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FINAL REPORT

Study on the Link Between Allergic Reactions and Chemicals in Textile Products

Principal

European Commission,
DG Enterprise and Industry

RPS advies- en ingenieursbureau bv

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Report reference : VRM11.8088

Date : 7 January 2013

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EXECUTIVE SUMMARY

Article 25 (and recital 27) of the Regulation 1007/2011/EU requires the Commission to assess hazardous substances used in textile products; in particular, to carry out a study to evaluate whether there is a causal link between allergic reactions and chemical substances or mixtures used in textile products in order to prepare, where appropriate, legislative proposals in the context of existing EU legislation.

This study was designed to investigate the link between allergic reactions and chemicals used and remaining on finished textile products. Besides establishing whether there is a causal link between allergic reactions and the chemicals substances and mixtures used in textile products, the study aimed to provide a priority list or an overview table of (sensitising and irritating) substances for considering, where appropriate, risk management measures in the context of existing EU legislation, as well as non-legislative risk management measures.

For this study, the existing regulatory definitions of sensitisation and irritation have been used to define what are the allergic reactions related to textile products. To identify the substances and mixtures which could cause allergic reactions related to textiles, the criteria for sensitisers and irritants set in the CLP Regulation have been used.

The study reviewed existing relevant EU Regulations/Directives (e.g. REACH, CLP, Biocidal Regulation, Cosmetics Regulation, EU Ecolabel etc.), the voluntary textile standards (i.e. Oeko-Tex Standard 100), relevant reports and documents, the relevant legal framework in three Member States (i.e. the Netherlands, Germany and France) and in two main trading partners (i.e. US and China). This, for a better understanding on the current risk management measures targeted at the known allergenic substances, aims to protect consumers from allergies caused by the chemical substances and mixtures which are used in textile processing and remaining on the finished textile products.

The study has investigated whether there is a causal link between allergic reactions and the substances/mixtures used and remaining on the finished textile products. This has been done by evaluating the available scientific literature and epidemiological information, and collecting information from industry via questionnaires on the uses of the allergenic chemical substances in textile products. The findings from the desk research showed that Allergic Contact Dermatitis (ACD) can be induced by textile dyes, textile finish resins and some of other textile auxiliaries such as softeners, water repellents, flame-retardants, biocides and mothproofs, and spot removers and dry cleaning agents. Based on the feedback from the textile industry to the questionnaires, the substance groups used and remaining on the finished textile products which have sensitising and/or irritating properties include disperse dyes, softeners, flame retardants, preservative and antimicrobial, fixing agents, formaldehyde, textile perfumes, easy care resins, chlorine resistances, antistatics, and antislip agents. However, information on the user group(s) of the textile products containing allergenic substances and data on the use concentration/percentage of these substances in textiles are lacking in the answers to the questionnaires. Furthermore, according to the textile industry, no alternative is currently available for these allergenic substances and no complaint has been received on any substances other than the reported allergenic substances in the feedback to the questionnaires.

It is difficult to determine the prevalence of contact dermatitis from textiles. This is partly because the studies published in literature refer almost exclusively to contact dermatitis from textile dyes. It is also because most of the available data is not recent. The fact that the patients were selected according to non-harmonised criteria makes the results from different studies difficult to compare. Moreover, the concentrations of sensitising and irritating chemical substances used and remaining on the finished textile product are unknown, making it very difficult to draw a conclusion on whether there is a link between these substances (at the levels remaining on finished textiles) and contact dermatitis (allergy).

Based on the findings in this study, three categories are suggested to prioritise the substances used in textile products. The prioritisation categories and criteria are:

- Category 1: Substances with classification of sensitisers included in the classification and labelling (C&L) Inventory (under CLP and self-notified by industry) and intended to remain on finished textile products
- Category 2: Substances with harmonised classification of sensitiser under CLP and not intended to remain but remain on finished textile products and cause textile allergies (e.g. impurity or component in formulation)
- Category 3: Substances with harmonised classification of irritant under CLP and intended to remain on finished textile products

Three different types of regulatory and non-regulatory actions are suggested. These suggestions shall be regarded as exploratory within the existing regulatory framework and it should be noted that further analysis is deemed necessary.

1) Propose new information requirements for consumers under relevant existing legislation
2) Propose to combine non-regulatory (voluntary action (e.g. codes of conduct, standards)) and further harmonization of control procedures of the presence of sensitisers against the information on the label.
3) Other proposed measures:
   - Derivation and harmonization of limit values for strong sensitisers based on quantitative risk assessment (QRA) method.
   - Further analysis in view of possible regulatory actions for the substances in category 2
   - Further investigation on exposure and risk assessment
   - Promote research and voluntary actions

The last but the least, there are also some assumptions and limitations in this study, such as:

- Technical textiles are not covered by this study.
- This study does not include the allergic reactions caused by or related to textile materials themselves such as silk and wool.
- This study focuses on the chemical substances used in textile products on their own and in mixture.
- Only the chemical substances used and remaining in the finished textile products are subjected to the current study.
- It is assumed that the interviewed textile industries (within the EU) have followed the best available techniques (BAT) addressed in the BREF textile.
- The current study does not include risk assessment of chemical substances.
- Market data and detailed information on actual quantities of the chemical substances used and remaining on the finished textile products are lacking.
- The present study did cover neither occupational exposure nor other production and supply chain related aspects.
- Where no known substitute solutions were found in the review, this does not imply that substitution might not be possible or has not been implemented in other parts of the supply chain.
- The test situations in the scientific literature may vary from the real exposure of consumers to the allergenic substances used and remaining on the finished textile products.

PREFACE AND ACKNOWLEDGEMENTS

This study is designed to investigate the link between allergic reactions and chemicals used and remaining on finished textile products, regarding Article 25 (and recital 27) of the Regulation 1007/2011/EU which requires the Commission to assess hazardous substances used in textile products; in particular, to carry out a study to evaluate whether there is a causal link between allergic reactions and chemical substances or mixtures used in textile products in order to prepare, where appropriate, legislative proposals in the context of existing EU legislation.

The project team wishes to thank for the support and the comments received from DG Enterprise - Unit E3: Textiles, Fashion, Design and Creative industries during the current study. We are particularly grateful to the contributors from involved textile associations and textile industries/companies, namely EURATEX, TEGEWA, ETAD, Verband der Nordwestdeutschen Textil- u. Bekleidungsindustrie e.v., InoTEX, AEDT, CIRFS, VGT-Vereniging van Grootwinkelbedrijven in Textiel, H&M and Coats PLC.

The project team hopes that this study will contribute to a better management of allergenic chemicals in textile products produced and imported in the EU.

1. INTRODUCTION

1.1 Background of the framework contract and service request

Within the Directorate General for Enterprise and Industry of the European Commission, several units (e.g. textiles, REACH, Chemicals Industry) play a role in the implementation of EU directives and regulations relevant for this study. Namely as regards to the provisions of Article 25 in the Regulation (EU) No 1007/2011[1] and in the provisions of the Regulation (EC) No 1907/2006[2] under its Title VIII of Restrictions on the manufacturing, placing on the market and use of certain dangerous substances and preparations and its Annex XVII of Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles.

All services provided in the context of the framework contract 30-CE-0220929/00-38 – Lot 1: Expertise in relation to marketing and use restrictions on dangerous substances and preparations will be directly related to the above-mentioned responsibilities and will provide support in their effective implementation.

The objective of the framework contract, under which a service request has been being made, is to provide technical support to the Commission to allow for risk reduction and management measures to be taken on a sound scientific basis. Final decisions with regard to possible new marketing and use restrictions, must take into account also the socio-economic implications.

Tasks related to this service request concern:

- Define allergic reactions in relation to textile products
- Establish a definition for substances or mixtures that could cause such allergic reactions
- Review relevant existing legislation
- Collect and review existing literature and epidemiological data referring to allergies caused/linked to textile products
- List chemical substances and mixtures that have shown to cause allergic reactions and that are used in textile products
- Establish whether there is a correlation and/or causal link between allergies and particular chemical substances or mixtures at the concentration present in textile products
- Establish a priority list or an overview table for possible regulatory action

1.2 Introduction of the current project

1.2.1 Background information

The current project is contracted and managed by DG Enterprise - Unit E3: Textiles, Fashion, Design and Creative industries. Regulation 1007/2011/EU on textile fibre names and related labelling and marking of the fibre composition of textile products is one of the working subjects of this unit.
This study focuses on the chemical substances and mixtures used and remaining on the finished textile products, including finishing agents, dyes, biocides, preservatives as well as nanoparticles. Textile products in this study shall encompass clothing, home textiles and other consumer products made up of at least 80% of textile fibres, as defined in Article 2 of Regulation (EU) No. 1007/2011.

RPS advies- en ingenieursbureau has been commissioned by the European Commission service DG Enterprise & Industry to conduct this study.

The main objective of this project is to

- establish whether there is a causal link between allergic reactions and the chemicals substances and mixtures used in textile products
- provide a priority list or an overview table of substances for proposing the appropriated risk management measures in the context of existing EU legislation, as well as non-legislative risk management measures

1.2.2 Assumptions and limitations

Due to the timeframe, budget and lacking of information, there are some assumptions and limitations in this study.

- Technical textiles are not covered by this study.
- This study does not include the allergic reactions caused by or related to textile materials itself such as silk and wool.
- This study focuses on the chemical substances used in textile products on their own and in mixture.
- Only the chemical substances used and remaining in the finished textile products are subjected to the current study. Those used in the processes and not intended to remain in the finished textile products are not in the scope of this study.
- It is assumed that the interviewed textile industries (within the EU) have followed the best available techniques (BAT) addressed in the BREF textile[3] for the pre-treatment (operations such as washing, bleaching, mercerisation) or dyeing of fibres or textiles.
- The current study does not include risk assessment (hazard assessment and exposure) of chemical substances used and remaining on the finished textile products.
- Market data and detailed information on actual quantities of the chemical substances used and remaining on the finished textile products are lacking.
- The present study did cover neither occupational exposure nor other production and supply chain related aspects. Information about exposure and consequences thereof is often lacking and it is rather difficult to track down the actual substances causing an allergy.
- Where no known substitute solutions were found in the review, this does not imply that substitution might not be possible or has not been implemented in other parts of the supply chain.
- In most of the available literature references regarding allergies related to textiles, the chemicals are tested by directly applying to human skin in patch tests instead of by applying in the textile materials. The migration of these chemicals from the textile products are not considered in these literature references. Since migration is one of the determinant factors for exposure, it is very difficult to compare the test situations to the real situation when the consumers are in contact with textiles containing allergenic substances.

1.2.3 Methodology

The general approach which is used in the current study is demonstrated in figure 1 below.

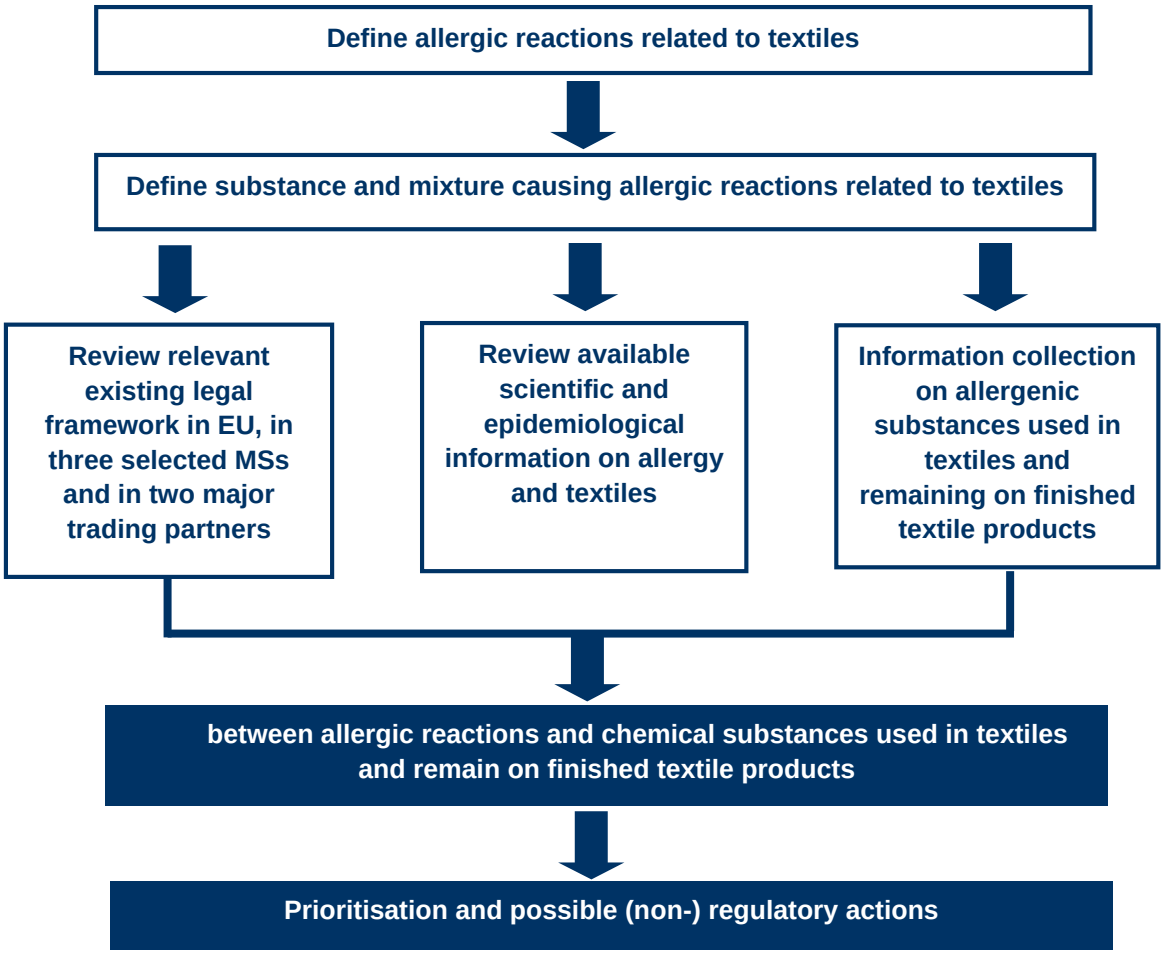

Figure 1 General approach of the project

1.2.4 Project management

The current project started on February 21, 2012 with an implementation period of 7 months. The kick-off meeting was held on April 12, 2012 at DG Enterprise in Brussels (the conclusions of the kick-off meeting is attached in Annex 1 of this report). The final meeting has been organised by DG Enterprise on October 30, 2012 when the major findings in the project were discussed with the relevant stakeholders.

The project synopsis summarising the implementation status of each task in this study is attached in Annex 2 of this report. This table has been updated and reported to inform DG Enterprise about the up-to-date progress of the project implementation.

2. ALLERGIC REACTIONS RELATED TO TEXTILE PRODUCTS

2.1 General information on allergic reactions related to textiles

Allergies to chemical substances are a growing problem in Europe and in the world. Allergies can occur in early age and can give rise to chronic eczema which requires and leads to long-term treatment, sick leave and pensions. In Denmark, for instance, around 20% of the population is allergic to chemical substances in the immediate environment and known allergies have increased over the past 10 years. (Danish EPA Chemicals Action Plan 2010 - 2013[4])

An allergic reaction is a hypersensitivity disorder of the immune system. Allergy occurs when a person's immune system reacts to normally harmless substances in the environment. Allergic reactions are distinctive because of excessive activation of certain white blood cells and basophils by Immunoglobulin E (IgE). Allergic conditions belong to the most common chronic diseases conditions occurring in Europe. Skin allergy, also called "contact dermatitis", is one of the most common skin diseases with a great socio-economic impact[5].

In the context of allergies, sensitization is the process by which a person becomes, over time, increasingly allergic to a substance (sensitizer) through repeated exposure to that substance. The substance may cause a mild response of the body during first couple of exposures but, as the allergy develops, the response becomes stronger with subsequent repeated exposures. After this allergy has developed, even short exposures to very low concentrations can cause severe reactions. Persons who have exhibited an allergy to certain substances are advised to avoid exposure to these types of substances. This can be very difficult as many allergenic substances are produced in high volumes and are widely used in daily life.

Numerous chemicals are used in textiles. Some of these chemicals can cause allergic reactions. The source of allergy to textiles can be the fabric itself and chemical additives used in processing the fabric. Some examples are given below:

- textile fibres: textile fibre can be natural (such as silk, wool, cotton or linen), synthetic (such as nylon, polyester, fibreglass, elastic[6] and elastane) or a combination of the two[7]
- dyes used in textiles: most reported allergic reactions have been to disperse dyes with azo and anthraquinone structures. These dyes are loosely held on the fabric structure and easily rubbed off on the skin[8,9,10]
- formaldehyde resins used on fabrics: an allergic reaction may be caused by formaldehyde released from textiles but also may actually be due to the resin and not to the released formaldehyde[11,12]
- remnants of soaps/detergents on washed textiles[13,14]
- friction from textiles (clothing): friction and sweating can result in a red and macerated skin present at the waistband area, under the arms, and the inner thighs. This rash can be infected by yeast or bacteria in hot and humid environments. This skin condition can be present in workers in industries such as foundries, farming, bakeries, restaurant kitchens and laundries where there are extremely humid conditions in addition to high heat[15]
- rubber additives and preservatives or the latex protein in protective latex gloves[16,17]
- chemicals used in processing of the textile
- oils, pesticides, greases, coal tar contaminates[18,19,20]
- fine metallic dust particles imbedded into textiles: when combined with sweat pruritic, erythematous, popular lesions can develop where the clothing is in contact with the skin[21,22]
- flame-retardant materials: allergic contact dermatitis from tris (2,3-dibromopropyl) phosphate[23] and 2,3-dibromocresylglycidyl ether[18] has rarely been reported.

As known, some factors and conditions can aggravate allergic reactions to chemicals in textiles. These factors include:

- genetic predisposition such as atopic syndrome;
- tender and sensitive skin such as that of infants;
- obesity;
- hyperhidrosis: It tends to leach dyes from the textile fabrics to the skin surface causing dermatitis;
- moisture: it causes more hydration of the epidermis which enhances more penetration of the sensitizers;
- increased skin surface lipids;
- tight clothing;
- skin conditions such as trauma;
- repeated friction from clothing;
- sebum, lack of cleanliness, overheating of the skin surface.

For textile fibres, immediate allergic reactions are less common. The symptoms of immediate allergy to textile products include wheals, redness, rash, respiratory and circulatory problems and even anaphylactic shock (to some dyes for instance)[24 25].

2.2 Definition of allergic reactions related to textiles used in this study

Commonly speaking, allergy is sensitisation. In public dictionary, the definition of sensitisation is "exposure to allergen that results in the development of hypersensitivity". Sensitisation is defined as "The act or process of inducing an acquired sensitivity or allergy" in Medial Dictionary. Irritation is a different process from sensitisation working via different mechanisms. However, some evidence shows that certain types of irritation may cause inflammation, leading to an allergic reaction. For this reason and from the perspective of consumer safety, irritation is also included in this study. Furthermore, sensitisation and irritation via both skin and respiratory exposure routes have been investigated. Regarding allergic reactions to chemicals in textile products, skin sensitisation and irritation is more frequent compared to respiratory sensitisation and irritation.

