosmetic effect" should not be confused with "care resistance".

3.11

claimed effect

ability of a cosmetotextile to produce the cosmetic effect claimed when using that specific cosmetotextile

3.12

product label

label permanently attached to or printed onto a cosmetotextile

3.13

marketing label or hand tag

label which is not permanently attached to or printed onto a cosmetotextile

4 Characteristics

4.1 General

Five characteristics are developed below: general aspects, safety evaluation, claimed effects, care resistances and labelling.

4.2 General aspects

4.2.1 Introduction

A cosmetotextile is a product which combines a cosmetic product and a textile (with or without a binder). This cosmetic product may be contained in a microcapsule for example.

The cosmetic product used in a cosmetotextile shall conform to European Cosmetics regulations. One condition for a substance or preparation to be a cosmetic is that it is intended to be released to the body.

The present technical report focuses on some parts of the European Cosmetics Directive 76/768/EEC which apply mainly to the cosmetotextile.

The textile of the cosmetotextile is only a "vehicle" to deliver a cosmetic product on different superficial parts of the human body. This textile should not be considered to be a cosmetic product.

Substances which are part of the textile (dyestuffs, textile auxiliaries, binders, microcapsules...) are not intended to be released to the body, and are therefore not considered to be cosmetic products.

A textile with those substances, which are part of the textile, falls within the scope of application of European Textile regulations.

Textiles which claim external biocide activity are excluded. They fall within the scope of the European Biocidal Products Directive 98/8/EC.

4.2.2 Recommendations

4.2.2.1 General

NOTE Special care should be given to the following points.

4.2.2.2 Quality control concerning textiles

The quality of the textile should be well controlled.

The following Table 1 proposes some suggestions:

Table 1 — Quality control concerning textiles

Criteria	Standard		
Colour fastness to water	EN ISO 105-E01		
Colour fastness to rubbing	EN ISO 105-X12		
Colour fastness to perspiration	EN ISO 105-E04		
Depending on care specifications:			
Colour fastness to domestic and commercial laundering	EN ISO 105-C06		
Colour fastness to dry cleaning	EN ISO 105-D01		

4.2.2.3 Good manufacturing practices for cosmetotextiles (GMP)

As far as the textile industry is concerned, cosmetotextiles should conform as closely as possible to the standard EN ISO 22716 relative to GMP for the cosmetic products.

The requirements for cosmetotextiles are based on the main textile reference frames used in the textile industry, such as European Ecolabel for textiles or other private labels.

4.3 Safety evaluation

4.3.1 Introduction

A cosmetotextile placed on the European market is deemed to be in accordance with the General Product Safety Directive 2001/95/EC.

The safety of a cosmetic product placed on the market within the EU is, in accordance with the European Cosmetics Directive 76/768/EEC, the full responsibility of the manufacturer, the first importer into the EU market or the marketer.

Information relating to the ingredients and undesirable effects should be made easily accessible to the public, (this is in accordance with article 7a (§1) of the European Cosmetics Directive 76/768/EEC).

4.3.2 Risk in relation to the cosmetotextile

4.3.2.1 **General**

The cosmetic product of a cosmetotextile usually consists of a complex composition of different ingredients. A toxicological profile is necessary for each ingredient. An overall toxicological evaluation for the cosmetic product is developed on the basis of these profiles.

In accordance with the SCCP (Scientific Committee on Consumer Products) notes of guidance (see Annex B); a safety evaluation of a cosmetic product comprises the following steps:

- a) a hazard identification for all ingredients;
- b) a dose response assessment;
- c) an exposure assessment;

d) a risk characterization.

The safety of binders and microcapsules, shell materials as well as other auxiliaries which are generally used in the manufacture of cosmetotextiles should also be subjected to a risk assessment. The textile base fabrics used for cosmetotextiles should carry no substance at levels that are of toxicological concern.

4.3.2.2 Hazard identification for ingredients

The hazard identification of the cosmetic ingredients is outlined in detail in the relevant SCCP notes of guidance (see annex B): "Based on the results of *in vivo* tests, *in vitro* tests, clinical studies, accidents, human epidemiological studies and, when available, Quantitative Structure Activity Relationship (QSAR) studies. The intrinsic physical, chemical and toxicological properties of the molecule under consideration are studied to identify whether the substance has the potential to damage human health".

Within the toxicological evaluation process of chemical substances, several toxicological parameters and methods are described. However, due to the application route of cosmetotextiles comparable to "leave-on" cosmetics (e.g. body lotion), the SCCP suggest, that as a minimum, the evaluation of a selected number of toxicological endpoints, described in the following.

Acute toxicity

The term "acute toxicity" is used to describe the adverse effects on health which may result from a single exposure to a substance via the oral, dermal or inhalation route.

For acute oral or dermal toxicity testing, which are relevant in this context, the reader may be referred to the relevant SCCP notes of guidance (see Annex B).

Skin irritation or dermal irritation

Skin irritation or dermal irritation is defined as reversible damage of the skin following the application of a test substance.

For skin irritation or dermal irritation testing the reader may be referred to the relevant SCCP notes of guidance (see Annex B).

Eye irritation or mucous membrane irritation

Eye irritation or mucous membrane irritation is defined as reversible damage of the eye or mucous membrane following the application of a test substance.

For eye irritation or mucous membrane irritation testing, the reader may be referred to the relevant SCCP notes of guidance (see Annex B).

Skin sensitization

A skin sensitizer is an agent that is able to cause an allergic response in susceptible individuals. The consequence of this is that following subsequent exposure via the skin, the characteristic adverse health effects of allergic contact dermatitis may be provoked.

For skin sensitization testing, the reader may be referred to the relevant SCCP notes of guidance (see Annex B).

Dermal / percutaneous absorption

The dermal / percutaneous absorption process is a global term which describes the passage of compounds across the skin.

CEN/TR 15917:2009 (E)

For dermal / percutaneous absorption testing, the reader may be referred to the relevant SCCP notes of guidance (see Annex B).

Repeated dose toxicity

Repeated dose toxicity comprises the adverse general (excluding reproductive, genotoxic and carcinogenic effects) toxicological effects occurring as a result of repeated daily dosing with or exposure to, a substance for a specific part of the expected lifespan of the test species.

For repeated dose toxicity testing, the reader may be referred to the relevant SCCP notes of guidance (see Annex B).

Mutagenicity / genotoxicity

Mutagenicity refers to the induction of permanent transmissible changes in the amount or structure of the genetic material of cells or organisms. These changes may involve a single gene or a gene segment, a block of genes or whole chromosomes. Effects on whole chromosomes may be structural and/or numerical.

Genotoxicity is a broader term and refers to potentially harmful effects on genetic material that are not necessarily associated with mutagenicity. Thus, tests for genotoxicity include those providing an indication of induced damage to DNA (but not direct evidence of mutation) via effects such as unscheduled DNA synthesis (UDS), sister chromatid exchange (SCE), DNA strandbreaks, DNA adduct formation or mitotic recombination (MR), as well as tests for mutagenicity.

For mutagenicity / genotoxicity testing, the reader may be referred to the relevant SCCP notes of guidance (see Annex B).

4.3.2.3 Dose-response assessment

SCCP: "Dose-response assessment covers the process in which the relationship between the toxic response and the exposure is studied. In the case of an effect with a threshold, the dosage at which no adverse effects are observed (NOAEL) is determined. If the NOAEL is not available, the lowest dosage at which an adverse effect is observed (LOAEL) is used.

4.3.2.4 Exposure assessment

SCCP: "Exposure assessment covers the process in which the amount and the frequency of human exposure to the compound are determined (including potential specific groups at risk, e.g. children, pregnant women)."