2.2.1 *Sensitisation*

According to the fourth revised edition of the CLP Regulation[26] and GHS[27], sensitisation includes two phases: the first phase is induction of specialized immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e. production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitised individual to an allergen. Usually, for both skin and respiratory sensitization, lower levels are necessary for elicitation than are required for induction.

Skin sensitisation

For skin sensitisation, an induction phase is required in which the immune system learns to react; clinical symptoms can then arise when subsequent exposure is sufficient to elicit a visible skin reaction (elicitation phase). As a consequence, predictive tests usually follow this pattern in which there is an induction phase, the response to which is measured by a standardised elicitation phase, typically involving a patch test. The local lymph node assay is the exception, directly measuring the induction response.

Evidence of skin sensitisation in humans normally is assessed by a diagnostic patch test. However, skin sensitisation related to textile products can not be identified correctly by directly applying common used patch tests. For textile materials, the patch test should be performed with a textile sample which contains the suspected chemicals with the highest concentration found in the textile products. In case that a chemical is only used in applications in which it is chemically bound to the textile, the patch test should also be examined with a textile sample to which the chemicals are chemically bound.

Another method to identify skin sensitisation related to textile products is bringing the textile sample (with the chemicals applied to it in a normal concentration) into contact with a solution (e.g. an artificial sweat solution) to extract the chemicals in the textile samples. This extraction solution will be used to perform a patch test. This method is similar to the way how Oeko -Tex® assesses the presence of heavy metals in textile samples: The textile sample is brought into contact with an artificial sweat solution and the concentration of the extracted heavy metals may not exceed a certain limit value.

It is also important to take into account of how the chemicals are used in textile products. Some chemicals are present at the surface (such as oils), some are incorporated in the fibre or coating (such as monomers, colorants), and some are chemically bound to the textiles (such as certain colorants). For the last 2 cases, the chemicals can not be immediately extracted. For those present at the surface, a migration will occur and needs to be evaluated. It can even become more complex when there are oils which can cause ‘extraction’ of other non-migrating compounds in the textiles. For example, surfactants can improve the migration of certain allergenic chemicals.

In summary, allergenic chemicals in textile products can only be correctly identified if the patch test is designed according to the way of how the chemicals are used in the textiles and according to the right amount of chemicals which migrates to the human skin during use. For example, if a colorant is applied to a textile product in a maximum concentration of 10%, the patch test should be done with a textile sample containing 10% of this colorant. It is of no use to test the pure colorant or a textile sample with a higher concentration of the colorant as the colorant is never present in the textile products at a concentration over 10%.

The conditions under which the textiles will be used and the possible chemical changes during use should be also considered when designing the patch test. For example, when testing formaldehyde, the following should be considered:

- free formaldehyde: immediate contact with the skin
- sweat will lead to cleaved formaldehyde
- the presence of oils and/or surfactants may improve the contact with the skin and improve the migration of formaldehyde

Respiratory sensitisation

For respiratory sensitisation, the pattern of induction followed by elicitation phases is shared with skin sensitisation.

For allergies to chemicals in textile products, the cases of respiratory sensitisation and irritation are less frequently seen as compared to skin sensitisation and irritation. In clothing for instance, respiratory problems are mostly limited to facemasks including worker protection masks and masks used by the general population. For other textile products, respiratory sensitisation and irritation is only of importance in cases of humans being exposed to a large textile surface area such as tents and interior textiles (furniture, carpets and wall covering).

2.2.2 *Irritation*

Skin irritation

According to the fourth revised edition of the CLP Regulation[26] and GHS[27], skin irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours. Dermal/skin irritation is defined in OECD TG 404 as “the production of reversible damage of the skin following the application of a test substance for up to 4 hours”.

Skin irritation can also be identified by using patch tests. However, as discussed in sensitisation section, a proper protocol for a patch test should be used referring to the realistic use conditions and correct amount of chemicals.

Respiratory irritation

There is no EU or OECD Technical Guidance for respiratory irritation. Inflammation or other adverse reactions caused by any substance in the respiratory system (lungs, nose mouth, larynx and trachea) belong to respiratory irritation. Respiratory irritation is often used to describe either or both of two different toxicological effects: sensory irritation and local cytotoxic effects.

Similar to respiratory sensitisation, respiratory irritation is less often observed compared to skin irritation for textile products.

3. SUBSTANCE/MIXTURE THAT COULD CAUSE ALLERGIC REACTIONS RELATED TO TEXTILE PRODUCTS

A substance or a mixture which could cause allergic reactions as defined in Chapter 2 (sensitisation and irritation) is a sensitiser or an irritant. The regulatory definitions of a sensitiser and an irritant in the existing chemical classification system such as the CLP Regulation and GHS have been used as a basis to establish the definitions of a substance or a mixture that could cause allergic reactions related to textile products in this study. The CLP Regulation will eventually replace the rules on classification, labelling and packaging of substances laid down in the Dangerous Substance Directive (DSD)[28] and preparations specified in Dangerous Preparation Directive (DPD)[29]. The transition period was until 1 December 2010 for substances and runs until 1 June 2015 for mixtures (preparations).

Many different chemical substances are used in the textile sector. It has been reported in a study of DG Enterprise and Industry in 2005 that the consolidated European textile supply chain uses about 1500 basic chemical substances and about the same number of speciality chemical substances, which combine to yield about 15000 mixtures (textile auxiliaries and dyestuffs) marketed by chemical suppliers and used in textile products[30]. It should be noted that not all the chemical substances used in textile products remain in the final products which are placed on the market for consumers. To cause allergic reactions of human during uses, the chemical substances must remain on the finished textile products to which the human are exposed via direct skin contact or via respiratory route. Therefore, for the purpose of the current study, substance or mixture that could cause allergic reactions related to textile products means the substance or mixture which remains on finished textile products and are classified as a sensitiser or irritant under the existing classification system; this limits the number of substances down to less than one hundred.

3.1 Sensitiser

A US EPA paper "recommendations of the Interagency Coordinating Committee on the Validation of Alternative Methods ("ICCVAM") regarding the Murine Local Lymph Node Assay's ("LLNA") ability to categorize the potency of chemicals causing allergic contact dermatitis", showed that a Technical Advisory Panel on Allergic Sensitization defined "a sensitizer is a substance that will induce an immunologically-mediated (allergic) response, including allergic photosensitivity. This allergic reaction will become evident upon re-exposure to the same substance. Occasionally, a sensitizer will induce and elicit an allergic response on first exposure by virtue of active sensitization".[31]

In the EU, the criteria to classify a chemical substance as a sensitiser are specified in the CLP Regulation (which implements the GHS in European legislation). The 2nd Adaptation to Technical Progress (2nd ATP) to the CLP Regulation has led to an inclusion of new sub-categories for skin and respiratory sensitisers[32]. The sub-categories indicate the potency of a sensitiser.

3.1.1 *Skin sensitisers*

Substance

According to the CLP Regulation, a substance shall be classified as a skin sensitiser in accordance with the criteria in the table below:

Category	Criteria
Category 1	Substances shall be classified as skin sensitisers (Category 1) where data are not sufficient for sub-categorisation in accordance with the following criteria: (a) if there is evidence in humans***** that the substance can lead to sensitisation

	by skin contact in a substantial number of persons; or (b) if there are positive results from an appropriate animal test[#].
Sub-category 1A	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitisation in humans. Severity of reaction may also be considered.
Sub-category 1B	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitisation in humans. Severity of reaction may also be considered.

**Human evidence can include:*

Category	***Criteria***
Sub-category 1A	*(a) positive responses at • 500 • g/cm2 (HRIPT, HMT — induction threshold);* *(b) diagnostic patch test data where there is a relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure;* *(c) other epidemiological evidence where there is a relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.*
Sub-category 1B	*(a) positive responses at > 500 • g/cm2 (HRIPT, HMT — induction threshold);* *(b) diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;* *(c) other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure.*

[#]Animal test results can include data with values indicated below:

Category	***Assay***	***Criteria***
Sub-category 1A	*Local lymph node assay*	*EC3 value • 2%*
	Guinea pig maximisation test	*• 30% responding at • 0.1% intradermal induction dose or* *• 60% responding at > 0.1% to • 1% intradermal induction dose*
	Buehler assay	*• 15% responding at • 0.2% intradermal induction dose or* *• 60% responding at > 0.2% to • 20% intradermal induction dose*
Sub-category 1B	*Local lymph node assay*	*EC3 value > 2%*
	Guinea pig maximisation test	*• 30% to < 60% responding at > 0.1% to • 1% intradermal induction dose or* *• 30% responding at > 1% intradermal induction dose*
	Buehler assay	*• 15% to < 60% responding at > 0.2% to • 20% topical induction dose or* *• 15% responding at > 20% topical induction dose*

Mixture

A mixture can be triggered to be classified as a skin sensitiser based on the generic concentration limits listed below:

Component classified as	**Generic concentration limits triggering classification of a mixture as Skin sensitiser category 1 (all physical states)**
Skin sensitiser category 1	• 1%
Skin sensitiser sub-category 1A	• 0.1%
Skin sensitiser sub-category 1B	• 1%

Concentration limits for elicitation of components of a mixture:

Component classified as	Generic concentration limits triggering classification of a mixture as Skin sensitiser category 1 (all physical states)
Skin sensitiser category 1	• 0.1%
Skin sensitiser sub-category 1A	• 0.01%
Skin sensitiser sub-category 1B	• 0.1%

3.1.2 *Respiratory sensitisers*

Substance

According to the CLP Regulation, a substance shall be classified as a respiratory sensitiser in accordance with the criteria in the table below:

Category	Criteria
Category 1	Substances shall be classified as respiratory sensitisers (Category 1) where data are not sufficient for sub-categorisation in accordance with the following criteria: (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity; and/or (b) if there are positive results from an appropriate animal test.
Sub-category 1A	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitisation rate in humans based on animal or other tests (*). Severity of reaction may also be considered.
Sub-category 1B	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitisation rate in humans based on animal or other tests (*). Severity of reaction may also be considered.

(*) At present, recognised and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.

Evidence that a substance can induce specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

When considering the human evidence, it is necessary for a decision on classification to take into account, in addition to the evidence from the cases:
(a) the size of the population exposed;
(b) the extent of exposure.
The evidence referred to above could be:

a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:
    (i) in vivo immunological test (e.g. skin prick test);
    (ii) in vitro immunological test (e.g. serological analysis);
    (iii) studies that indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g. repeated low-level irritation, pharmacologically mediated effects;
    (iv) a chemical structure related to substances known to cause respiratory hypersensitivity;
b) data from one or more positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

Clinical history shall include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history shall also include a note of other allergic or airway disorders from childhood, and smoking history. The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is however recognised that in practice many of the examinations listed above will already have been carried out.

Data from appropriate animal studies which may be indicative of the potential of a substance to cause sensitisation by inhalation in humans may include:

I. measurements of Immunoglobulin E (IgE) and other specific immunological parameters in mice;
II. specific pulmonary responses in guinea pigs.

Mixture

A mixture can be triggered to be classified as a skin or respiratory sensitiser based on the generic concentration limits listed below:

Component classified as	**Generic concentration limits triggering classification of a mixture as respiratory sensitiser category 1**	
	Solid/liquid	**Gas**
Respiratory sensitiser category 1	• 1%	• 0.2%
Respiratory sensitiser sub-category 1A	• 0.1%	• 0.1%
Respiratory sensitiser sub-category 1B	• 1%	• 0.2%

Concentration limits for elicitation of components of a mixture:

Component classified as	**Generic concentration limits triggering classification of a mixture as respiratory sensitiser category 1**	
	Solid/liquid	**Gas**
Respiratory sensitiser category 1	• 0.1%	• 0.1%
Respiratory sensitiser sub-category 1A	• 0.01%	• 0.01%
Respiratory sensitiser sub-category 1B	• 0.1%	• 0.1%

3.2 Irritant

3.2.1 *Skin irritant*

Substance

The criteria for classifying a substance as a skin irritant according to CLP are:

Category	**Criteria**
Irritant	- Mean value of • 2,3 - • 4,0 for erythema/eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or - Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or - In some cases where there is pronounced variability of response among

	animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.

In GHS (revised version 4), the criteria for classifying a substance as a mild irritant are also given. When known, the substances classified as mild irritants which are used and remain on finished textile products are also considered in this study.

Category	Criteria
Mild irritant	Mean value of • 1.5 < 2.3 for erythema/eschar or for oedema from gradings in at least 2 of 3 tested animals from grades at 24, 48 and 72 hours or if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions (when not included in the irritant category above).

Animal irritant responses within a test can be quite variable. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a test material might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also fulfil this criterion. However, it should be ascertained that the responses are the result of chemical exposure.

Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2 or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a material shall be considered to be an irritant.

Mixture

If there are data showing that (an) ingredient(s) is/are corrosive or irritant at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture shall be classified accordingly. Generic concentration limits of ingredients classified for skin irritant that trigger classification of the mixture as irritant to skin are presented below:

Sum of ingredients classified as	Concentration triggering classification of a mixture as skin Irritant
Skin corrosive categories 1A, 1B, 1C	• 1% but < 5%
Skin irritant category 2	• 10%
(10 x Skin corrosive category 1A, 1B, 1C) + Skin irritant category 2	• 10%

3.2.2 *Respiratory irritant*

The criteria for classifying substances for respiratory tract irritation are:

a) respiratory irritant effects (characterised by localised redness, oedema, pruritis and/or pain) that impair function with symptoms such as cough, pain, choking, and breathing difficulties are included. This evaluation will be based primarily on human data;
b) subjective human observations could be supported by objective measurements of clear respiratory tract irritation (RTI) (such as electrophysiological responses, biomarkers of inflammation in nasal or bronchoalveolar lavage fluids);
c) the symptoms observed in humans shall also be typical of those that would be produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensitive airways. Ambiguous reports simply of 'irritation' shall be excluded as this term is commonly used to describe a wide range of sensations including those such as smell, unpleasant taste, a tickling sensation, and dryness, which are outside the scope of classification for respiratory irritation;

d) there are currently no validated animal tests that deal specifically with RTI, however, useful information may be obtained from the single and repeated inhalation toxicity tests. For example, animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and histopathology (e.g. hyperemia, edema, minimal inflammation, thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above. Such animal studies can be used as part of weight of evidence evaluation;
e) this special classification would occur only when more severe organ effects including in the respiratory system are not observed.

3.3 Sensitiser and irritant related to textile products in current study

The chemical substances mixtures used and that remain on the finished textile products and which are classified under CLP/GHS or DSD/DPD as below are considered as sensitisers in this study.

Skin sensitiser	CLP/GHS	H317: May cause an allergic skin reaction	
	DSD/DPD	R43: May cause sensitization by skin contact	No pictogram
Respiratory sensitiser	CLP/GHS	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	
	DSD/DPD	R42: May cause sensitization by inhalation.	No pictogram

The chemical substances mixtures used and remain on the finished textile products and classified under CLP/GHS or DSD/DPD as below are considered as irritants in this study.

Skin irritant	CLP/GHS	H315: Causes skin irritation	
	DSD/DPD	R38: Irritating to skin	No pictogram
Respiratory irritant	CLP/GHS	H335: May cause respiratory irritation	No pictogram
	DSD/DPD	R37: Irritating to respiratory system	No pictogram

4. REVIEW RELEVANT EXISTING LEGAL FRAMWORKS

The existing legal frameworks which are relevant to the current study have been reviewed. This leads to an understanding on which chemical substances are of concern due to their sensitisation and/or irritation properties and which of these substances are regulated at EU level. The reviewed documents include:

1) Relevant EU Regulations/Directives
2) Voluntary textile standards, relevant report and documents
3) Relevant legal frameworks in three selected MSs (i.e. The Netherlands, France and Germany)
4) Relevant legal frameworks in main trading partners (e.g. US and China)

4.1 Relevant EU Regulations/Directives

The EU Regulations/Directives/Standards reviewed are summarized below:

- REACH Regulation (Regulation (EC) No 1907/2006)
- CLP Regulation (Regulation (EC) No 1272/2008)
- Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products[33]
- Workers protection (Directive 89/391/EEC[34], Directive 98/24/EC[35], Directives 91/322/EEC[36], 2000/39/EC[37], 2006/15/EC[38] and 2009/161/EU[39], Directive 2004/37/EC[40], Directive 94/33/EC[41] and Directive 92/85/EEC[42])
- Cosmetics (Regulation (EC) No 1223/2009[43] on cosmetic products)
- Toys (Council Directive 2009/48/EC[44]) and its amendments
- Regulation (EC) No 648/2004 containing the last adopted amendment Regulation (EU) No 259/2012 on detergents[45]
- General Product Safety Directive 2001/95/EC[46] (RAPEX)
- Regulation (EC) No 66/2010 on the EU Ecolabel[47] including Commission Decision 2009/567/EC[48]

4.1.1 REACH Regulation (Regulation (EC) No 1907/2006)

REACH (EC Regulation 1907/2006) is the Regulation for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals. It entered into force on 1st June 2007 to streamline and improve the former legislative framework on chemicals in the EU. Via REACH processes, much information of chemical substances is known. Based on the available information, certain substances are restricted or banned for some uses or applications. Regarding the purpose of this study, REACH Annex XVII (Restriction list), SVHC (Substance of Very High Concern) list known also as Candidate list and Authorisation list have been reviewed. The chemical substances which are included in these lists and classified under CLP as sensitisers or irritants are summarised below.

<u>REACH Annex XVII (Restriction)</u>

REACH Restriction list has been reviewed. Some substances with sensitising and/or irritating properties are found in this list. However, the reasons why these substances are included in the Restriction list are not necessary due to their sensitising and/or irritating properties.

Table 1 below summarises the substances found in Annex XVII which are classified as sensitisers or irritants under CLP (or notified classification in the – classification and labelling – C&L Inventory), and which are used in textiles.

Table 1 Chemical substances found in Annex XVII which are classified as sensitisers or irritants under CLP (or notified classification in C&L Inventory) and are used in textile products

Function group	Substance name	CAS no.	Classification under CLP related to allergy	
			Harmonized	Self-notified
Flame retardants	tris (2,3 dibromopropyl) phosphate	126-72-7		Skin Irrit. 2, H315
	tris(aziridinyl)phosphinoxide	545-55-1		Skin Irrit. 2, H315
Azodyes	a mixture of: disodium (6-(4-anisidino)-3- sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5- dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)	EC 405-665-4	Skin Sens. 1, H317	
Dye carriers	trichlorobenzene	120-82-1	Skin Irrit. 2, H315	
Dyeing	lead methanesulphonate	17570-76-2	Skin Irrit. 2, H315	
Coating agents	di-n-octyl phthalate dnop	117-84-0		Skin Sens. 1, H317 Resp. Sens. 1, H334
Biocides, chlorinated phenols	pentachlorophenol (pcp)	87-86-5	Skin Irrit. 2, H315	
	2,3,4,6 tecp	58-90-2	Skin Irrit. 2, H315	
	2,3,5,6 tecp	935-95-5		Skin Irrit. 2, H315
Autifungal agents	Stannic hydroxyborane	75113-37-0	Skin Sens. 1, H317	
Lubricating agents	Diisodecylphthalate DIDP	26761-40-0		Skin Irrit. 2, H315

SVHC list (Candidate list)

As defined in Art. 57 of REACH, substances which meet the criteria below can be identified as SVHCs (Substances of Very High Concern):

- Carcinogenic, Mutagenic or toxic to Reproductsion (CMR) 1A or 1B according to the CLP Regulation
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria in Annex XIII of REACH
- Identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to human health or the environment of an equivalent level of concern as those above (e.g. endocrine disrupters)

84 chemical substances are currently on the Candidate list with the last update on June 18 2012. Although many of these substances are included due to their CMR or PBT/vPvB properties, some of them are also known as sensitisers or irritants. For instance, among the dossiers submitted for SVHC identification in August 2012, three concern respiratory sensitisers. They could be included in the Candidate list as substances of equivalent concern according to art. 57(f) of REACH. The substances in the Candidate list which are classified as sensitisers or irritants under CLP (or notified classification in C&L Inventory), and which are used in textile products are listed in table 2.