4.3.2.5 Risk characterization

SCCP: Risk characterization covers the process in which the probability that the molecule under investigation causes damage to human health and the level of risk, are examined. In the case of a threshold effect, the Margin of Safety (MoS) is calculated in accordance with the following equation:

$$MoS = \frac{NOAEL}{SED}$$

where

NOAEL represents the No Observable Adverse Effect Level, and

SED represents the Systemic Exposure Dosage.

Hazard assessment, dose-response assessment, exposure assessment and risk characterization result in toxicological profiles of each ingredient enabling in the end a safety evaluation of the cosmetic product.

A further human sensitization test (Human Repeated Insult Patch Test, HRIPT) of the cosmetic product on a textile [to be defined, e.g. White cotton] should be used as a confirmatory test to ensure that the final product is not sensitizing for the population.

4.3.3 Requirements for a cosmetic dossier

Beside the toxicological evaluation of a cosmetic product in accordance with the European Cosmetics Directive 76/768/EEC any manufacturer, importer of a cosmetic product to the EU or marketer of a cosmetotextile is obliged to keep the following information readily available for the competent authorities:

- the qualitative and quantitative composition of the cosmetic formulation; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;
- b) the physical, chemical and microbiological specifications of the raw materials and the finished cosmetic product and the purity and microbiological control criteria of the cosmetic product;
- c) the method of manufacture conforming to the good manufacturing practice for cosmetics laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community should possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation;
- d) assessment of the safety for human health of the finished product. To that end, the manufacturer should take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure. It should take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. There should be inter alia a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene. Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be available. In this connection, and when so requested for monitoring purposes, it is obliged to indicate the place so chosen by the monitoring authority or authorities concerned. In this case this information should be easily accessible;
- e) the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person should hold a diploma as defined in Article 1 of Council Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;
- f) existing data on undesirable effects on human health resulting from use of the cosmetic product;
- g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product;
- h) data on any animal testing performed by the manufacturer, his agent or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any animal testing performed to conform to the legislative or regulatory requirements of non-member countries.

The above requested information might be filed in the form of a cosmetic dossier, which should be stored at the address mentioned on the labelling (see 4.6.3). In case of several addresses, the above mentioned one should be highlighted.

4.3.4 Notification of the cosmetic product of cosmetotextiles to national poison centres

Before a cosmetotextile can be placed on the market, in some countries of the EU, a notification of the cosmetic product of the cosmetotextile is necessary. In these countries, the relevant national poison centres have to be notified. The rationale is, that if unexpected health effects, to the consumer, occur, medical personnel can request, from the poison centres, information on the composition of the cosmetic product for an effective first aid. The notification usually comprises the INCI ingredient list of the cosmetic product, their quantities as well as the intended use of the application. The notification shall also include identification of the cosmetic product (e.g. name, code) (see 4.6.2).

4.4 Claimed effects

4.4.1 Introduction

The objective of this clause is to assist manufacturers of cosmetotextiles substantiate the claims of cosmetotextiles. Since new claims and the techniques to confirm them are constantly evolving, it is not an intention to provide obligatory and/or binding methodologies. In this respect, state-of-the art methods and/or generally accepted methods should be taken into account.

Within the European Cosmetics Directive 76/768/EEC, article 7 requires proof of the effects claimed for cosmetic products, where justified by the nature of the effect or product and this proof should be made readily available to competent authorities. In addition, in accordance with the European Cosmetics Directive 76/768/EEC (7th amendment) article 6, "Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have". The European Cosmetics Directive 76/768/EEC as well as other laws and guidelines are further defined at the EU and/or international or national levels and are not negated or refined by this policy.

No legally binding standards are available for cosmetic testing although generally accepted methods are available. A number of documents are available describing cosmetic claimed effect testing. These all serve as a loose framework in which the manufacturer can find guidance (see Annex B).

It is important to note, that use of cosmetic claims are subject to restriction in accordance with advertising laws and other national or international legislation.

Furthermore, they may not be deceptive or mislead the consumer. The wording of the claim should reflect the level of data used to substantiate the claim. A claim can be subjective, e.g. "skin looks better", without needing substantial scientific support or it can be founded on objective data, e.g. "moisturizes the skin".

Although full adherence is not necessary (see also J. Serup, 2001, Annex B), studies to test cosmetics or cosmetotextiles using human volunteers should be carried out according the spirit of good clinical practice (GCP) in general accordance with the Declaration of Helsinki and the ICH tripartite guidelines in accordance with their most recent versions (http://www.wma.net/e/policy/b3.htm).

4.4.2 Methodology

Any claim about the properties or effects of a product should be credible, verified and may not be misleading for the consumer. General descriptions on principles and procedures for claim substantiation can be found in the above mentioned normative references, e.g. the COLIPA guidelines (see Annex B). Claim substantiation can be obtained via various methodologies, e.g.:

- a) experimental studies using human subjects (a list of typically used test methods for cosmetic claim substantiation can be found in 4.4.3.), e.g.:
 - 1) bioengineering methods or other objective technical methods;

- 2) clinical testing with trained judges to evaluate the effects;
- 3) sensory evaluation using trained panels or consumers;
- b) consumer research studies using subjective endpoints (e.g. preferences, opinions) of the consumer as a measure;
- c) in vitro testing or other non-human or instrumental testing:
- d) literature (this should be of sound scientific or academic nature);
- e) generally accepted knowledge (e.g. shampoo cleanses hair).

Other examples are given in Table 2. Laboratory testing or reference to literature can be used to explain certain parts of a claim or to add information to it but should not be solely used to confirm the claimed effects of a cosmetotextile or its cosmetic product. All studies should be carried out with relevant and defined end-points to substantiate the claim. They should be representative for the marketed use, based on acceptable methods for substantiating the particular claim and should be designed to ensure the results will apply to use conditions. Ethical aspects, e.g. the Declaration of Helsinki in its newest version, should be taken into consideration. All tests on humans require mandatory toxicological clearance prior to testing and in accordance with GCP-standards, informed consent should be given by the volunteer. Ideally, studies should be performed double-blind and randomized. Tests need to be performed using the final composition to be marketed. Any claims not verified via human testing with the cosmetotextile need to document the transfer of adequate amounts from the textile to the skin in order to have the claimed effect. The durability of the cosmetic effects should be indicated in the claims (e.g. skin care effects last up to 5 care and use cycles; results from clinical tests with 20 volunteers and daily wear).

CEN/TR 15917:2009 (E)

4.4.3 Examples (non-exhaustive list, without hierarchy in the listed methods)

Table 2 — Examples of test methods for cosmetic claim substantiation

Classic experimental parameter/method 1	Classic experimental parameter/method 2	Classic experimental parameter/method 3
Transepidermal water loss (TEWL)		
Conductimetry (measurement of skin water content through its electrical conductivity, e.g. via corneometry)	Visual evaluation by a trained person	
Cutometry	Ballistometry	Torquemetry
pH-meter		
Visual assessment by a trained person	Imaging of the skin or skin prints (e.g. profilometry or fringe projection)	
Visual assessments by a trained person	Chromametry (e.g. Mexameter)	Evaluation via imaging
Visual assessment of dimpling by a trained person	Evaluation of the improvement of the skin micro-relief (anti-dimpling effect) by profilometry or fringe projection of replicas or in vivo	Measurement of skin elasticity/tone (see above)
	parameter/method 1 Transepidermal water loss (TEWL) Conductimetry (measurement of skin water content through its electrical conductivity, e.g. via corneometry) Cutometry pH-meter Visual assessment by a trained person Visual assessments by a trained person Visual assessment of dimpling by a trained	Transepidermal water loss (TEWL) Conductimetry (measurement of skin water content through its electrical conductivity, e.g. via corneometry) Cutometry Ballistometry PH-meter Visual assessment by a trained person Visual assessments by a trained person Visual assessment of dimpling by a trained person by a trained person Evaluation of the improvement of the skin micro-relief (anti-dimpling effect) by profilometry or fringe projection of replicas or in