Table 2 Chemical substances found in the Candidate list which are classified as sensitisers or irritants under CLP (or notified classification in C&L Inventory), and which are used in textiles

Function group	Substance name	CAS no.	Classification under CLP related to allergy	
			Harmonized	Self-notified
Dyeing	Potassium chromate	7789-00-6		Skin Sens. 1, H317
	Ammonium dichromate	7789-09-5	Skin Sens. 1, H317 Resp. Sens. 1, H334	
	Potassium dichromate	7778-50-9	Skin Sens. 1, H317 Resp. Sens. 1, H334	
Solvent	1-methyl-2-pyrrolione	872-50-4	Skin Irrit. 2, H315	

Authorisation list

Authorisation list (Annex XIV of REACH) contains a list of substances which are prioritised from the Candidate list. The prioritisation is based on the available information on intrinsic properties, uses and volumes of the substances on the EU market. Placing on the market and use of the substances listed on Authorisation list requires an authorisation. The substances on the Authorisation list are also the ones meeting the criteria stated in Art. 57 of REACH.

The Authorisation list has currently included 14 chemical substances. The most close authorisation application deadline is February 21, 2013. Two substances on this list are found to be classified as sensitisers or irritants under CLP and are used in textiles (listed in Table 3 below). These substances, which are in ECHA recommendation, are not yet included in Annex XIV.

Table 3 Chemical substances found in the Authorisation list which are classified as sensitisers or irritants under CLP and are used in textiles

Function group	Substance name	CAS no.	Classification under CLP related to allergy	
			Harmonized	Self-notified
Textile scouring	trichloroethylene	79-01-6	Skin Irrit. 2, H315	
Catalyst	Chromium trioxide	1333-82-0	Skin Sens. 1, H317 Resp. Sens. 1, H334	

4.1.2 CLP Regulation (Regulation (EC) No 1272/2008)

To investigate the current situations of chemical substances which might have sensitising and/or irritating properties, a search has been done through the Classification & Labelling Inventory (C&L Inventory).

The C&L Inventory contains classification and labelling information on notified and registered substances received from manufacturers and importers. It also includes the list of harmonised classifications listed in Table 3.1 of Annex VI to the CLP Regulation and as adapted with Regulations n.790/2009 and 286/2011, so called 1st and 2nd ATP to CLP. This inventory is based on the classification notified by industries. The classifications notified by industries and are not yet listed in Annex VI of the CLP Regulations are not approved classifications. The number of notifications and substances in the inventory will increase over time. As such, the data in this inventory is refreshed by ECHA on a regular basis.

The search results have been summarised in Table 4 on the total number of sensitisers (Category 1) and irritants which have been notified. Table 5 lists the results of the search on harmonised sensitisers (Category 1) and irritants under the CLP Regulation including the adaption of 1st and 2nd ATP.

Table 4 Total number of sensitisers (Category 1) and irritants which have been notified under REACH

Notified classification under REACH	Number of substances
Skin Sens. 1	10267
Skin Sens. 1A	64
Skin Sens. 1B	136
Resp. Sens. 1	2393
Resp. Sens. 1A	7
Resp. Sens. 1B	25
Skin Irrit. 2	53384

Table 5 Number of substances with harmonised classification of sensitisers (Category 1) and irritants

Harmonised classification under CLP	Number of substances
Skin Sens. 1	1252
Skin Sens. 1A	10
Skin Sens. 1B	24
Resp. Sens. 1	231
Resp. Sens. 1A	3
Resp. Sens. 1B	12
Skin Irrit. 2	898

It has to be noted that the concept of sub-categories (1A and 1B) for category 1 sensitisers which indicates the potency of sensitisers has only been introduced very recently. Therefore, for example in Table 5 1252 category 1 skin sensitisers with harmonised classification, only 10 have been assigned to 1A sub-category and 24 has been assigned to 1B sub-category. The most of the category 1 skin sensitisers (1252-10-24=1218) have not been assigned to any of the sub-categories as their sensitisation potency has not been evaluated or is unknown. It is the same case for respiratory sensitisers in the above list.

In this study, the substances used and remaining on finished textile products are reported by the involved textile associations and industries via questionnaires (Chapter 6). Based on the findings through C&L Inventory search and the input of the industries in Chapter 6, an overview table (Table 6) has been generated with the sensitisers and/or irritants which are notified in C&L Inventory and which are used and remain on finished textile products.

Table 6 Sensitisers and/or irritants notified in C&L Inventory and reported to be used and to remain on finished textile products

Function group	Substance name	CAS no.	Classfication in C&L Inventory related to allergy	
			Harmonised	Self-notified
Disperse dyes	Disp. Blue 1	2475-45-8	Skin Sens. 1, H317 Skin Irrit. 2, H315	
	Disp. Blue 3	2475-46-9		Skin Sens. 1, H317 Skin Irrit. 2, H315
	Disp. Blue 35	12222-75-2		Skin Sens. 1, H317
	Disp. Blue 106	68516-81-4		Skin Sens. 1, H317

				Resp. Sens. 1, H334
	Disp. Blue 124	15141-18-1/ 61951-51-7		Skin Sens. 1, H317
	Disp. Blue 183:1	2537-62-4		Skin Sens. 1, H317
	Disp. Blue 291	56548-64-2/ 51868-46-3		Skin Sens. 1, H317 Skin Irrit. 2, H315
	Disp. Blue	3065-87-0		Skin Sens. 1, H317
	Disp. Green 9	58979-46-7		Skin Sens. 1, H317
	Disp. Orange 1	2581-69-3		Skin Sens. 1, H317
	Disp. Orange 3	730-40-5		Skin Sens. 1, H317 Skin Irrit. 2, H315
	Disp. Orange 30	5261-31-4		Skin Sens. 1, H317
	Disp. Orange 37 / 76	13301-61-6		Skin Sens. 1, H317
	Disp. Orange 44	4058-30-4		Skin Sens. 1, H317
	Disp. Red 1	2872-52-8		Skin Sens. 1, H317
	Disp. Red 11	2872-48-2		Skin Sens. 1, H317 Skin Irrit. 2, H315
	Disp. Red 17	3179-89-3		Skin Sens. 1, H317
	Disp. Red 82	30124-94-8		Skin Sens. 1, H317
	Disp. Violet 57	1594-08-7		Skin Sens. 1, H317
	Disp. Violet 93	66557-45-7/ 52697-38-8		Skin Sens. 1, H317
	Disp. Yellow 3	2832-40-8	Skin Sens. 1, H317	
	Disp. Yellow 9	6373-73-5		Skin Sens. 1, H317
	Disp. Yellow 42	5124-25-4		Skin Sens. 1, H317
	Disp. Brown 1	23355-64-8		Skin Sens. 1, H317 Resp. Sens. 1, H334
Other dyes	Solvent Yellow 1	60-09-3		Skin Sens. 1, H317
	Solvent Yellow 2	60-11-7		Skin Sens. 1, H317 Skin Irrit. 2, H315
	Solvent Yellow 3	97-56-3	Skin Sens. 1, H317	
	Solvent Yellow 163	13676-91-0		Skin Sens. 1, H317
Dye related substances	Sodium [3-hydroxy-4-[(1-hydroxy-8-sulpho-2-naphthyl)azo]naphthalene-1-sulphonato(4-)]chromate(1-)	70942-15-3		Skin Sens. 1, H317 Resp. Sens. 1, H334
Softeners	Amides, from 2-[(2-aminoethyl)amino]ethanol and hydrogenated tallow fatty acids	68155-12-4		Skin Sens. 1, H317 Skin Irrit. 2, H315
Flame retardants	THPC-urea; Tetrakis(hydroxymethyl)phosphonium chloride, oligomeric reaction products with urea	27104-30-9		Skin Sens. 1, H317

	THPC; tetrakis(hydroxymethyl)phosphonium chloride	124-64-1		Skin Sens. 1, H317 Resp. Sens. 1, H334 Skin Irrit. 2, H315
Preservatives, antimicrobials	Dimethyltetradecyl[3-(trimethoxysilyl)propyl]ammonium chloride	41591-87-1		Skin Sens. 1, H317
Fragrances	D-Limonene	5989-27-5	Skin Sens. 1, H317 Skin Irrit. 2, H315	
Formaldehyde	Formaldehyde	50-00-0	Skin Sens. 1, H317	

4.1.3 Biocidal Products (Regulation (EU) No 528/2012)

Regulation (EU) 528/2012 on the use and placing on the market of biocidal products will enter into force on January 2013. This Regulation will repeal and replace the current Directive on biocidal products (98/8/EC).

Art. 2 of the new Regulation defines that the scope of this Regulation includes biocidal products and biocides treated articles. Annex V of the Regulation set out a list of the types of biocidal products covered. Textiles are mentioned in Annex V under Product-type 2 in Main group 1 (Disinfectants) and Product-type 9 (Fibre, leather, rubber and polymerised materials preservatives) in Main group 2 (Preservatives).

In the Regulation, it reads:

> MAIN GROUP 1: Disinfectants
>
> Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals
>
> Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.
>
> MAIN GROUP 2: Preservatives
>
> Product-type 9: Fibre, leather, rubber and polymerised materials preservatives
>
> Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration.

Sensitising and irritating substances are not specifically listed or mentioned in this Regulation.

4.1.4 Workers protection (Directive 89/391/EEC, Directive 98/24/EC, Directives 91/322/EEC, 2000/39/EC, 2006/15/EC and 2009/161/EU, Directive 2004/37/EC, Directive 94/33/EC, Directive 92/85/EEC Directives 2006/15/EC, 20000/39/EC and 2009/161/EC)

Above mentioned directives have been reviewed to investigate which chemical substances could cause sensitisation and irritation in workers during work process. A short explanation has been given below to each reviewed directive. According to these directives, sensitisers and irritants for workers should be identified based on the classification criteria set in DSD/DPS which has been repealed and amended by the CLP Regulation.

- Framework Directive 89/391/EEC
- Directive 98/24/EC sets out minimum standards on health and safety for those working with chemical agents.
- Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values (Attached as Annex 3 of this report);
- Commission Directive 2006/15/EC establishing a second list of indicative occupational exposure limit values (Attached as Annex 4 of this report);;
- Indicative limit values for occupational exposure for some chemical substances are listed also in: Commission Directive 91/322/EEC establishing indicative limit values (Attached as Annex 5 of this report);
- 2009/161/EU third list of indicative OELs (Attached as Annex 6 of this report);
- Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)
- Directive 94/33/EC - young workers: Work which is likely to entail specific risks for young people within the meaning of paragraph 1 includes: work involving harmful exposure to the physical, biological and chemical agents referred to in point I of the Annex, e.g. substances and preparations classified according to Directives 67/548/EEC and 88/379/EEC as irritant (Xi) and with one or more of the following risk phrases: may cause sensitization by inhalation (R42), may cause sensitization by skin contact (R43);
- Directive 92/85/EEC - introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

4.1.5 Cosmetics (Regulation (EC) No 1223/2009 on cosmetic products)

This Regulation has significantly amended Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. It establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.

Article 14 of Regulation 1223/2009 states that cosmetic products shall not contain any of the following:

- prohibited substances listed in Annex II of the Regulation
- restricted substances not according to the restrictions laid down in Annex III of the Regulation
- colorants other than those listed in Annex IV of the regulation or not according to the conditions laid down in that Annex
- preservatives which are not listed Annex V of the regulation or not according to the conditions laid down in that Annex
- UV-filters other than those listed in Annex VI or not according to the conditions laid down in that Annex

These Annexes have been translated from the Annexes in Directive 76/768/EEC. The translation/correlation table can be found in Annex X of Regulation 1223/2009. The status of all these Annexes up to 14 December 2010 have been described in a report of Scientific Committee on Consumer Safety (SCCS)[49] and are showed in table 7 below. Among these annexes, Annex III lists potentially sensitising fragrances for consumers.

Table 7 The status of cosmetic ingredients included in Annexes II, III, IV, VI and VII of Directive 76/768/EEC

Annexes in Directive 76/768/EEC	Status December 2010
Annex II (forbidden substances)	1365 entries

Annex III, Part 1 (restrictions)	208 entries
Annex III, Part 2 (restrictions, provisionally allowed)	31 entries
Annex IV, Part 1 (list of colouring agents)	153 colourants
Annex IV, Part 2 (colouring agents, provisionally allowed)	empty
Annex VI, Part 1 (preservatives)	54 preservatives
Annex VI, Part 2 (preservatives, provisionally allowed)	empty
Annex VII, Part 1 (UV filters)	26 UV filters
Annex VII, Part 2 (UV filters, provisionally allowed)	empty

Research in Scientific Committee on Consumer Safety (SCCS) shows that around 16% of eczema patients in the European population are sensitised to fragrance ingredients[50]. Contact to fragrance ingredients may develop contact allergy. Based on the SCCNFP (Scientific Committee on Cosmetic Products and Non-Food Products) draft opinion (SCCNFP/0017/98[51]) in 1999, 26 fragrance substances were introduced into Annex III of Directive 76/768/EEC by the 7th amendment (2003/15/EC)[52]. Annex III of Directive 76/768/EEC has been translated to Annex III of Regulation 1223/2009. These 26 fragrances are listed in Table 8 and Table 9 below. At the time there were insufficient scientific data to allow for the determination of dose response relationships and/or thresholds for these allergens. Nevertheless, in a pragmatic administrative decision the limits of 0.01 and 0.001% were set, for rinse-off and leave-on products respectively.

Table 8 Fragrance chemicals, which according to existing knowledge, are most frequently reported and well-recognised consumer allergens

Substance name	**CAS no.**
Amyl cinnamal	122-40-7
Amylcinnamyl alcohol	101-85-9
Benzyl alcohol	100-51-6
Benzyl salicylate	118-58-1
Cinnamyl alcohol	104-54-1
Cinnamal	104-55-2
Citral	5392-40-5
Coumarin	91-64-5
Eugenol	97-53-0
Geraniol	106-24-1
Hydroxycitronellal	107-75-5
Hydroxymethylpentyl-cyclohexenecarboxaldehyde	31906-04-4
Isoeugenol	97-54-1

Table 9 Fragrance chemicals, which are less frequently reported and thus less documented as consumer allergens

Substance name	**CAS no.**
Anisyl alcohol	105-13-5
Benzyl benzoate	120-51-4
Benzyl cinnamate	103-41-3
Citronellol	106-22-9
Farnesol	4602-84-0
Hexyl cinnamaldehyde	101-86-0
Lilial	80-54-6
d-Limonene*	5989-27-5
Linalool	78-70-6

Methyl heptine carbonate	111-12-6
3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5
Oak moss	90028-68-5
Tree moss	90028-67-4

***** *D-limonene has been reported by the textile industries to be used in textile product in Chapter 6.*

Annex II of Regulation 1223/2009 includes the substances which are prohibited to use in cosmetic products. Among these substances, some of them are also allergens such as the ones listed in Table 10 below.

Table 10 Non exhaustive list of allergens included in Annex II of Regulation 1223/2009 (List of Substances Prohibited in Cosmetic Products)

Substance name	**CAS no.**
Alanroot (Inula helenium)	97676-35-2
Allylisothiocyanate	57-06-7
Benzyl cyanide	140-29-4
p-tert-Butylphenol (Wormseed oil)	98-54-4
Diethyl maleate	141-05-9
Dihydrocoumarin (6,7-Dihydrogeraniol)	119-84-6
Dimethyl citraconate	617-54-9
6,10-Dimethyl-3,5,9-undecatrien-2-one (Pseudoionone)	141-10-6
Diphenylamine	122-39-4
Ethyl acrylate	140-88-5
trans-2-Heptenal	18829-55-5
trans-2-Hexenal diethyl acetal	67746-30-9
trans-2-Hexenal dimethyl acetal	18318-83-7
Hydroquinone monoethyl ether (4-Ethoxyphenol)	622-62-8
7-Methoxycoumarin	531-59-9
4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
Methyl trans-2-butenoate	623-43-8
7-Methylcoumarin	2445-83-2
5-Methyl-2,3-hexanedione (Acetyl isovaleryl)	13706-86-0
Musk Ambrette (solution only)	83-66-9
4-Phenyl-3-buten-2-one	122-57-6
Verbena oil (Lippia citriodora Kunth)	8024-12-2

4.1.6 Toys (Directive 2009/48/EC) and its amendments

In order to ensure a high level of protection of children against risks caused by chemical substances in toys, the use of dangerous substances deserves careful attention. These dangerous substances in particular included substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under the existing classification system, allergenic substances and certain metals.

Toys Safety Directive 2009/48/EC specify that toys shall not contain the following allergenic fragrances. However, in case that presence of traces of these fragrances is technically unavoidable under good manufacturing practice, the presence of these fragrances shall not exceed 100 mg/kg in final products.

These allergenic fragrances are indicated in Table 11 below. This Directive establishes also migration limits for several elements, including heavy metals, and organic tin compounds that are classified H317 under CLP (may cause an allergic skin reaction, e.g. Co and Ni) and H315 (causes skin irritation, e.g. TBT tributyl tin). These substances may occur in textile products and are included in EU Ecolabel Regulation and Oeko-tex standard 100.

Table 11 Allergenic fragrances which shall not be present in toys

Substance name	CAS no.
Alanroot oil (Inula helenium)	97676-35-2
Allylisothiocyanate	57-06-7
Benzyl cyanide	140-29-4
4 tert-Butylphenol	98-54-4
Chenopodium oil	8006-99-3
Cyclamen alcohol	4756-19-8
Diethyl maleate	141-05-9
Dihydrocoumarin	119-84-6
2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
Dimethyl citraconate	617-54-9
7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
Diphenylamine	122-39-4
Ethyl acrylate	140-88-5
Fig leaf, fresh and preparations	68916-52-9
trans-2-Heptenal	18829-55-5
trans-2-Hexenal diethyl acetal	67746-30-9
trans-2-Hexenal dimethyl acetal	18318-83-7
Hydroabietyl alcohol	13393-93-6
4-Ethoxy-phenol	622-62-8
6-Isopropyl-2-decahydronaphthalenol	34131-99-2
7-Methoxycoumarin	531-59-9
4-Methoxyphenol	150-76-5
4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
Methyl trans-2-butenoate	623-43-8
6-Methylcoumarin	92-48-8
7-Methylcoumarin	2445-83-2
5-Methyl-2,3-hexanedione	13706-86-0
Costus root oil (Saussurea lappa Clarke)	8023-88-9
7-Ethoxy-4-methylcoumarin	87-05-8
Hexahydrocoumarin	700-82-3
Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
2-Pentylidene-cyclohexanone	25677-40-1
3.6,10-Trimethyl-3.5,9-undecatrien-2-one	1117-41-5
Verbena oil (Lippia citriodora Kunth)	8024-12-2
Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
4-Phenyl-3-buten-2-one	122-57-6
Amyl cinnamal	122-40-7

Amylcinnamyl alcohol	101-85-9
Benzyl alcohol	100-51-6
Benzyl salicylate	118-58-1
Cinnamyl alcohol	104-54-1
Cinnamal	104-55-2
Citral	5392-40-5
Coumarin	91-64-5
Eugenol	97-53-0
Geraniol	106-24-1
Hydroxy-citronellal	107-75-5
Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
Isoeugenol	97-54-1
Oakmoss extracts	90028-68-5
Treemoss extracts	90028-67-4

In addition, the names of the following allergenic fragrances (showed in Table 12) shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof.

Table 12 Allergenic fragrances shall be listed on toys; label or packaging when used concentrations exceed 100 mg/kg

Substance name	**CAS no.**
Anisyl alcohol	105-13-5
Benzyl benzoate	120-51-4
Benzyl cinnamate	103-41-3
Citronellol	106-22-9
Farnesol	4602-84-0
Hexyl cinnamaldehyde	101-86-0
Lilial	80-54-6
d-Limonene*	5989-27-5
Linalool	78-70-6
Methyl heptine carbonate	111-12-6
3-methyl-4-(2.6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

***** *D-limonene has been reported by the textile industries to be used in textile product in Chapter 6.*

4.1.7 Detergents (Regulation (EC) No 648/2004 as last amended by Regulation (EU) No 259/2012 [45]

Regulation (EC) No 648/2004 intends, among others, to protect consumers against allergenic substances present in detergents such as certain fragrances and preservatives. Regulation (EC) No 648/2004 requires specific labelling to inform consumers about the presence of allergenic substances in detergents.

The 26 allergenic substances mentioned in Directive 2003/15/EC (7th amendment to Directive 76/768/EEC, Annex III, part 1) must be labelled on the packaging of detergents if added at concentration exceeding 0.01% w/w. These 26 allergenic substances are indicated in Table 13 below. Furthermore, the Regulation foresees in Annex VII that additional allergenic fragrances identified under the Cosmetics Product legislation are to be labelled also on detergents, if present above 0.01 % w/w (or any more specific risk-based limit established by the SCCS). Article 9(3) foresees that where

individual risk-based concentration limits for the fragrance allergens are established by the Scientific Committee on Consumer Safety (SCCS), the Commission shall adopt delegated acts in order to adapt that limit accordingly.

Table 13 The 26 allergenic substances mentioned in Directive 2003/15/EC

Substance name	CAS no.
Amyl cinnamal	122-40-7
Amylcinnamyl alcohol	101-85-9
Benzyl alcohol	100-51-6
Benzyl salicylate	118-58-1
Cinnamyl alcohol	104-54-1
Cinnamal	104-55-2
Citral	5392-40-5
Coumarin	91-64-5
Eugenol	97-53-0
Geraniol	106-24-1
Hydroxycitronellal	107-75-5
Hydroxymethylpentyl-cyclohexenecarboxaldehyde	31906-04-4
Isoeugenol	97-54-1
Anisyl alcohol	105-13-5
Benzyl benzoate	120-51-4
Benzyl cinnamate	103-41-3
Citronellol	106-22-9
Farnesol	4602-84-0
Hexyl cinnamaldehyde	101-86-0
Lilial	80-54-6
d-Limonene*	5989-27-5
Linalool	78-70-6
Methyl heptine carbonate	111-12-6
3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5
Oak moss	90028-68-5
Tree moss	90028-67-4

***** *D-limonene has been reported by the textile industries to be used in textile product in Chapter 6.*

4.1.8 General Product Safety Directive 2001/95/EC (RAPEX[53])

RAPEX is the EU rapid alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers –with the exception of food, pharmaceutical and medical devices, which are covered by other mechanisms. Since 1 January 2010, as regards goods subject to EU harmonisation regulation, the system also facilitates the rapid exchange of information on products posing a serious risk to the health and safety of professional users and on those posing a serious risk to other public interests protected via the relevant EU legislation (e.g. environment and security). Both measures ordered by national authorities and measures taken voluntarily by producers and distributors are reported by RAPEX.

The annual report of RAPEX in 2011[54] shows that five product categories of consumer products werw most frequently notified and accounted for 74% of all products notified in 2011. Among these five product categories, “Clothing, textiles and fashion items” was the most notified (27%), followed by

´Toys´ (21%). Both categories account together for almost half (48%) of all notifications distributed through the RAPEX system in 2011. However, it should be noted that the product category "Clothing, textiles and fashion items" also includes shoes and the fashion goods made of the materials such as plastic and leather other than textiles. Furthermore, the major notification in the product category "Clothing, textiles and fashion items" are related to suffocation or strangulation risk in children's clothing and not related to the use of restricted chemicals.

One of the chemical factors leading to the prominence of this category in the findings of non-compliance was the adoption of Commission Decision 2009/251/EC on dimethyl fumarate (DMF). DMF is a strong novel sensitizer found to be used as an anti-mould treatment especially in shoes, textiles and furniture.

4.1.9 Regulation (EC) No 66/2010 on the EU Ecolabel[47] including Commission Decision 2009/567/EC[48]

The EU Ecolabel is a voluntary scheme which means that manufacturers, importers and retailers do not have obligations and can choose to apply for the label for their products.

Regulation (EC) No 66/2010 lays down rules for the establishment and application of the EU Ecolabel scheme. Commission Decision 2009/567/EC has updated the original criteria for the EU Ecolabel for textiles. In the Annex of Commission Decision 2009/567/EC, criteria for processes and chemicals have been set. Under point 23(Potentially sensitising dyes), for obtaining a EU Ecolabel the dyes which shall not be used in textile due to their sensitisation properties are listed. These potentially sensitising dyes can be found in Table 14 below.

Table 14 Potentially sensitising dyes which shall not be used in Ecolabel textiles

C.I. Disperse Blue 3
C.I. Disperse Blue 7
C.I. Disperse Blue 26
C.I. Disperse Blue 35
C.I. Disperse Blue 102
C.I. Disperse Blue 106
C.I. Disperse Blue 124
C.I. Disperse Brown 1
C.I. Disperse Orange 1
C.I. Disperse Orange 3
C.I. Disperse Orange 37
C.I. Disperse Orange 76 (previously designated Orange 37)
C.I. Disperse Red 1
C.I. Disperse Red 11
C.I. Disperse Red 17
C.I. Disperse Yellow 1
C.I. Disperse Yellow 9
C.I. Disperse Yellow 39
C.I. Disperse Yellow 49

In addition, some other substances which are used in textiles and included in Ecolabel criteria due to other concerns have been also classified as sensitisers or irritants under the existing classification system. Table 15 gives an example of these substances.

Table 15 Other potentially sensitising or/and irritating substances mentioned in Ecolabel criteria

Function group	Substance name	CAS no.	Harmonised classification under CLP related to allergy
Acrylonitrile	acrylonitrile	107-13-1	Skin Sens. 1, H317 Skin Irrit. 2, H315 STOT SE 3, H335
Organic tin compounds Which are restricted under REACH	TBT		Skin Irrit. 2, H315
Pesticides	2,4,5-T	93-76-5	Skin Sens. 1, H317 STOT SE 3, H335
	captafol	2425-06-1	Skin Sens. 1, H317
	Toxaphene	8001-35-2	Skin Irrit. 2, H315 STOT SE 3, H335
	Pentachlorophenol	87-86-5	Skin Irrit. 2, H315 STOT SE 3, H335
Impurities in dyes and pigments	Cobalt	7440-48-4	Skin Sens. 1, H317 Resp. Sens. 1, H334
	Nickel	7440-02-0	Skin Sens. 1, H317
azo dyes which by reductive cleavage of one or more azogroups may release aromatic amines listed	o-aminoazotoluene	97-56-3	Skin Sens. 1, H317
	p-chloroaniline	106-47-8	Skin Sens. 1, H317
	4,4'-diaminobiphenylmethane	101-77-9	Skin Sens. 1, H317
	3,3'-dichlorobenzidine	91-94-1	Skin Sens. 1, H317
	3,3'-dimethyl-4,4'-diaminobiphenylmethane	838-88-0	Skin Sens. 1, H317
	2,4-toluenediamine	95-80-7	Skin Sens. 1, H317
	2,6-xylidine	87-62-7	Skin Irrit. 2, H315 STOT SE 3, H335
dyestuffs classified as CMR	Disperse Blue 1	2475-45-8	Skin Sens. 1, H317 Skin Irrit. 2, H315
	Disperse Orange 11	82-28-0	Skin Sens. 1, H317
	Disperse Yellow 3	2832-40-8	Skin Sens. 1, H317
formaldehyde	formaldehyde	50-00-0	Skin Sens. 1, H317

4.2 Voluntary textile standards, relevant reports and documents

Voluntary textile standards (i.e. Oeko-Tex Standard 100), relevant reports and documents have been reviewed. The main findings and references are given below.

4.2.1 Oeko -Tex® Standard 100 (version 4-2012)

Oeko-Tex label is a private label which has by far the widest coverage of any label in the field of textiles in Europe – 53,000 companies were covered in 2005[55]. The Oeko-Tex criteria are outlined in the Oeko-Tex Standard 100.

The substances mentioned in Oeko-Tex Standard 100 regarding sensitising and irritating properties are included in Table 16 below.

Table 16 Potentially sensitising or/and irritating substances mentioned in Oeko-Tex Standard 100 criteria

Function group	Substance name	CAS no.	Harmonised classification under CLP related to allergy
formaldehyde	formaldehyde	50-00-0	Skin Sens. 1, H317
Heavy metals	Cobalt	7440-48-4	Skin Sens. 1, H317 Resp. Sens. 1, H334
	Nickel	7440-02-0	Skin Sens. 1, H317
Pesticides	2,4,5-T	93-76-5	Skin Sens. 1, H317 STOT SE 3, H335
	2,4-D	94-75-7	Skin Sens. 1, H317 STOT SE 3, H335
	azinophosmethyl	86-50-0	Skin Sens. 1, H317
	captafol	2425-06-1	Skin Sens. 1, H317
	Cypermethrin	52315-07-8	STOT SE 3, H335
	Dichlorprop	120-36-5	Skin Irrit. 2, H315
	Esfenvalerate	66230-04-4	Skin Sens. 1, H317
	Malathion	121-75-5	Skin Sens. 1, H317
	MCPA	94-74-6	Skin Irrit. 2, H315
	Mecoprop	93-65-2	Skin Irrit. 2, H315
	Toxaphene	8001-35-2	Skin Irrit. 2, H315 STOT SE 3, H335
	Trifluralin	1582-09-8	Skin Sens. 1, H317
chlorinated phenols	Pentachlorophenol	87-86-5	Skin Irrit. 2, H315 STOT SE 3, H335
	2,3,4,6-Tetrachlorophenol	58-90-2	Skin Irrit. 2, H315
Organic tin compounds	TBT		Skin Irrit. 2, H315
Other	OPP	90-43-7	Skin Irrit. 2, H315 STOT SE 3, H335
arylamines having carcinogenic properties	o-aminoazotoluene	97-56-3	Skin Sens. 1, H317
	p-chloroaniline	106-47-8	Skin Sens. 1, H317
	4,4'-diaminobiphenylmethane	101-77-9	Skin Sens. 1, H317
	3,3'-dichlorobenzidine	91-94-1	Skin Sens. 1, H317
	3,3'-dimethyl-4,4'-diaminobiphenylmethane	838-88-0	Skin Sens. 1, H317
	2,4-toluenediamine	95-80-7	Skin Sens. 1, H317
	2,6-xylidine	87-62-7	Skin Irrit. 2, H315 STOT SE 3, H335
dyestuffs classified as carcinogenic	Disperse Blue 1	2475-45-8	Skin Sens. 1, H317 Skin Irrit. 2, H315
	Disperse Orange 11	2832-40-8	Skin Sens. 1, H317
dyestuffs classified as allergenic	Disperse Blue 1	2475-45-8	Skin Sens. 1, H317 Skin Irrit. 2, H315
	Disperse Yellow 3	2832-40-8	Skin Sens. 1, H317
Chlorinated benzenes and toluenes	o-dichlorobenzene	95-50-1	Skin Irrit. 2, H315 STOT SE 3, H335
	1,2,4-trichlorobenzene	120-82-1	Skin Irrit. 2, H315
	a-chlorotoluene	100-44-7	Skin Irrit. 2, H315 STOT SE 3, H335

	a,a,a-trichlorotoluene	98-07-7	Skin Irrit. 2, H315 STOT SE 3, H335
	a,a-dichlorotoluene	98-87-3	Skin Irrit. 2, H315 STOT SE 3, H335
	a,a,a,4-tetrachlorotoluene	5216-25-1	Skin Irrit. 2, H315 STOT SE 3, H335
Solvent residues	N-methyl-2-pyrrolidone	872-50-4	Skin Irrit. 2, H315 STOT SE 3, H335
volatile organic compounds (emission into air)	formaldehyde	50-00-0	Skin Sens. 1, H317
	toluene	108-88-3	Skin Irrit. 2, H315
	Styrene	100-42-5	Skin Irrit. 2, H315

4.2.2 German Federal Institute for Risk Assessment (BfR) Information No. 018/2007 "Introduction to the problems surrounding garment textiles"[56]

In this paper, some potentially allergenic auxiliaries and finishing agents for garment textiles such as formaldehyde, flame retardants, dyes and dye carriers, organic tin compounds and biocides have been discussed. The allergic reactions to textiles have been also reviewed in the current paper. In summary, the conclusions are:

- 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.
- In the case of disperse dyes with a sensitising potential in textiles, 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.
- 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.
- For precautionary reasons certain azo dyes, that can be cleaved into carcinogenic aromatic amines, were banned in the Consumer Products Ordinance. It can be assumed that these dyes are 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.
- There are hardly any data on exposure to textile auxiliaries.
- Exposure to dyes, related to skin area, is between 1 ng and 1 • g pro cm^2 depending on colour fastness.
- Exposure 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. BfR recommends in particular that triclosan should not be used. Active biocidal substances should always be declared.

4.2.3 Dutch National Institute for Public Health and the Environment (RIVM) Report 320025001/2008 “Allergens in Consumer Products”[57]

This project was initiated by The Dutch Food and Consumer Products Safety Authority (VWA) to investigate the size of the problem caused by allergens in consumer products including textiles, with the purpose to indicate the importance of controlling allergenic substances in consumer products and to point the direction of possible further investigations in this field.

Allergic diseases are among the most common chronic disorders in the Western countries. In general, the prevalence of contact dermatitis (3.7% in men and 5.4% in women in the Netherlands) is relatively high when compared to other allergic diseases such as asthma, rhinitis and food allergy (3-5%, 1.5-3% and 1-3%, respectively). In European epidemiological studies it was demonstrated that the prevalence of contact dermatitis was in the range of 7-28%. A substantial part of the cases are caused by allergens present in consumer products.

This document demonstrates that different policy measures are implemented, varying from a ban, labeling, concentration limits and consumer education to protect consumers from allergenic effects. However, the results of this project showed that the current legislation is not sufficient to prevent the occurrence of contact dermatitis.

In conclusion, a substantial part of consumer products contain allergenic substances resulting in relatively high prevalence of contact dermatitis. Despite the current legislation, contact dermatitis is still a problem. What is urgently needed is the derivation of safe limits of frequently used allergens in consumer products by the use of a validated Quantitative Risk Assessment (QRA) method which also takes aggregate exposure into account. Also a monitoring system is needed for the effectiveness of the QRA method. In addition, information on the levels of sensitisers in consumer products and frequency of use is needed in combination with prevalence of contact dermatitis, including time trends.

4.2.4 Italian Health and Textile Association (Associazione Tessile e Salute) “Chemical substances in Textile Products and Allergic Reactions”[58]

This document was drafted by the Italian Health and Textile Association (IHTA) aiming to contribute to the current “Study on the link between allergic reactions and chemicals in textile products”. It contains collected data on substances or substance classes used in the whole processes of textile manufacturing and the substances in textiles which have caused contact dermatitis. The document has no legal relevance, in the context of the regulatory framework in Italy.

Information about the prevalence of contact dermatitis from fabrics in Italy has been indirectly obtained from the latest epidemiological study carried out by the Italian Contact and Environmental Dermatitis Research Group (*Gruppo Italiano Ricerca Dermatiti da Contatto e Ambientali* - GIRDCA) for the five year period 1994-1998. Clothing represented the fourth most important cause of non-occupational contact dermatitis (8.5%), after cosmetics, metal accessories and pharmaceuticals, and ranking before shoes. The allergens that most frequently cause dermatitis from fabrics are the dyes, especially disperse dyes. These are followed by finishing resins and adhesive resins, particularly when they are able to release formaldehyde. The prevalence and sensitisation to formaldehyde, however, seems to be progressively decreasing. Finally, a point not to be neglected is the impact of “emerging” allergens, which are mainly used by non-European manufacturers, especially Asian producers. Some “emerging” allergens have recently been found responsible for numerous cases of contact dermatitis; of these, a noteworthy example is dimethyl fumarate (DMF), a preservative banned in Europe since 1998 but still used in Asian countries.

Furthermore, another epidemiological study carried out on dermatitis originating from fabrics in cooperation with the Italian Association for Allergological, Professional and Environmental Dermatology (Società Italiana di Dermatologia Allergologica Professionale e Ambientale - SIDAPA) has been included in the IHTA document. The SIDAPA study found that fabrics were the cause in 69.1% of patients, metallic garment accessories in 16.5% and shoes in 14.4%. In regard to fabrics, the contact was non-occupational in 88.8% of cases. Extrapolating the data of dermatitis caused only by fabrics, it was found that these were most frequent in female patients (67,5%) and from the 3rd to the 7th decade of life (average age: 43.5). This epidemiological study confirmed that, in regard to the cases of non-occupational contact dermatitis caused by fabrics, the dyes represented the most common cause (44.3%). In agreement with the data from literature, the positive reactions were more often caused by dyes (78.9% of the total number of cases of ACD), especially Disperse blue 124 (54.3%) and disperse blue 106 (28.5%), with current occurrence in almost all cases. Moreover, allergic sensitisation to formaldehyde (5.9%) seems to have less aetiological importance compared to the past.

4.2.5 Finnish EPA "Risk management and governance of chemicals in articles – Case study textiles"[59]

This report is the following of a preliminary report "Control of chemicals in articles – Preliminary report" (Helsinki, 2010). In this preliminary report, the current situations of both legislative and voluntary control of chemicals in articles as well as to identify the deficiencies of management measures were described. The report "Risk management and governance of chemicals in articles – Case study textiles" addresses and illustrates the issue of control of chemicals in textiles and gets better understanding of the problem.

The report covers the entire life cycle of textiles. The chemicals or chemicals classes used in different stages of textile and clothing manufacturing and related risks to the environment are described. Moreover, the current risk management measures for the chemicals in textiles have been discussed in this report. These measures include relevant legislations, environmental labelling systems and voluntary systems used by enterprises.