(to be continued)

CEN/TR 15917:2009 (E)

Basic cosmetic functionality	Classic experimental parameter/method 1	Classic experimental parameter/method 2	Classic experimental parameter/method 3
Lightening/whitening	Colorimetric evaluation of skin + macrophotographs	Use test - self evaluation by users + control by a dermatologist in accordance with a predefined scale.	
Anti-heavy/anti-tired legs	Measurement of the blood circulation in the legs before / after treatment, e.g. via Laser-Doppler analyses		
Hair growth retarding	Measurement of hair growth on macrophotographs	Measurement of the hair diameter using a microscope	
Deodorant/anti-perspirant	Anti-odour test: also called "sniff-test". Armpit odour is evaluated by a trained specialist	Anti-perspirant: During this test, a cotton pad is put under the armpit. The volunteers rest for a certain time in a sauna. The sweat quantity is evaluated by gravimetry (weight of the cotton before / after the sauna period as well as left and right/treated vs. untreated comparisons).	

4.5 Care resistance

4.5.1 Introduction

A specific aspect of cosmetotextiles is that the intensity of their cosmetic effect decreases during the use and care procedures.

The objective of this part is to propose a simulation test to evaluate the resistance to care of the cosmetic product of cosmetotextiles; that is to say whether the right amount was applied initially and bound properly.

It does not relate exactly to a use and care situation and does not necessarily correlate to the durability of the cosmetic effects (claimed effects in accordance with 4.4).

This test will be used for the development of the cosmetotextiles to determine the quantity remaining after care and for quality control.

4.5.2 Methodology

This method measures the care resistance of a cosmetotextile. The care resistance is evaluated by determining the quantity of cosmetic product remaining on the cosmetotextile after a given number of care cycles. The care conditions are those described in the ISO standards applied for care of textile articles in accordance with EN ISO 6330 for washing and prEN ISO 3175-1 for dry cleaning.

The methodology proposed is:

- a) prior to the initial care cycle, the amount of a cosmetic product on the cosmetotextile is determined using chemical analyses with a validated method and, where applicable, one proposed by the cosmetic manufacturer;
- b) performance of a predetermined number of care sequences (in accordance with ISO standards). The number is dependent on the expected number of care cycles for the care resistance of the cosmetotextile;
- c) after conducting the required care cycles, the amount of the remaining cosmetic product on the cosmetotextile is determined using the same method used prior to care.

4.5.3 Materials, reagents and apparatus

4.5.3.1 Care operations

The materials and reagents used for the care procedures are those described in the standards defined by EN ISO 330 and prEN ISO 3175-1.

4.5.3.2 Extraction and chemical analyses

The quantity of cosmetic product is determined as follows:

- extraction of the cosmetic product with any validated method that can be used to extract the cosmetic
 product (examples are: accelerated solvent extraction, Soxhlet or ultrasound). The method of
 extraction should be proposed by the supplier of the cosmetic product or the supplier of
 microcapsules;
- 2) determination of the quantity of the cosmetic product using chemical analyses with a validated method and, where applicable, one proposed by the cosmetic manufacturer (examples are GC, HPLC). In the case of a mixture of several ingredients, some lead molecules of the mixture should be measured and used as surrogate markers for the mixture.

Two examples of methods of extraction and quantitative analysis are reported in 4.5.6.

4.5.4 Calculation

The percentage of remaining cosmetic product is calculated after the required number of care cycles. The reference is the sample before initiation of the care cycles.