Based on the survey performed in the study and other source, priority chemicals with regard to environmental and human health hazards from chemicals in textiles were identified. These priority chemicals include substances defined internationally within the Water Framework Directive (both at EU level and nationally) and the HELCOM Baltic Sea Action Plan, and nationally. However, these chemicals are identified more regarding to the environment and occupational exposures.

In table 4 of this report, the substances from textiles which can cause sensitisation risks for humans are listed. For examples, formaldehyde, isocyanates, DMF, and heavy metals such as Cr and Ni, were mentioned in the table.

4.2.6 Danish EPA "Danish surveys on chemicals in consumer products"

For more than a decade the Danish EPA has been engaged in work to identify chemical substances in a number of consumer products, such as toys, cosmetics, clothes, furniture etc.

The effort is targeted towards products that might contain problematic chemicals, or products that consumers are highly exposed to.

The latest reports of 118 surveys are listed on the website of Danish EPA (http://www.mst.dk/English/Chemicals/consumers_consumer_products/danish_surveys_consumer_products/).

A survey on chemicals in textiles[60] has been completed in 2011 (Survey no. 113 2011 Chemicals in Textiles (only available in Danish)). The report is drafted in Danish with a four pages summary and conclusions in English. The primary purpose of this survey is to describe:

Production of textiles outside the EU

- Eco- and health labels on the Danish market
- Chemicals which are found in clothes/textiles
- Case: water consumption and consumption of chemicals for production of a conventional T-shirt and an eco-labelled T-shirt

The main conclusions of the project are:

- The main part of the imported clothes/textiles to Denmark comes from the East.
- Clothes/textiles can contain a long range of dangerous chemicals in small or larger amounts. The chemicals residues are caused by the large use of chemicals in the production of the textiles.
- Many of the chemicals can, however, be washed out of the textiles when washed in the washing machine.
- Especially phthalates, some heavy metals, and antibacterial agents are not washed out of the textiles during wash. However, phthalates and to some degree also the heavy metals can be avoided by buying ecolabelled or health-labelled textiles.
- On the Danish market, it is possible to find the following eco-labels and health-labels: the EU Flower, the Nordic Swan, the Swedish Bra Miljöval (Good Environmental Choice), Oko-Tex 1000 and Oko-Tex100. Besides these, the following labels that stand for organic production can be found on the Danish market: GOTS, IVN, KRAV, DEMETER and Soil Association.
- For the production of one cotton T-shirt (250 g) about 500 to 1040 grams of chemicals and about 37-225 liter of water is used (growing of cotton is not included here). The use of water is not expected to be lower for production of an ecolabelled T-shirt compared to a non-ecolabelled T-shirt. On the other hand, the use of chemicals to produce an ecolabelled (organically grown) T-shirt will be lower compared to the use of chemicals to produce a non-ecolabelled T-shirt.

4.2.7 European Risk Observatory Report" Occupational skin diseases and dermal exposure in the European Union (EU-25): Policy and practice overview"[61]

This report presents an overview of dermal exposures and skin diseases. It contains the principal policies relating to the recognition and recording of skin diseases, as well as the recognition, assessment and control of dermal exposure to chemical, biological and physical risk factors in the European Union (EU-25). The document concludes with some challenges, prospects and recommendations.

The types of detrimental effects discussed in this report include localised harmful effects and systemically harmful effects from dermal penetration and occupational dermatoses. Some of the results included in the report are discussed in Chapter 5 of the current report.

4.2.8 UK Health and Safety Executive (HSE) publication – Dyes and chemicals in textile finishing[62]

This is the first in a series of HSE Information Sheets concerning the safe handling of dyes and chemicals in textile finishing. In this piece of introduction document, dyes and dye related substances known as allergenic are addressed:

- Some reactive dyes are recognised respiratory sensitisers**.** Breathing in respiratory sensitisers can cause occupational asthma. Once a person is sensitised, re-exposure to even very small amounts of the same dye may result in allergic symptoms such as a runny or stuffy nose, watery or prickly eyes, wheezing, chest tightness and breathlessness. Some dyes can cause similar allergic skin reactions. Certain reactive, vat and disperse dyes are recognised skin sensitisers.

- Regarding dye related chemicals, perhaps the most prevalent health problems associated with dyeing and finishing processes arise from exposure to chemicals acting as irritants. These may cause skin irritation, itchy, stuffy noses, sneezing and sore eyes. They include formaldehyde-based resins, ammonia, acetic acid, some shrink-resist chemicals and optical whiteners, soda ash and bleach.

4.3 Relevant legal frameworks in three selected MSs (i.e. The Netherlands, France and Germany)

Relevant legal frameworks in three selected Member States (i.e. The Netherlands, Germany and France) have been reviewed. The reason to choose the Netherlands is that the Netherlands has actively performed much work on sensitisers such as data gathering on sensitisers, risk assessment and occupational safety. Germany has a large textile industry and has a number of national research institutes or research organisations which are largely involved in the information generation of sensitising substances in textiles. Furthermore Germany has always had a prominent role in consumer safety. France is known as the centre of fashion and clothing in Europe and has an important textile sector. The most relevant findings and references in this framework are given below.

4.3.1 The Netherlands

The EU relevant legislations have been implemented in Dutch Acts. For example:

- Commodities Act Art. 8 states that it is prohibited to sell products which are expected to be a danger to safety or health of humans – based on the GPSD 2001/95/EC
- Classification of substances is according to the criteria in Annex VI of DSD 67/548/EC (amended in the CLP Regulation) which is implemented in corresponding Dutch Act i.e. Dutch (Environmentally) hazardous Substance Act (WMS)"
- Limitations Directive 76/769/EEC (amended by the REACH Regulation) is implemented in corresponding Dutch Acts e.g. the Commodities Act for consumer products.

4.3.2 Germany

ChemVerbotsV: Regulation on bans and restrictions of placing dangerous substances, preparations and products under the chemicals Act. The chemicals in this regulation which are identified as irritant or sensitizing are summarized below in Table 17.

Table 17 Potentially sensitising or/and irritating substances mentioned in ChemVerbotsV

Function group	Substance name	CAS no.	Classification under CLP
Benzene	Benzene	71-43-2	H315: Causes skin irritation
Dibutyltin hydrogen borate	Dibutyltin hydrogen borate	75113-37-0	H317: May cause an allergic skin reaction
pentachlorophenol	Pentachlorophenol	87-86-5	H315: Causes skin irritation

			H335: May cause respiratory irritation
azo-colourants	trisodium bis(5-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-) / reaction mass of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-)	EC number: 405-665-4	H317: May cause an allergic skin reaction
toluene	toluene	108-88-3	H315: Causes skin irritation

In Germany, there are also Technical Rules (TR) related to hazardous substances from the Federal Institute for Occupational Safety and Health (BAuA). These Rules provide information on activities with hazardous substances. For example:

- TRGS 401: documents the risks resulting from skin contact. Substances which are irritating to the skin (R38) or may cause sensitisation by skin contact (R43) are covered as being hazardous substances.
- TRGS 402: documents the risks concerned with inhalation exposure from activities with hazardous substances
- TRGS 600: deals with the substitution of hazardous substances. Skin irritation and sensitisation are part of the used criteria for possible substitutions.
- TRGS 614: is concerned with the limitations for the use of colorants, which can cleave into carcinogenic aromatic amines.

4.3.3 France

- Code de l'environnement, Partie legislative, book V, Title II, Chapter I is compliant with REACH, CLP, EC 689/2008 (export and import of dangerous chemicals) etc.
- Code de l'environnement, Partiereglementaire, book V, Title II, Chapter I, Section II

The chemical substances mentioned in these regulations and identified as sensitizing and/or irritating, are shown below in Table 18.

Table 18 Potentially sensitising or/and irritating substances mentioned in relevant French regulations

Function group	Substance name	CAS no.	Classification under CLP
Dibutyltin hydrogen borate	Dibutyltin hydrogen borate	75113-37-0	H317: May cause an allergic skin reaction
colorant bleu	trisodium bis(5-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-) / reaction mass of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-	EC number: 405-665-4	H317: May cause an allergic skin reaction

	naphtholato)chromate(1-)		
chlorinated phenols	Pentachlorophenol	87-86-5	H315: Causes skin irritation H335: May cause respiratory irritation

The French Ministry of Work, Employment, Professional Training and Social Dialogue also lists chemicals and products which pose an occupational danger or risk. In the list of "dangerous chemical products (ACD)"[63], allergy is considered as a danger or a risk. Next to this general document for chemicals, there are also specific listings, for example for formaldehyde[64] and mercury[65].

For the risk assessment of chemicals, there is also a document by INRS (Cahiers de notes documentaires - Hygiène et sécurité du travail - N° 178, 1er trimestre 2000), in which the substances with irritating and sensitising properties are assessed.

France also has ANSES (Agence Nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail), previously known as AFFSET. This agency provides scientific research on several chemicals and their effects on occupational health and safety, such as formaldehyde and dimethyl fumarate (DMF).

4.4 Relevant legal frameworks in main trading partners

The legal frameworks in two main trading partners, US and China, have been reviewed and the most relevant findings and references are given below.

4.4.1 Relevant legal framework in US

In US, textiles are regulated by many regulations considering chemical safety and the environment. The most relevant government organisations are Occupational Safety & Health Administration (OSHA)[66] and Environmental Protection Agency (EPA)[67]. OSHA focuses on chemicals and health while EPA manages the emission of chemicals to the environment during manufacturing of textiles.

Within the legal framework related to textiles in US, there are OSHA standards, Federal Registers (rules, proposed rules, and notices), directives (instructions for compliance officers), and standard interpretations (official letter of interpretation of the standards) related to textiles. However, the most of the standards are related to the carcinogenic chemical substances.

Below, some examples have been given on some important standards in US regarding textiles which are relevant to the current study.

Frequently cited NSF/ANSI/OSHA standards

- 19101200: Hazard Communication
- 19100134: Respiratory Protection
- 19101048: Occupational exposure to Formaldehyde
- 19100138: Hand Protection
- 19100262: Textiles

Hazard recognition

Control of Dust From Powder Dye Handling Operations.	US Department of Health and Human Services (DHHS), National Institute for Occupational

	Safety and Health (NIOSH) Publication No. 97-107 (1997, June 26). Reduction of worker exposure to powdered dye through ventilation, work practice controls and limiting bulk container height.

There are no established limits/requirements indicated in the mentioned standards and guidance.

EPA regulates Textile Manufacturing Sector (NAICS 313). This sector consists of establishments engaged in spinning natural and manmade fibers into yarns and threads. There are then woven or knitted into fabrics, and the fabrics are dyed and finished.

4.4.2 Relevant legal framework in China

The Standardization Administration of China (SAC) is the central accrediting body for all activity related to developing and promulgating national standards in China. The China National Certification and Accreditation Administration (CNCA) is the primary government agency responsible for supervision of China's conformity assessment policies. Both SAC and CNCA are administratively under the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ).

In China, various standards are used for textiles. One of the important standards related to textiles is National General Safety Technical Code for Textile Products (GB18401-2010) [68] which replaces GB18401-2003 from August 1, 2012. The standard divides all textile products into three categories: infant products, skin contact products and non-skin contact products. Products are assessed in comparison with the specific technical requirements listed in Table 19 below. Infant products should comply with the requirement of type A, skin contact products should at least comply with Type B and non-skin contact should at least comply with Type C. All components that make up an infant product shall meet the Type A technical requirements as specified by the table below. The component less than 1% of the whole weight of non-infant products can be exempted from testing.

Table 19 Technical requirements for different categories of textile products

Requirement		**Type A**	**Type B**	**Type C**
Formaldehyde (mg/kg)		• 20	• 75	• 300
pH		4.0 – 7.5	4.0 – 8.5	4.0 – 9.0
Color fastness/Degree •	Water resistance (C/C, C/S)	3 - 4	3	3
	Acid/alkaline sweater resistance (C/C, C/S)	3 - 4	3	3
	Dry rubbing resistance	4	3	3
	Saliva resistance (C/C, C/S)	4	-	-
Odor		Odorless		
Decomposable carcinogenic aromatic amine dyes*		Banned		

* *Decomposable carcinogenic aromatic amine dyes*

	Substance Name	***CAS no.***
1	*4-Aminobiphenyl*	*92-67-1*
2	*Benzidine*	*92-87-5*
3	*4-Chloro-o-toluidine*	*95-69-2*
4	*2-Naphthylamine*	*91-59-8*

5	*o-Aminoazotoluene*	*97-56-3*
6	*5-Nitro-o-toluidine*	*99-55-8*
7	*p-Chloroaniline*	*106-47-8*
8	*2,4-Diaminoanisole*	*615-05-4*
9	*4,4'-Diaminobiphenymethane*	*101-77-9*
10	*3,3'-Dichlorobenzidine*	*91-94-1*
11	*3,3'-Dimethoxybenzidine*	*119-90-4*
12	*3,3'-Dimethylbenzidine*	*119-93-7*
13	*3,3'-Dimethy1-4,4'-diaminobiphenylmthane*	*838-88-0*
14	*p-Cresidine*	*120-71-8*
15	*4,4'-Methylene-bis-(2-chloroaniline)*	*101-14-4*
16	*4,4'-Oxydianiline*	*101-80-4*
17	*4,4'-Thiodianiline*	*139-65-1*
18	*o-Toluidine*	*95-53-4*
19	*2,4-Toluylendiamine*	*95-80-7*
20	*2,4,5-Trimethylaniline*	*137-17-7*
21	*o-Anisidine*	*90-04-0*
22	*4-Aminoazobenzene*	*60-09-3*
23	*2,4-Xylidine*	*95-68-1*
24	*2,6-Xylidine*	*87-62-7*

4.5 Discussion on the findings of review of relevant existing legal frameworks

There are several textile standards (e.g. Oeko-Tex Standard) as well as retailers' purchasing requirements (e.g. IKEA, GAP, H&M, Puma, Triumph, etc.), which many European textile companies are already following. However, it has been found that the information on the label is not always correct[53 57]. For example, checking whether or not certain allergenic substances are present in textile products and whether the used concentration is within the limit concentration could become an obligation in the future. To ensure that the use of chemicals in textiles is safe for consumers and to ensure a level playing field for textile businesses, internationally agreed standards might be necessary. For the time being, there is no standard method to analyse the allergenic dyes in textiles. However, CEN/TC 248/WG 26 on EU restricted substances in textiles is currently working on the standardisation of the method for the analysis of allergenic dyes and the method may be available soon.

At present, different types of regulations are used to protect the consumers from an allergic reaction. Besides "prohibited to use", two types of limits are used for sensitisers:

- Maximum limit values
  Examples are nickel (Nikel Directive 1994) and preservatives in cosmetics (Annex VI part 1&2 of Cosmetic Directive). The concentration may not exceed the maximum limit value.
- Limits of declaration
  For example, in the Cosmetics Directive, the limit for sensitising fragrances is 0.001% and 0.01% for leave on and rinse off products, respectively (Annex III). This limit indicates a minimal concentration for labelling, not a maximum. The concentration used may exceed the limit, even up to 100%, when the ingredient is declared on the label. The limit may be useful for already sensitised people to prevent elicitation.

However, for the most of the allergens, the maximum limit values are not based on Quantitative Risk Assessment (QRA) but arbitrarily chosen. Without a quantitative basis, it is impossible to assess whether these limits are sufficient to protect consumers from allergies. Therefore, an approach for QRA of sensitisers should be established. Furthermore, declaration limits might prevent already

sensitised people from elicitation, by avoiding products with the specific sensitiser on the label, but they do not necessarily protect new sensitisation cases. For sensitisers that need to be declared, also a maximum limit value could to be derived. For example, for those that are classified as strong or moderate sensitisers not only a limit of declaration should be used, but also specific maximum limit values could be derived.

For the sensitisers for which the limits have been set for textiles, these limit values may vary in different countries. For example, the regulations on formaldehyde for textiles in different countries including limits are presented in Table 20 below.

Table 20 The existing regulations on formaldehyde for textiles in different countries

Country	**Regulations on formaldehyde for textiles**	
	Conditions	**Requirements**
Netherlands	direct contact with skin	- Any containing more than 120 ppm formaldehyde must be labelled "Wash before first use" - After washing, these products must not contain more than 120 ppm
Germany	direct contact with skin	Release more than 1500 ppm formaldehyde must bear a label that states: "Contains formaldehyde. Washing this garment is recommended prior to first time use in order to avoid irritation of the skin."
France	For baby products & direct contact with skin	20 ppm
	direct contact with skin	100 ppm
	Not direct contact with skin	400 ppm
US		If a product contains 0.1% or more formaldehyde or can release formaldehyde into the air above 0.1 ppm, then the product label must include the following information, as required by OSHA's Formaldehyde standard, 29 CFR 1910.1048(m)(3): - a statement that the product has formaldehyde in it - the name and address of the manufacturer, importer, or other company responsible for the product - a statement that the employer and MSDSs can readily give health hazard information. Additionally, if the product can release formaldehyde into the air above 0.5 ppm, the label must also have the following information: - a list of all product health and safety hazards - the phrase "Potential Cancer Hazard".
China	For infants and babies	Less than 20 ppm
	direct contact with skin	Less than 75 ppm
	Not direct contact with skin	Less than 300 ppm

To protect the consumers from allergic reactions caused by textiles at a high level, harmonisation on the maximum limit values might be needed.

5. REVIEW OF AVAILABLE INFORMATION ON ALLERGY AND TEXTILES

5.1 Textile and the skin

5.1.1 General information

For millenniums, textile fabrics have been improved to assist in thermal and moisture regulation to and from the human body through engineering of fibres, yarns and fabric construction, and developing fabric finishes[69]. The main functions of clothes are protecting from environmental injuries and helping to regulate skin temperature and moisture. The interaction of textiles and the skin can be beneficial to people while it can also pose a threat to the health and well-being of people. For example, certain colorants and chemical-finish compounds contained in textile fabrics may transfer to skin and cause allergic reactions.

The skin is the interface between the body and the environment[70]. Each skin type has a specific skin physiology and is more or less adapted for protection against multiple stress factors. Human skin, except for palms and soles, is quite thin and of variable thickness. It has two layers: the epidermis (outer) and dermis (inner). Collagen and elastic components in the dermis allow it to function as a flexible barrier. The skin provides a unique shield which protects within limits against mechanical forces, or penetration by various chemical agents. The skin limits water loss from the body and guards against the effects of natural and artificial light, heat and cold. Intact skin and its secretions provide a fairly effective defence zone against micro-organisms, providing mechanical or chemical injury does not impair this defence. Figure 2 provides an illustration of the skin and subcutaneous tissue.

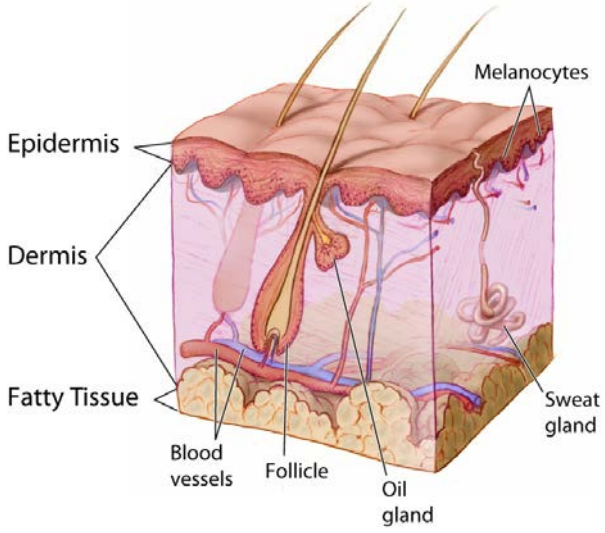

Figure 2 Various layers of the skin[71]

Clothing in particular interacts with the functions of the skin in a dynamic pattern[72]. Mechanical properties like roughness of fabric surface are responsible for non-specific skin reactions like wool intolerance orkeratosis follicularis. Thermoregulation, which is mediated by local blood flow and evaporation of sweat, is an important subject for textile-skin interactions. There are age-, gender- and activity-related differences in thermoregulation of skin that should be considered for the development of specifically designed fabrics.

5.1.2 Effects of textile on the skin

The skin is also an important immune organ with non-specific and specific activities. In the case of textiles, chemicals on or in the fibres of the textile can migrate on and into the skin and lead to skin symptoms, mainly dermatitis. Dermatitis is the inflammation of skin evidenced by itching, redness, and various skin lesions. Dermatitis may be due to one of several causes: systemic disease; skin irritants such as corrosives, acids, and alkalis; contact allergens such as textile dyes, resins or additives, or hypersensitivity to conditions that would not normally cause skin irritation[73]. Furthermore, the skin conditions such as hyperhidrosis, diabetic parients and aged skin, and genetic background (atopic dermatitis) can also increase chance of dermatitis.

The diagnosis of allergic types of contact dermatitis caused by clothing may be difficult because of its considerable clinical polymorphism and possible unusual patterns. In fact it could present with edematous, sometimes figurate, plaques, erythematous papules, purpuric lesions, erythema multiforme-like eruption, pigmented lesions, pustular lesions, generalized erythroderma.

The dermatitis caused by reaction of the skin in contact with a substance (contact dermatitis) includes:

- Allergic Contact Dermatitis (ACD),
- Contact Uticaria (CU),
- Erythema Multiforme-like Contact Uticaria (EMCD),
- Purpuric Allergic Contact Dermatitis (PACD)
- pigmented contact dermatitis
- pustular allergic contact dermatitis
- erythroderma contact dermatitis
- contact dermatitis presenting as lichen amyloidosis

In addition, tight clothing may cause Irritant Contact Dermatitis (ICD) resulting in:

- Miliaria
- Folliculitis
- Pressure urticarial

Besides above mentioned types of contact dermatitis, there is phototoxic dermatitis. This type of dermatitis occurs when the allergen or irritant is activated by sunlight.

ACD and ICD are the most important cutaneous conditions arising from clothing and other fabrics. These two types of contact dermatitis often appear to be visually identical. Based on the effects, it is hard to make a distinction between ACD and ICD. The distinction between ACD and ICD is based on a patient's history and clinical features, in combination with diagnostic patch testing.

- ACD: An allergic reaction is specific to the individual and to a substance (or a group of related substances) called an allergen. Allergy is a hypersensitivity (oversensitivity) to a particular substance, and always involves the immune system. All areas of skin that are in contact with the allergen develop the rash. The rash will disappear if you avoid contact with the substance.
- ICD: An irritant substance is one that would cause inflammation in almost every individual if it was applied in sufficiently high concentration for long enough. An irritant reaction is caused by the direct contact of an irritant substance with the skin and does not involve the immune system.

5.2 Scientific literature and epidemiological information on allergies and textiles

5.2.1 Skin contact dermatitis and chemicals in textiles

Textiles can cause cutaneous diseases. According to the report of Italian Health and Textile Associations[58], frequency of cases that textiles cause cutaneous diseases seems to increase over time with the globalisation of the textile market which consequently leads to the increasing market of products from the countries where manufacturing is less regulated and controlled.

It is difficult to determine the prevalence of contact dermatitis from textiles. It is partly because the studies published in literature refer almost exclusively to contact dermatitis from textile dyes. It is also because that the major part of the available data is not recent. That the patients in the conducted studies were selected with various criteria makes the results from different studies difficult to compare.

In Germany, between 1 and 2% of contact dermatitis in dermatological clinics are triggered by textiles[56]. The latest epidemiological study carried out by the Italian Contact and Environmental Dermatitis Research Group (GIRDCA) for the period of 1994-1998[74] indicates that textile (clothing) represented the fourth cost important cause of non-occupational contact dermatitis (8.5%) in Italy, after cosmetics, metal accessories and pharmaceuticals and followed by shoes. The substances in textiles which the most frequently cause contact dermatitis are dyes, especially disperse dyes. For instance, around 2/3 of all textile related cases of allergy are attributed to disperse dyes[75] [76]. At the second place, there are finishing resins and adhesive resins, particularly when they release formaldehyde. The prevalence and sensitisation to formaldehyde and formaldehyde resins, however, are progressively decreasing[56] [58].

The Italian Health and Textile Associations has mentioned in her report[58] that an epidemiological study has been carried out on contact dermatitis from textiles in cooperation with the Italian Association for Allergological, Professional and Environmental Dermatology (Società Italiana di Dermatologia Allergologica Professionale e Ambientale - SIDAPA). This study focused on both non-occupational and occupational contact dermatitis caused by textile fabrics as well as garment accessories and shoes. The results show that fabrics were the cause in 69.1% of patients, metallic garment accessories in 16.5% and shoes in 14.4%. In regard to fabrics, the contact was non-occupational in 88.8% of cases. This study confirmed that, in regard to the cases of non-occupational contact dermatitis caused by fabrics, the dyes represented the most common cause (44.3%). In agreement with the data from literature, the positive reactions were more often caused by dyes (78.9% of the total number of cases), especially Disperse blue 124 (54.3%) and disperse blue 106 (28.5%), with current occurrence in almost all cases. Moreover, allergic sensitisation to formaldehyde (5.9%) seems to have less aetiological importance compared to the past.

Allergic Contact Dermatitis (ACD)

ACD often results from an immune response to small, structurally simple, non-protein molecules which are capable of being absorbed by the skin. Thousands of different substances may trigger sensitisation and therefore cause ACD, including medicines, antioxidants, preservatives, antiseptics, biocides, pesticides, disinfectants and cleaning agents, metals, constituents of plastic and rubber materials, oils, pigments and dyes, cosmetics, depilatory waxes, Peru balsam, rosin, turpentine, plant (latex) and animal proteins and enzymes[61].

Allergic reactions, which are more frequent, require prior sensitisation to a substance and only develop when there is further contact with the substance after this induction period. Innate hypersensitivity reactions can be the result of an abnormal natural sensitivity in certain individuals to certain products. They may appear at first contact.

In a sensitized individual, ACD appears 24 to 96 hours after contact with the causative allergen. Its initial localization is at the site of contact[5]. The edges of the lesions may be well demarcated. However, it may also propagate in the immediate vicinity or to distant unrelated sites. Hands and face may be affected because of exposure to dyed textiles and/or because of contact with cross-reacting substances, such as hair dyes.

Possible allergens used in textiles causing ACD

Textile dyes

The most frequent allergens are textile dyes which are causes of acute dermatitis with rapid onset[77]. These reactive agents are also the principal ones in occupational allergic contact dermatitis from textile. This condition differs from the other forms of ACD for its location that normally regards the hands, the eyelids, the forearms and the wrists.

Textile dyes can be classified based on the procedure involved in applying dyes to textile. Information on fibre composition is the best information available from which one can reasonably deduce the colorant class or classes to which the colorant(s) on the fabric belong(s)[78 56]. Table 21 indicates the function group, chemical properties, dyeing principle of dyes linked to ACD, as well as the textile products in which the dyes are used.

Table 21 Overview of dyes linked to ACD

Function group	Substance name	Chemical properties	Dyeing principle	In which textile products the substance is used	Ref.
Disperse dyes	Disperse Blue 35 Disperse Blue 85 Disperse Blue 106 Disperse Blue 124 Disperse Red 1 Disperse Red 11 Disperse Red 17 Disperse Brown 1 Disperse Brown 2 Disperse yellow 3 Disperse Orange 3 Naphthol AS p-phenylenediamine (PPD)	- lipophilic (partially water solubility of approximately 30 mg per litre) - small molecules - mainly azoic and anthraquinone ones - additional organic solvents (dye accelerators, carriers) are used	Dispersing agents, balanced distribution, carriers, and chemical fibres	Synthetic fibres (such as polyester, acrylic/polyacrylonitrile and olefin/polypropylene), acetate and sometimes nylon fibres.	8 58 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96
Basic dyes	Basic Red 46 Basic Brown 1 Basic Black 1 Brilliant Green Turquoise		Binding via ion exchange	Wool, silk, cotton cellulosics and polyacrylnitriles.	75
Acid dyes	Acid Yellow 23 Supramine Yellow & Red Acid Violet 17	Include monoazoic, diazoic, triphenylmethane and antraquinone compounds	Binding via ion exchange	Wool, other protein fibres and some man-made fibres (nylon).	75
Direct dyes	Direct Black 38 Direct Orange 34	Water-soluble, treated with copper, chrome or formaldehyde to improve wet-fastness.	Deposition in cavities	Wool, cotton, flax (linen)	8 78
Vat dyes	Vat Green 1	Water-insoluble dyes, anthraquinones or indigoids	Redox dyeing process, high degree of fastness In use	Cellulosics and some wool	97
Reactive dyes	Red Cibacron CR (Reactive Red 238) Violet Remazol 5R (Reactive Violet 5)	Water-soluble, azo or anthraquinone structure or phthalocyanin derivative group, connected to a reactive group	Covalent binding to the fibres	Cotton, silk, wool and polyamides	98 99
Sulphur dyes				Cotton, particularly for black colors and work clothes	100
Dyes synthesized in	Coupling agents (naphthanols)	Insoluble azoics	Diazotised amine, coupled on fibre	Cellulosics and polyesters	

the fibre					
Oxidation base dyes, including phthalocyanin dyes		Aromatic amines, diamines and aminophenols oxidized with hydrogen peroxide	Color the fibre's interior	Sometimes cotton, generally fur and hair	
Pigments		Azo dyes, anthraquinones, phthalocyanins, indigoids and triphenylmethane, not readily soluble.	Textile printing, differ from dyes because they have no fibre affinity and are held to fabric with a resin binder	All textile products	[100]

The most common sensitizers belong to the disperse dye group, which loosely hold onto the fibres and are easily rubbed off[94]. Disperse blue 106 and disperse blue 124 have been reported to cause an allergic contact dermatitis to a variety of garments, which include underwear, blouses, pants, swimming suits, pantyhose, shoulder pads, and the velvet material of leggings and body suits. Literature data report their prevalence of sensitisation ranging between 3.1%[101] and 5.2%[102 103 104 105 106]. Patch tests with disperse dyes performed on children with suspected ACD and/or atopic dermatitis have shown a positivity of 4,6%: the most common sensitizer was Disperse Yellow 3[90]. It was discovered that in Israel the prevalence of sensitisation to Disperse Blue 124 and Disperse Blue 106 is similar to that in Italy, while in Australia sensitisation to Disperse Blue 106 and mainly Basic Red 46 prevails[58].

The basic dyes are the next most common allergens. They are mainly used to dye wool, silk, cotton cellulose and polyacrylonitriles[73].

According to the study of Hatch KL in 2003[78], among the colorants of the application classes of direct dyes, vat dyes, reactive dyes, sulphur dyes, azoic dyes and pigments, only 3 colorants (namely Direct Orange 34, Direct Black 38 and Vat Green 1), among the thousands of colorants in these classes have been identified as ACD allergens. However, it should be noted that with few exceptions textile dyes other than disperse dyes are not included in standard patch test series. Until now, even disperse dyes were tested routinely only in Italy and Portugal[77].The evidence on whether any non-disperse dye is an allergic contact allergen is scarce and debatable because they are rarely in patch test series.

Patch testing is routinely performed by applying a baseline series of the most frequently occurring contact allergens and those contact allergens that may be missed without routine screening. The choice of test concentration is based on patch test experience such that there's a minimum number of irritant reactions and a maximum of clinically explicable allergic positive reactions.

In regard to the reactive dyes, many have been identified as ACD allergens[78]. However, once applied to fabric they cannot be the cause of ACD because they are covalently bonded to the cellulose polymers, and any excess dye on a fabric has a valence state which destroys its ability to be an ACD allergen.

Textile finish resins

After textile dyes, formaldehyde and textile finish resins (also called durable-press resins or permanent press clothing finishes) are the most frequent reported allergens[77]. Formaldehyde resins often induce chronic dermatitis. These reactive agents are also the ones which have been of concern for occupational ACD in textile industries. The ACD caused by exposure to these agents differs from the other types of ACD for its locations of dermatitis are normally hands, eyelids, forearms and wrists[77].

The prevalence of ACD caused by formaldehyde in textiles in study population is to date calculated to be between 1.2% and 2.4% of the cases reported in the US and 4.2% in Israel[11 107 108 109].

Textile finish resins are widely applied on cotton, cotton/polyester or wrinkle-resistant linen[110]. Textile finish resins can also improve nylon and make it electrically antistatic. Other qualities of textile finish resins are expressed by their capabilities of improving fabric touch and appearance and rendering it waterproof, non shrinkable and mothproof. Most textile finish resins release variable amounts of formaldehyde which is considered to be one of the major causes of textile contact allergy.

Three major types of textile finish resins:

- the older formaldehyde based resins, include urea formaldehyde (dimethylol urea)resins and melamine-formaldehyde resins;

- the more recent cyclized urea derivatives, include dimethylol ethylene urea (DMEU), dimethyloldihydroxy ethylene urea (DMDHEU), dimethylol propylene urea (DMPU), dimethyloldihydroxy propylene urea(DMDHPU). These resins release various amounts of free formaldehyde. For instance, it has been suggested that DMDHEU may be the main cause of formaldehyde-associated allergy[12].
- recently also a third group of textile finish resins as substitute to formaldehyde has been developed. This case the alternatives synthetic resins developed are based on other aldehydes like glyoxal[56]. In terms of its chemical structure, reactivity, molecular size and its toxicity, glyoxal is very similar to formaldehyde.

Other textile finish resins are:
- dihydroxy dimethyl-imidazolidinone (DHDMI). DHDMI has been found not to release free formaldehyde[111] and is applied mostly in children's and infant's clothing[12].
- carbamate derivatives, especially used for mixed cotton-polyester, which release moderate amounts of formaldehyde.
- polycarboxylic acid systems, such as butane tetracarboxylic acid (BTCA), citric acid or modified poliycarboxylic acids.

Furthermore, the following substances are occasionally used to develop textile finish resins for textiles:
- polymeric acetates,
- silicone polymers,
- triazones,
- methyloldimethylhydantoin,
- epoxide resins,
- chloro-alkyl crosslinkers,
- chloromethyl ethers of polyhydric alcohols,
- divinylsulfone derivatives and
- tris (beta sulfato-ethyl) sulfonium salt.

In the report of BfR in 2007[56], it is concluded that allergic reactions to formaldehyde in garment textiles have not been of any relevance in previous years and formaldehyde containing resins in garment textiles plays no longer a role as allergens. Instead, glyoxal can be a candidate to be added to the list of occupational allergens in the healthcare sector[112]. However, this conclusion seems to be contradictory compared to the results from some other discussions. For example, in 2004 formaldehyde has been classified as human carcinogen by the International Agency on Research of Cancer (IARC). In addition, formaldehyde resins are used on fabrics and an allergic reaction may be caused by formaldehyde released from textiles have been showed in many literature references. According to the CLP Regulation, formaldehyde has been classified as H317, that means it may trigger allergenic reactions, and it was among the most frequently substances notified through the RAPEX system.
Limits for formaldehyde are not only established in voluntary schemes, such as Ecolabel and Oeko-tex standard, but also in several legislations (such as for example in China, Japan, USA, Germany, Austria, Finland, France, Norway, The Netherlands, Czech Republic and Slovenia). In a European survey on the release of formaldehyde from textiles carried out by the JRC in 2007[113], 221 textile samples bought on the European market were analysed. Results showed that 11% of samples intended for direct contact with skin released more than 30 mg/kg of formaldehyde (Ecolabel limit), the highest value being 162 mg/kg. In addition, formaldehyde has been classified as posing human health risks (+++), also to workers, in the Finnish case study textiles discussed in Chapter 4.2.5 of this report.

Other textile auxiliaries

A great number of chemicals other than dyes and textile finish resins are applied to textiles to impart special characteristics. These include:

- softeners,
- water repellents,
- flame-retardants,
- biocides and mothproofs.
- spot removers and dry cleaning agents

Except flame-retardants and biocides, the function groups mentioned above are normally not considered as sensitisers leading to ACD. It has been reported that flame retardants can cause ACD. There are only rare episodes of ACD caused by flame retardant chemicals described[23] [114]. ACD caused by biocides are rare, except for triclosan. Triclosan is reported to be used as a fungicide in 'odor eater' socks[115].

Substances found in textiles which may cause ACD include:

- Epoxy resins on textile labels in an unhardened form and epoxy resins used as a knee-patch adhesive;
- Antimicrobial 2,3,5,6-tetrachloro-4(methylsulfonyl)pyridine in table cloth[115]

Irritant Contact Dermatitis (ICD)

ICD is caused by contact with a substance that directly damages and irritates the skin. ICD can occur during first exposure and does not require an induction process. During development of ICD, skin inflammation is induced through activation of innate skin immunity and does not include specific immunity as it in ACD. The edges of the lesions may be well demarcated and will not propagate in the immediate vicinity.

Different substances used in textiles may cause ICD. These include the textile itself such as wool, certain types of phthalates, epoxy resins, tributyltin and sometimes mercurial compounds and detergents[73]. ICD can be divided into two groups: those caused by chemical irritants and those caused by physical irritants. The preliminary search showed that the observations of ICD due to textile products have been only made before 1976. This is because the applicable legislation has substantially changed since 1976.

ICD remains understudied compared to ACD. Most articles on contact dermatitis concern ACD. So far there is no diagnostic test available for ICD.

Other types of contact dermatitis

Contact urticaria (CU)

The number of patients described with CU is low. In a previous review of the European Commission, Joint Research Centre (JRC) on Human Exposure to Chemicals in Textiles[73], there were around 15 studies reported and circa 22 subjects identified having CU due to textile fibres (wool and silk), reactive dyes, textile resin as Tinofix S or textile lubricants as stearyl and cetyl alcohol.

CU is an immediate-type dermal reaction due to release of histamine and other pro-inflammatory substances from mast cells in the skin and tissues. The pathogenesis may be immune-mediated (probably an immediate hypersensitivity phenomenon IgE-mediated) or not immune-mediated. Some cases of CU with delayed onset have also been described (till 6 hours). This seems to be due to a delayed percutaneous penetration of large molecules of the responsible substance[77].

Erythema multiforme-like Contact Dermatitis (EMCD)
The pathogenesis of EMCD is not yet clear. It might be due to the induction of dermatitis in the site of primary contact. At the primary contact site the production of circulating antibodies and immune-complexes are generated. Erythema multiforme is a dermatosis in which the basic lesion is the most characteristic. Contact with degreasing agents such as tri-chlorethylene can cause this type of lesion[116].

The number of cases of EMCD is very low[73]. There are 12 observations reported with the following eliciting agents: nickel, cobalt, disperse dyes (Disperse Blue 124, Disperse Red 1, Disperse Orange 3, Disperse Orange 6, Disperse Black 1, Disperse Blue 106), dimethylaminoazobenzene (DMAAB) and para-aminoazobenzene (PAAB).