4.5.5 Test report

The test report shall include the following information:

- 1) type or designation of tested material, both the textile article and cosmetic product;
- 2) number and size of samples tested;
- 3) testing conditions: care operations, extraction and chemical analysis methods, lead molecules used as surrogate markers;
- 4) calculation of the percentage of cosmetic product remaining after the care cycles;
- 5) any deviation from the standard procedure.

4.5.6 Examples of extraction and chemical analyses

4.5.6.1 Textile treated with microcapsules containing a perfume

The perfume is linally acetate. The microcapsules should be broken during the extraction step to extract completely the encapsulated linally acetate. That is the reason why it is preferable to extract the perfume by Accelerated Solvent Extraction (ASE). Acetone has been established as the best solvent to extract linally acetate. The ASE uses high pressure and high temperature that enable the polymer membrane of the microcapsules to be broken to extract all the linally acetate. Then, the linally acetate is measured by GC. Thus, the quantity of linally acetate on cosmetotextile before and after care cycles is determined.

4.5.6.2 Textile treated directly with cosmetic product (no capsules, no binder)

A Soxhlet may be used for extraction by using a solvent that dissolves the cosmetic product. Examples of solvents could be ether, alcohol, etc.

Then, the cosmetic product is analysed by GC or HPLC. Thus, the quantity of cosmetic product on cosmetotextile before and after care cycles is determined.

4.6 Labelling

4.6.1 Introduction

A cosmetotextile should be marketed with a product label.

There are some exceptions such as socks and pantyhose. For these articles, the necessary information could appear on the package only.

The cosmetotextile should be supplied with marketing label or hang tag, to provide necessary information to the consumer (for example the mandatory INCI list).

Any information on both product label and marketing label or hang tag should be written in the national languages of the country where it is marketed.

4.6.2 Product labelling

Any information on the product label should be written in indelible, easily legible and visible lettering.

This label should bear, as the minimum, the following information:

- 1) the textile composition, in application of European Directive 96/74/EC on textile names and its amendments;
- 2) the care conditions in accordance with EN ISO 3758 "Textiles. Care labelling code using symbols";
- the traceability number (for example the finishing batch number of manufacture or the reference for identifying the goods);
- 4) the identification of the cosmetic product.

4.6.3 Marketing labelling requirements

The information provided with the cosmetotextile on the marketing label or hand tag should mention the following pieces of information:

- 1) the wording cosmetotextile in accordance with the present European Technical Report;
- 2) the list of ingredients, in accordance with article 6 of the European Cosmetics Directive 76/768/EEC;
- 3) a statement that it is recommended to keep the information provided with the cosmetotextile during its life;
- 4) the name or style and the address or registered office of the manufacturer or the person responsible for marketing the product who is established within the European Union. Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking;
- 5) the limit date of optimal use (if shelf life is under thirty months), meaning until which the product, stored under appropriate conditions, retains its cosmetic function and does not cause any damage to human health when used under normal or reasonably foreseeable conditions, taking account, in particular, the product's presentation, its labelling, any instructions of use and disposal, as well as any other indication or information provided by the manufacturer or manufacturer's authorized agent or by any other person responsible for placing the product on the European market. The date should be mentioned by the words: "Best used before the end of..." followed by either:
 - i) the date itself, or
 - ii) details of where the date appears on the packaging.

If necessary, this information should be supplemented by an indication of the conditions which would be satisfied to define the stated durability.

The date should be clearly expressed and should consist of the month and the year, in that order. Indication of the limit date of optimal use should not be mandatory for cosmetotextiles for which the limit date exceeds 30 months;

- 6) particular precautions to be observed in use, especially for the substances listed in Annexes III, IV, VI and VII of the European Cosmetics Directive 76/768/EEC on cosmetic products;
- 7) the function / the claims of the product, unless it is clear from the presentation of the product.

In case of some information required by the European Cosmetics Directive 76/768/EEC cannot be printed on the marketing label or hang tag, then the symbol given in Annex VIII of European Cosmetics Directive 76/768/EEC can be applied.