Purpuric allergic contact dermatitis (PACD)
PACD is not an uncommon clinical form of ACD due to exposure to textile dyes and resins[117]. Purpuric or lichenoid dermatitis occurs in the areas covered by the fabric. This type of dermatitis may be due to the azo dyes, formaldehyde and finishes rather than to a certain type of cloth. The reaction may start on the inner side of the thighs or arms and spread to affect most covered areas by the sensitizing cloth.

Base on the literature search, the allergens which can evoke the development of PACD include: Disperse Blue 106, Disperse Blue 124, Disperse Blue 85, Disperse Orange 3, Disperse Blue 35, Disperse Blue 153, Disperse Yellow 27, formaldehyde resins, isopropyl-phenyl-paraphenylenediamine(IPPD), ethyleneureamelamineformaldehyde, dimethyloldihydroxyethyleneurea, tetramethylolacetylenediurea, urea formaldehyde, melamine formaldehyde and Disperse Red 17[23 117 118 119 120 121 122 123 124 125 126 127 128]. Disperse blue dyes are the most often observed eliciting agents. However, the number of observations is low (around 27 observations)[73].

Other forms of allergic types of contact dermatitis caused by textiles are rarely reported. These include:

- *Pigmented contact dermatitis*
  It has been reported that 167 Danish patients developed this type of dermatitis after washing their clothing with a detergent which contained a mixture of 1-(3-chlorphenyl)-3-phenyl-pyrazoline and 1-(3-chlorphenyl)-3-(4-chlorphenyl)-pyrazoline[129]. An azo coupling component Naphthol AS (3-hydroxy-2-naphtoic acid anilide) has been reported the cause of this type of dermatitis[130].
- *Pustular allergic contact dermatitis*
  This type of contact dermatitis has been described very rarely. The most frequent allergens identified are Disperse Blue 124, Disperse Blue 85, Disperse Red 17 and Disperse Blue 106[131].
- *Erythroderma*
  Erythroderma may persist as long as contact with the allergen is not avoided with erythematous oedematous and erythemato-squamous lesions[100]. Regarding the responsible substances, textile dyes[131] and formaldehyde resins[108] have been reported.
- *Contact dermatitis presenting as lichen amyloidosis*
  This type of contact dermatitis has been reported in one case resulting from a exposure to formaldehyde and formaldehyde resins[132].
- *Phototoxic textile dermatitis*
  Phototoxic textile dermatitis is caused by substances that are transformed into allergens on sun exposure. Disperse Blue 35 has been reported as a cause of phthotoxic dermatitis[133 134]. It has been suggested that optical whiteners, applied directly to textile fibres or incorporated into detergents, may be responsible of phototoxic reactions[100].
- *Miliaria*

Miliaria occurs when obstructed sweat migrates into the living layers of the epidermis as well as the upper dermis. In textile industry, tight clothing may cause follicular irritation resulting in miliaria or folliculitis, elasticized clothing in particular where the garments fit too snugly[135]. Also when clothing absorbs sweat poorly, as is the case for Nylon, miliaria might occur[100].

- *Folliculitis*
  Patients with pseudomonas folliculitis usually give a history of exposure to warm water in a whirlpool, a public bath like a hot tub or some recreational spa for swimming. The rash can be local or generalized. It begins as papules, evolves then to papulopustules. Pruritus and pain may accompany the lesions[77]. Folliculitis has been found after recreational use of diving suits in some studies[136 137].
- *Pressure urticaria*
  Pressure urticaria may develop at skin area where the clothing fits too snugly[135]. For example, elasticized clothing may cause skin eruptions as a consequence of mechanical pressure[100].

The substances used in textiles (including the substances intended and not intended to remain on finished textiles) and conditions which have been reported to cause the contact dermatitis other than ACD and ICD described in this section are summarised in Table 22 below.

Table 22 The substances/reasons in textiles which link to other types of contact dermatitis than ACD and ICD

Type of contact dermatitis	Reported allergens
CU	- textile fibres (wool and silk), - reactive dyes, - textile resin as Tinofix S - textile lubricants as stearyl and cetyl alcohol.
EMCD	- nickel, - cobalt, - disperse dyes (Disperse Blue 124, Disperse Red 1, Disperse Orange 3, Disperse Orange 6, Disperse Black 1, Disperse Blue 106), - dimethylaminoazobenzene (DMAAB) - para-aminoazobenzene (PAAB).
PACD	- disperse dyes (Disperse Blue 106, Disperse Blue 124, Disperse Blue 85, Disperse Orange 3, Disperse Blue 35, Disperse 153, Disperse Yellow 27, Disperse Red 17) - formaldehyde resins, urea formaldehyde, melamine formaldehyde, ethyleneureamelamineformaldehyde - isopropyl-phenyl-paraphenylenediamine (IPPD), - dimethyloldihydroxyethyleneurea, - tetramethylolacetylenediurea,
Pigmented contact dermatitis	- optical whitener (Tinopal CH 2566) or other optics bleachers - - azo coupling component Naphthol AS (3-hydroxy-2-naphtoic acid anilide)
Pustular allergic contact dermatitis	- Disperse Blue 124, Disperse Blue 85, Disperse Red 17 and Disperse Blue 106
Erythroderma	- formaldehyde

Contact dermatitis presenting as lichen amyloidosis	-	formaldehyde and formaldehyde resins
Phototoxic textile dermatitis	-	Disperse Blue 35 and optical whiteners
Miliaria	-	sweat, pressure (tight clothing, nylon)
Folliculitis	-	Pseudomonas present in diving suits
Pressure urticaria	-	pressure

Atopic dermatitis

Atopic dermatitis (AD) is a chronically relapsing skin disorder with an immunologic basis. Staphylococcus aureus can cause secondary infection in AD and it may promote inflammation in eczema that does not look infected. It is an inherited cutaneous inflammatory condition which may affect 10% of infants[138]. AD patients are often sensitive to contact allergen. For example, some studies have shown that more patch test positive results for textile dyes have been observed in AD subjects compared to normal subjects[90 105 131 139].

Conventional silk which has smooth fibres has been used for the patients who have AD[140]. AD due to dust mite and cat allergens can be prevented with silver-coated textiles.

Itchy, red skin rash, heat rash and textiles[73]

Heat rash (Miliariarubra) is very common skin condition in newborns and in the first few weeks of life. Older children can also get miliariarubra, in which case it is often called “prickly heat.”

Ever since children began to wear diapers, diaper rash has been the most common skin disorder of infancy. A rash in the diaper area might be caused by for instance friction, irritants, allergies, infections, seborrhea, psoriasis and diarrhea.

Sensitive groups

The most common factors contributing to the development of ACD are pre-existing skin conditions such as ICD[141]. Cuts or scratches into which allergenic substances can enter, also contribute to the development of ACD. The chemical nature of the substance is important (for example, whether it is an acid, an alkali, or a salt), as are the amount and concentration that comes into contact with the skin, and the length and frequency of the exposure.

Important individual factors include the resistance of the skin which increases with age. Hereditary factors influence the variety of reactions in different persons exposed to the same allergen.

Environmental factors play a significant role. For example, hot weather cause sweating, which can dissolve some types of substances and mixtures, increasing their toxicity for the skin. But sweating may also provide a protective function because it may dilute or "wash out" substances. Dry air can cause chapping of the skin, increasing the possibility of allergies.

In addition to direct skin contact, allergy may be caused by airborne natural rubber latex. Thus, sensitized, yet undiagnosed, individuals are at risk when in contact with airborne immunologic contact urticaria allergens.

Individuals with AD are predisposed to immunologic contact urticarial (emedicine Medscape contact uticaria syndrome). Cross-allergy can also induce immunologic contact urticaria reactions. The patient may be sensitized to one protein and react to other proteins that contain the same or similar allergenic molecules.

Contact dermatitis to clothes is usually located in the axillae, which is due to the release of allergens from the textile under the action of sweat and friction.

Textile contact dermatitis is more common in women than in men because women wear close-fitting and colourful clothing more often. New clothing is most likely to provoke allergic contact dermatitis, since most allergens decrease in concentration in clothing following repeated washings.

5.2.2 Respiratory sensitisation/irritation and chemicals in textiles[73]

Early cases of potential hypersensitiveness to textile fibre such as silk and exacerbation of asthma attacks were reported by several authors. Publications before 1940 reported cases of asthma supposed to be due to a silk[142 143 144]. However, these studies did not prove sensitivity immunologically or clinically and also did not show that silk was the only sensitisation. In another study, a 6[1]/2-year-old girl silk sensitivity was proven immunologically and clinically by suitable diagnostic criteria; moreover, the respiratory system was the only shock organ, and silk was the only sensitisation[145]. Two reports related asthma, cyanosis and respiratory shock to silk as a contaminant in vaccines used in filtering procedures[146 147].

Some studies showed that the individuals allergic to skin are atopic[148 149]. The main allergen of silk textiles is sericin, a gelatinous nitrogenous material extracted from crude silk and other similar fibre by boiling water, which glues together two fibroin filaments of the silk thread.

Respiratory health effects associated with textiles in the indoor environment can also occur indirectly. House dust mites and their debris and excrements that contain the allergens are normally found in the home in beds, mattresses, pillows, carpets and furniture stuffing. House dust mites, pets, insects, plants, moulds and chemical agents in the indoor environment are important causes of diseases such as allergic asthma and rhino-conjunctivitis. Thus the increase in morbidity and mortality for asthma and allergies may also be due to an increase in exposure to allergens in the indoor environment[150 151].

Other studies concerning respiratory sensitisation can be found, but these are often related to occupational exposure. There is for example a study on respiratory sensitisation of colorants by INRS[152]. In this study it is indicated that reactive colorants pose a risk of respiratory irritation when present as powder, which is easily inhalable. In the light of evaluating chemicals and their risks in consumer products, this type of risk is of course of less importance.

5.3 Nanotechnology in textiles

Nanomaterials and nanotechnological applications are increasing rapidly in textile production and finishing. “Nano” finishing is the term used to describe the application of particles (between 10nm and 100nm in size) and also the application of oligomer or polymer substances which form a thin layer. Nano particles may be integrated into synthetic fibres or applied to the surface of fibres during final finishing textiles to add durability and permeability and to facilitate cleaning. The applied layers may freely coat the fibres or be covalently bound to the fibre material. Examples are the biocide finishing of fibres using silver particles and sunscreen finishing with titanium dioxide or zinc oxide. Nanotechnology in cosmetic textiles is also a growing market particularly in ladies’ tights.

When it comes to possible hazard potential, the focus in the case of textiles is on nano particle abrasion and inhalational or oral exposure. Given the size of the particles it is not assumed that here is any uptake of textile material through the skin[56].

Currently, regulatory and non-regulatory governance of nanomaterials is under development, especially regarding environmental and health risks[59]. Scientific bodies (SCENIHR, EFSA, EMA) and OECD concur that risk assessment methodologies are generally applicable to nanomaterials, even though specific aspects related to nanomaterials still require further development. Despite a continuous improvement on toxicological knowledge about nanomaterials (indicating that nanomaterials are similar to other chemicals in that some are toxic and others are not), very little empirical and verifiable information on the environmental fate and biological effects of these materials is as yet available. Analytical methods and predictive models have yet to be developed to measure the occurrence of nanomaterials in various matrices, environmental and other.

Nanomaterials are defined by Commission Recommendation 2011/696/EU. They are also covered by the definition of 'substance' in REACH legislation. Several official bodies have been set up for nanomaterials at EU level, especially in the area of chemicals control. Moreover, there are important voluntary initiatives, notably the European Commission’s Code of Conduct for Responsible Nanosciences and Nanotechnologies Research.

6. INFORMATION COLLECTION ON CHEMICALS IN TEXTILE PRODUCTS

6.1 General information on textile industry in the EU

The textile and clothing industry is a diverse and heterogeneous industry which covers an important number of activities from the transformation of “natural” or “man-made” fibres to yarns and fabrics to the production of a wide variety of products such as hi-tech synthetic yarns, wool, bed-linen, industrial filters, geo-textiles, clothing etc.

In relation to textile materials, the terms "man-made", "synthetic" and "artificial" fibres are often used interchangeably. According to the manufacturing processes used, "synthetic" fibres are those gained through polymerization of organic monomers, while "artificial" fibres are obtained through chemical transformation of natural organic polymers.

The number of substances and mixtures used in the textile supply chain is enormous. In the 2005 study on the impact of REACH in the textile industry[30] it is concluded that European textile supply chain uses about 1500 basic substances and about the same number of specialty substances, which combine to yield about 15 000 mixtures.

The data and figures below from EURATEX give an indication on the textile and clothing import and export in EU-27 in 2011.

Table 23 Textile suppliers of EU-27 in 2011 (top 5)

	Country	Million Euro
1	China	7,678
2	Turkey	3,947
3	India	2,701
4	Pakistan	1,967
5	United States	1,040
	Total	17,333

Figure 3 Percentage of top 5 textile suppliers of EU-27 in 2011 (top 5)

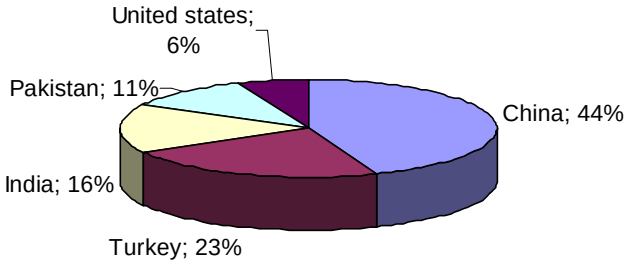

Table 24 Textile customers of EU-27 in 2011 (top 5)

	Country	Million Euro
1	United States	1,944
2	Turkey	1,679
3	China	1,579
4	Switzerland	1,386
5	Tunisia	1,355
	Total	7,943

Table 25 Clothing suppliers of EU-27 in 2011 (top 5)

	Country	Million Euro
1	China	29,744
2	Turkey	8,195
3	Bangladesh	7,522
4	India	4,627
5	Tunisia	2,413
	Total	52,501

Figure 4 Percentage of top 5 clothing suppliers of EU-27 in 2011 (top 5)

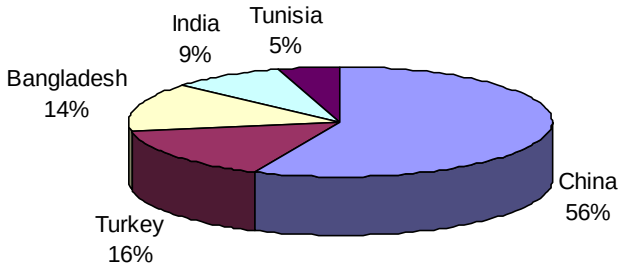

Table 26 Clothing customers of EU-27 in 2011 (top 5)

	Country	Million Euro
1	Switzerland	3,302
2	Russia	2,734
3	United States	1,795
4	Hong Kong	1,154
5	Japan	1,097
	Total	10,082

6.2 Information gathering via questionnaires

6.2.1 General information

The information of chemical substances was collected by the mean of questionnaires (attached as annex 7 of this report). The questionnaires have been made with the assistance of textile associations and industries for three target groups:

- Questionnaire for importer and retailer of textiles
- Questionnaire for manufacturer, formulator and importers of substance and mixtures used in textiles
- Questionnaire for users of substance and mixtures for textile products

The questionnaires were distributed via textile associations and to individual textile companies. The filled in questionnaires were received from the associations and companies listed in Table 27 below.

Table 27 The associations and companies who responded to the questionnaires

Name of the association or company	Region covered or based country	Role in supply chain according to the questionnaire feedback
AEDT-The European Association of Fashion Retailers	Europe	Retailer and importer of finished textile products
CIRFS-the European Man-made Fibres Association	Europe	User of textile chemicals
Coats PLC	Hungary	User of textile chemicals
ETAD-the Ecological and Toxicological Association of Dyes and Pigments manufacturers	Europe	Producer of textile dyes
Euratex-The European Apparel and Textile Confederation	Europe	Producer of textile and clothing products
H&M	Europe	Retailer and importer of finished textile products
InoTEX	Czech Republic	Producer, importer and formulator of textile auxiliaries (including dyes) User of textile chemicals
TEGEWA-the German Association of Producers of Textile Auxiliaries and Textile Dyestuffs	Germany	Producer of textile auxiliaries and textile dyestuffs
Verband der Nordwestdeutschen Textil- u. Bekleidungsindustrie e.v.	Germany	Retailer and importer of finished textile products User of textile chemicals
VGT-Vereniging van Grootwinkelbedrijven in Textiel	The Netherlands	Retailer and importer of finished textile products

The number of questionnaires received is relatively high compared to the comparable studies. However, much information requested in the questionnaires (e.g. use concentration, user group etc.) are lacking in textile industries. No information on alternatives is available. Moreover, some substances listed in the questionnaires are not workable as the name is trade name and the CAS no. of the substance is not indicated. Figure 5 below shows the percentage of workable information from the questionnaires. The received questionnaires are attached in Annex 8 of this report.

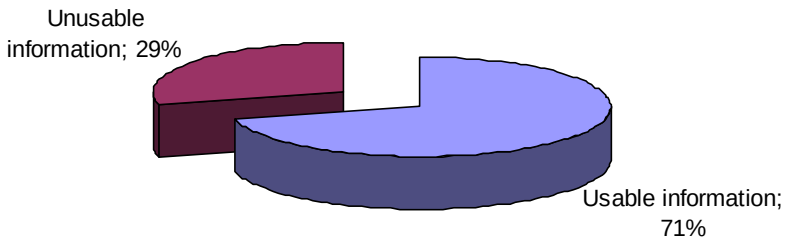

Figure 5 Percentage of usable information vs. unusable information from the questionnaires.

Due to the lacking of information and due to the confidentiality, the textile industries did not provide or only a few industries provided answers to some of the questions in the questionnaires. The information requested in the questionnaires and received includes:

- Role of the replying company
- Whether a sensitiser (H317/R43 or H334/R42) or a irritant (H315/R38 or H335/R37) is used in the textile products
- Information on the sensitising or irritating substance (not all the responded industries)
- Function group of the sensitising or irritating substance (not all the responded industries)
- In which type of textile products the sensitising or irritating substance is used and remains (not all the responded industries)

The information requested in the questionnaires and not received are:

- User group(s) of the textile products which contains sensitising or irritating substances
- Concentration or percentage range of the substance remained on the finished textile products

All the textiles industries which responded the questionnaires answered “no” to the questions below:

- Availability of alternatives
- Whether complaints have been received on the substances other than the ones indicated

6.2.2 Market volume and exposure

Market volume estimation

Based on the discussion with the textile associations and companies/industries involved in the present study, it is difficult to obtain information on market volumes of chemicals substances. This is due to the following reasons:

- There is no database for this information.
- This information might be confidential for the companies and they will not share this information for competitive reasons.
- Most of the substances are purchased in a mixture (such as dyeing mixture) or are contained in an article (e.g. finished textile products). In many cases, it is unknown which substances are in the mixture or in the article.