Annex A (informative)

Regulations

A.1 Cosmetics regulations

- 1) Consolidated European Cosmetics Directive 76/768/EEC
- 2) Inventory and common nomenclature of ingredients employed in cosmetic products 2006/257/EC

A.2 Textile regulations

- 1) Consolidated directive on textile names requires the labelling of the fibre composition of textile products 96/74/EC
- Consolidated directive on certain methods for the quantitative analysis of binary textile fibre mixtures 96/73/EC
- 3) Consolidated directive on the quantitative analysis of ternary fibre mixtures 73/44/EC
- 4) Directive on the classification, packaging and labelling of dangerous substances 67/548/EC
- 5) Directive on the classification, packaging and labelling of dangerous preparations 1999/45/EC
- 6) Directive on restrictions on the marketing and use of certain dangerous substances and preparations 76/769/EEC
- 7) Directive on azoic dyestuffs 2002/61/EC
- 8) Directive on blue azoic dye 2003/03/EC
- 9) Directive on PCP 1999/51/EC
- 10) Directive on nickel 1994/27/EC
- 11) Directive on cadmium 1991/338/EEC
- 12) Directive on mercury 1989/677/EEC
- 13) Directive on asbestos 1999/77/EC
- 14) Directive on flame retardants 2003/11/EC
- 15) Directive on phthalates 2005/84/EC
- 16) Directive on PFOS 2006/122/EC

Annex B (informative)

Guidelines

- OECD (Organisation for Economic Co-operation and Development) guidelines for toxicological tests (further described in SCCP's -Scientific Committee on Consumer Products- notes of guidance)
- 2) The SCCP's notes of guidance for the testing of cosmetic ingredients and their safety evaluation (http://ec.europa.eu/health/ph risk/committees/04 sccp/docs/sccp s 04.pdf)
- Guidelines for the Evaluation of the Efficacy of Cosmetic Products, 2nd edition, 2001 COLIPA (<u>www.colipa.com</u>)
- 4) J. Serup, 2001, Efficacy testing of cosmetic products. Skin Research and Technology, 7: 141-151
- 5) Guidelines for Cosmetic Advertising and Labelling Claims, 2003, CCTFA
- 6) Guidance documents published by the European Group on Efficacy Measurement of Cosmetics and Other Topical Products (EEMCO)
- 7) Cosmetic Claims Substantiation, Ed. L. Aust, CRC Press, 1997, ISBN-10: 0824798554

BSI - British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: +44 (0)20 8996 9000. Fax: +44 (0)20 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: +44 (0)20 8996 9001. Fax: +44 (0)20 8996 7001 Email: orders@bsigroup.com You may also buy directly using a debit/credit card from the BSI Shop on the Website http://www.bsigroup.com/shop

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact Information Centre. Tel: +44 (0)20 8996 7111 Fax: +44 (0)20 8996 7048 Email: info@bsigroup.com

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: +44 (0)20 8996 7002 Fax: +44 (0)20 8996 7001 Email: membership@bsigroup.com

Information regarding online access to British Standards via British Standards Online can be found at http://www.bsigroup.com/BSOL

Further information about BSI is available on the BSI website at http://www.bsigroup.com.

Copyright

Copyright subsists in all BSI publications. BSI also holds the copyright, in the UK, of the publications of the international standardization bodies. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photocopying, recording or otherwise – without prior written permission from BSI.

This does not preclude the free use, in the course of implementing the standard, of necessary details such as symbols, and size, type or grade designations. If these details are to be used for any other purpose than implementation then the prior written permission of BSI must be obtained.

Details and advice can be obtained from the Copyright and Licensing Manager. Tel: +44 (0)20 8996 7070 Email: copyright@bsigroup.com

BSI Group Headquarters 389 Chiswick High Road, London, W4 4AL, UK Tel +44 (0)20 8996 9001 Fax +44 (0)20 8996 7001 www.bsigroup.com/ standards