For the reasons above, no data has been made available to indicate substance specific information on market volume. In-house data of TEGEWA in 2011 (Table 28) gives some indications on the market volume of chemical substances per category. The members of TEGEWA are the producer of textile auxiliaries and textile dyestuffs. The market share of TEGEWA member companies is estimated to be 80 – 85% in EU-27. However, it has to be noted that these data do not represent the whole EU market for the substances produced, imported and used in textiles as TEGEWA only covers the producers of textiles and the producers of substances used in textiles. The information on imported textile substances or the substances contained in the imported textile products are not represented by TEGEWA data. Moreover, this information can not be used as a proxy for exposure also because the substance category is very broad and substances specific information are lacking.

Table 28 Textile auxiliaries sold by TEGEWA member companies to the textile and fiber processing industry in EU-27 in 2011

Substance category*	Tonnage	Whether it is intended to remain on the finished textile products
Auxiliaries for fibers and yarns (spin finishes)	19,000	Not intended to remain
Auxiliaries for weaving and knitting	5,500	Not intended to remain
Pretreatment agents	12,500	Not intended to remain
Dyeing auxiliaries (without dyestuffs)	44,000	Not intended to remain
Printing auxiliaries	15,500	Partly intended to remain
Finishing auxiliaries	69,000	Intended to remain
Multipurpose auxiliaries	12,000	Not intended to remain

***** *This information cannot be used as a proxy for exposure, because the groupings are too broad; more detailed information would be needed.*

Exposure

The exposure of consumers to the potential allergens used and remaining on finished textiles products can not be estimated based on the information reported by the textile industries via the questionnaires. This is because that most of the industries are not able to give answers to the questions related to exposure, like in which products the substances are used, users groups (children or general population), and concentration of substance used.

In the report from the Italian Health and Textile Association, the percentages of some chemical mixtures used at the finishing stage of the manufacturing have been indicated[58]. The most important information is summarised in Table 29 below. However, this information is not sufficient for an indication on the exposure of consumers to the potential allergens used and remaining on finished textiles products.

Table 29 The percentage indication on the use of chemical mixtures in textiles finishing stage

Manufacturing processes	Chemical mixtures	Percentage used in textiles
Dyeing – protein fibre dyeing	Levelling agent, acetic acid	0.1-3%
Dyeing – cellulose fibre dyeing	Anti-foaming agent, acid dyes, premetallised dyes	0.01-8%
Dyeing – Synthetic fibre dyeing	Softener, silicone softener, anti-reducing agent, fixing agent, wetting agent, sequestering agent, levelling agent,	0.1-6% Specifically: for reactive dyes 0.1-10%

	reactive dyes, sodium sulphate, sodium carbonate	for sodium sulphate and carbonate 5-100%
	Softener	1-6%
	Dispersant, acetic acid, cationic dyes, acidic dyes, premetallised dyes, disperse dyes	Products 0.1-3% Dyes 0.1-6%
Printing – Direct printing	Acrylate thickener, emulsifier, binder, cross-linking agent, softener, dispersant, pigments	0.5-2% Specifically: binder 8%
Printing – Discharge printing	Thickener, deaerating agent, hygroscopic agent, Rongalite C, potassium carbonate	Thickener 50% Deaerating agent 0.5% Hygroscopic agent 4% Rongalite C 10% Potassium carbonate 6%
	Dyes	0.1-6%
Printing – Ink-jet printing	Disperse ink, pigment ink	40%
Finishing – Special chemical finishing	Softener, acetic acid,	Softener 0.5-6% Acetic acid 0.03-0.3%
	Wetting agent	0.05-1%
Finishing - Coating	Acrylic thickener, catalyst	0.02%
	Acrylic resin, polyurethane resin, pigment, fire retardant, anti-foaming agent	3-5% Specifically: pigment 0.03% fire retardant 10%

It should be noted that the true exposure of consumers to the potential allergenic substances on finished textile products is to the substances which can be released from the products and absorbed by the skin (or airway). According to the findings of BfR[56], it is almost impossible to indicate a specific value for textile dyes because the degree of release may vary considerably. The exposure to dyes depends on which dye category, dye content (colour intensity) and fastness are examined in the respective textile substrate. It is also necessary to consider the conditions of wear and dermal absorption.

The exposure to textiles via the skin can be assessed based on migration data and skin penetration data. However, there is not much data is available on the migration and penetration of dyes and textile auxiliaries. Based on the studies evaluated, BfR recommends the following default values as worst case assumptions when no measurement results are available (Table 30). These default values are based on experimental data determined by way of example for the initial estimation of possible exposure.

Table 30 BfR recommended default values as the worst case assumption if no other values are available

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.

Given the properties (small molecular size, high lipophilicity) of disperse dyes 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. Dispersive dyes loosely hold onto the fibres and are easily rubbed off.

Disperse-dye-positive patients are likely to have a considerable number of suspect items because polyester fibre is a component in many fabrics. Acetate (cellulose acetate) is a popular lining fabric in lined jackets and slacks and in fanny/formal dresses. Triacetate and nylon is a fibre combination often in fabrics for women's intimate apparel and sleepwear.

Dye fastness is a measure of the ability of the fabric to retain dye molecules under various conditions. The phrase 'at time of purchase' has been used because dye fastness changes (usually improves) as a textile product is used, because dye molecules may be lost during laundering, as the fabric is abraded (rubbed) and as dye molecules are destroyed by the sun, ozone and other agents. Considering the dyes fastness does not allow items to be removed from the suspect list but allows items to be grouped as 'more likely suspects' and 'less likely suspects'. Consider the:

- wet fastness or color bleeding
- fastness to rubbing.
- fastness to perspiration

6.2.3 Allergenic substances used and remaining on finished textile products

The outcomes of the questionnaires are summarised in the tables below by allergenic characteristics (sensitising or irritating) and function groups. The type of textile products in which the substances are used and whether the used substances remain on finished textile products are also indicated in the tables.

Sensitising substances

Disperse dyes

- Skin sensitiser (H317/R34)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Disp. Blue 1	2475-45-8	Natural & synthetic fibres, textile incl. pigment print, clothing, bed linen	Yes
2	Disp. Blue 3	2475-46-9	Natural & synthetic fibres, textile incl. pigment print	Yes
3	Disp. Blue 7	3179-90-6	Natural & synthetic fibres, textile incl. pigment print	Yes
4	Disp. Blue 26	3860-63-7	Natural & synthetic fibres, textile incl. pigment print	Yes
5	Disp. Blue 35	12222-75-2	Natural & synthetic fibres, textile incl. pigment print, clothing	Yes
6	Disp. Blue 73	1222-78-5	Suit, tie, scarf	Yes
7	Disp. Blue 102	12222-97-8	Natural & synthetic fibres, textile incl. pigment print	Yes
8	Disp. Blue 106	68516-81-4 12223-01-7	Natural & synthetic fibres, textile incl. pigment print, clothing	Yes
9	Disp. Blue 124	15141-18-1 61951-51-7	Natural & synthetic fibres, textile incl. pigment print, clothing	Yes
10	Disp. Blue 183:1	2537-62-4	Synthetic fibres	Yes
11	Disp. Blue 291	56548-64-2 51868-46-3	Synthetic fibres underlining, clothing	Yes
12	Disp. Blue	3065-87-0	Garments	Yes
13	Disp. Green 9	58979-46-7	Synthetic fibres	Yes
14	Disp. Orange 1	2581-69-3	Natural & synthetic fibres, textile incl. pigment print	Yes
15	Disp. Orange 3	730-40-5	Natural & synthetic fibres, textile incl. pigment print,	Yes
16	Disp. Orange 11	82-28-0	Natural & synthetic fibres, textile incl. pigment print	Yes
17	Disp. Orange 30	5261-31-4	Synthetic fibres	Yes
18	Disp. Orange 37 / 76	12223-33-5 51811-42-8 13301-61-6	Natural & synthetic fibres, textile incl. pigment print, clothing	Yes
19	Disp. Orange 44	4058-30-4	Synthetic fibres	Yes
20	Disp. Orange 149	85136-74-9	Natural & synthetic fibres, textile incl. pigment print	Yes
21	Disp. Red 1	2872-52-8	Natural & synthetic fibres, textile incl. pigment print, clothing	Yes
22	Disp. Red 11	2872-48-2	Natural & synthetic fibres, textile incl. pigment print	Yes
23	Disp. Red 17	3179-89-3	Natural & synthetic fibres, textile incl. pigment print	Yes

24	Disp. Red 82	30124-94-8	Synthetic fibres	Yes
25	Disp. Red 279	72827-94-2	Synthetic fibres	Yes
26	Disp. Violet 1	168681-27-4	Yarn	Yes
27	Disp. Violet 57	1594-08-7	Synthetic fibres	Yes
28	Disp. Violet 93	66557-45-7 52697-38-8	Synthetic fibres, underlining	Yes
29	Disp. Yellow 1	119-15-3	Natural & synthetic fibres, textile incl. pigment print	Yes
30	Disp. Yellow 3	2832-40-8	Natural & synthetic fibres, textile incl. pigment print, clothing	Yes
31	Disp. Yellow 9	6373-73-5	Natural & synthetic fibres, textile incl. pigment print	Yes
32	Disp. Yellow 23	6250-22-3 6250-23-3	Natural & synthetic fibres, textile incl. pigment print	Yes
33	Disp. Yellow 39	12236-29-2	Natural & synthetic fibres, textile incl. pigment print	Yes
34	Disp. Yellow 42	5124-25-4	Garments; suit, tie, scarf	Yes
35	Disp. Yellow 49	54824-37-2	Natural & synthetic fibres, textile incl. pigment print	Yes
36	Disp. Yellow 82	12239-58-6	Synthetic fibres	Yes
37	Disp. Brown 1	23355-64-8	Natural & synthetic fibres, textile incl. pigment print	Yes

- Respiratory sensitiser (H334/R42)

No disperse dye with respiratory sensitising characteristics which is used in textiles has been reported in the questionnaires.

Reactive dyes

- Skin sensitiser (H317/R34)

	Substance name	**CAS no.**	**In which type of textile products it is used and remains?**	**Whether remaining on finished textile products?**
1	React. Black 5	17095-24-8	Natural fibres(especially cotton), yarn, garment, sheeting, fabric for suit	No
2	React. Black 8 (Co) React. Black 8	70776-55-5 70776-54-4	Natural fibres(especially cotton), garments, suit, tie, scarf	No
3	React. Blue 13	14692-76-3	Natural fibres(especially cotton), garments, suit, tie, scarf, sheeting	No

4	React. Black 31 (4 Na)	12731-63-4	Natural fibres(especially cotton)	No
5	React. Black 39	68259-02-9	Natural fibres(especially cotton), suit, tie, scarf, sheeting and garments	No
6	React. Black 50	70210-42-3	Yarn, fabric for suit	No
7	React. Black		Yarn	No
8	React. Blue 29	280-400-1	Garments	No
9	React. Blue 49	72214-18-7	Natural fibres(especially cotton), suit, tie, scarf, sheeting and garments	No
10	React. Blue 50	12225-61-5	Natural fibres(especially cotton)	No
11	React. Blue 114	72139-17-4	Natural fibres(especially cotton), yarn	No
12	React. Blue 116	71786-55-5	Sheeting and garments	No
13	React. Blue 198	84434-51-5	Natural fibres(especially cotton)	No
14	React. Blue 204	85153-92-0	Natural fibres(especially cotton)	No
15	React. Blue 220	90341-71-2 101678-62-0 128416-19-3	Natural fibres(especially cotton), suit, tie, scarf, sheeting and garments	No
16	React. Blue 221	760902-85-0 84057-71-6	Natural fibres(especially cotton), yarn	No
17	React. Blue 264	161935-19-9	Yarn	No
18	React. Blue 279		Yarn	No
19	React. Blue	90341-72-3	Sheeting and garments	No
20	React. Orange 4 (acid) React. Orange 4 (3 Na)	73816-75-8 70616-90-9	Natural fibres(especially cotton)	No
21	React. Orange 12 React. Orange 12 (3 Na) React. Orange 12 (x Na) React. Orange 12 (acid)	82600-93-9 70161-14-7 93658-87-8 35642-64-9	Natural fibres(especially cotton), sheeting and garments	No
22	React. Orange 30	72639-29-3 276-752-0	Sheeting and garments	No
23	React. Orange 35	70210-13-8	Sheeting and garments, suit, tie, scarf	No
24	React. Orange 64	83763-57-9	Natural fibres(especially cotton), sheeting and garments	No
25	React. Orange 67	83763-54-7	Natural fibres(especially cotton)	No
26	React. Orange 72	71902-15-3	Natural fibres(especially cotton)	No

27	React. Orange 86 (acid) React. Orange 86 (3 Na)	76213-76-8 57359-00-9	Natural fibres(especially cotton)	No
28	React. Orange 91	63817-39-0	Natural fibres(especially cotton)	No
29	React. Orange 107 (2 Na) React. Orange 107	85765-41-9 94158-82-4	Natural fibres(especially cotton), sheeting and garments	No
30	React. Orange 132	149850-31-7	Yarn	No
31	React. Orange (2 Na)	129009-88-7	Natural fibres(especially cotton)	No
32	React. Red 3:1	93941-05-0/ 93941-07-2	Natural fibres(especially cotton), suit, tie, scarf, sheeting and garments	No
33	React. Red 24 (3 Na)	70210-20-7	Natural fibres(especially cotton)	No
34	React. Red 24:1	162127-93-7	Natural fibres(especially cotton)	No
35	React. Red 65	70210-40-1	Natural fibres(especially cotton)	No
36	React. Red 66	70210-39-8	Natural fibres(especially cotton), fabric for suit	No
37	React. Red 83	70210-00-3	Natural fibres(especially cotton)	No
38	React. Red 120	61951-82-4	Natural fibres(especially cotton)	No
39	React. Red 123 (2 Na) React. Red 123 (x Na)	68959-17-1 85391-83-9	Natural fibres(especially cotton), sheeting and garments, yarn	No
40	React. Red 124	72152-49-9	Natural fibres(especially cotton), sheeting and garments	No
41	React. Red 158 (Na/Li Salt)	83400-11-7	Natural fibres(especially cotton), sheeting and garment, yarn	No
42	React. Red 159 (Na/Li Salt)	83400-12-8	Natural fibres(especially cotton), yarn, sheeting and garments	No
43	React. Red 187	72829-25-5	Natural fibres(especially cotton)	No
44	React. Red 195 (5 Na)	77365-64-1	Natural fibres(especially cotton)	No
45	React. Red 225 (x Na)	83399-95-5	Natural fibres(especially cotton)	No
46	React. Red 231		Yarn	No
47	React. Red 239	89157-03-9	Yarn	No
48	React. Red 241	133608-49-8	Natural fibres(especially cotton)	No
49	React. Red 245	137100-10-8	Natural fibres(especially cotton)	No
50	React. Red 264	171599-85-2	Yarn	No
51	React. Red ed-7b		Yarn	No
52	React. Red lf-b	763101-82-2	Yarn	No
53	React. Red SR 6947	130201-57-9	Suit, tie, scarf	No

54	React. Yellow 25	72139-14-1	Natural fibres (especially cotton)	No
55	React. Yellow 27	75199-00-7 278-108-4	Natural fibres (especially cotton), sheeting and garments, yarn	No
56	React. Yellow 39	70247-70-0	Natural fibres (especially cotton), garments, yarn, fabric for suit, tie, scarf	No
57	React. Yellow 95	84045-63-6	Natural fibres (especially cotton), sheeting and garments	No
58	React. Yellow 125		Yarn	No
59	React. Yellow (x Na)	763101-82-2	Natural fibres (especially cotton)	No
60	React. Yellow (4 Na)	148967-78-6	Natural fibres (especially cotton)	No
61	React. Violet 33	69121-25-1	Natural fibres (especially cotton)	No
62	React. Violet red		Yarn	No
63	React. Brown 11	70161-16-9	Natural fibres (especially cotton)	No
64	React. Brown 19	83399-85-3 280-398-2	Natural fibres (especially cotton), garments	No
65	React. Green 21	71243-96-4	Sheeting and garments	No

- Respiratory sensitiser (H334/R42)

	Substance name	**CAS no.**	**In which type of textile products it is used and remains?**	**Whether remaining on finished textile products?**
1	React. Black 5	17095-24-8	Natural fibres (especially cotton), yarn, garment, sheeting, fabric for suit	No
2	React. Black		Yarn	No
3	React. Blue 19	2580-78-1	Natural fibres (especially cotton)	No
4	React. Blue 21	73049-92-0	Natural fibres (especially cotton), yarn, garments	No
5	React. Blue 38 (4 Na)	97280-68-7	Natural fibres (especially cotton)	No
6	React. Blue 114	72139-17-4	Natural fibres (especially cotton), yarn.	No
7	React. Blue 160	68132-91-2	Natural fibres (especially cotton)	No
8	React. Blue 171	68133-24-4	Natural fibres (especially cotton)	No
9	React. Blue 203	84229-70-9	Natural fibres (especially cotton)	No
10	React. Blue 204	85153-92-0	Natural fibres (especially cotton)	No
11	React. Blue 221	760902-85-0 84057-71-6	Natural fibres (especially cotton), yarn	No

12	React. Orange 4 (acid) React. Orange 4 (3 Na)	73816-75-8 70616-90-9	Natural fibres (especially cotton),	No
13	Reactive Orange 12 React. Orange 12 (3 Na) React. Orange 12 (x Na) React. Orange 12 (acid)	82600-93-9 70161-14-7 93658-87-8 35642-64-9	Natural fibres (especially cotton), sheeting and garments	No
14	React. Orange 14	12225-86-4	Natural fibres (especially cotton),	No
15	Reactive Orange 16 React. Orange 16 (2 Li)	20262-58-2 106027-83-2	Natural fibres (especially cotton), sheeting and garments, suit, tie, scarf and furniture	No
16	React. Orange 64	83763-57-9	Natural fibres (especially cotton), sheeting and garments	No
17	React. Orange 67	83763-54-7	Natural fibres (especially cotton)	No
18	React. Orange 86 (acid) React. Orange 86 (3 Na)	76213-76-8/ 57359-00-9	Natural fibres (especially cotton)	No
19	React. Orange 91	63817-39-0	Natural fibres (especially cotton)	No
20	React. Red 21 (4 Na) React. Red 21	85940-66-5 80419-51-8	Natural fibres (especially cotton), yarn	No
21	React. Red 29 (acid) React. Red 29 (5 Na) React. Red 29 (4 Na)	77093-20-0 94006-25-4 70865-39-3	Natural fibres (especially cotton)	No
22	React. Red 43 (3 Na)	64181-81-3	Natural fibres (especially cotton)	No
23	React. Red 65	70210-40-1	Natural fibres (especially cotton)	No
24	React. Red 66	70210-39-8	Natural fibres (especially cotton)fabric suit	No
25	React. Red 120	61951-82-4	Natural fibres (especially cotton)	No
26	React. Red 123 (2 Na) React. Red 123 (x Na)	68959-17-1 85391-83-9	Natural fibres (especially cotton), sheeting and garments, yarn	No
27	React. Red 219	149057-72-7	Natural fibres (especially cotton)	No
28	React. Red 225 (x Na)	83399-95-5	Natural fibres (especially cotton)	No
29	React. Violet 5 (3 Na)	63105-49-7	Natural fibres (especially cotton)	No
30	React. Violet 33	69121-25-1	Natural fibres (especially cotton)	No
31	React. Yellow 25	72139-14-1	Natural fibres (especially cotton)	No
32	React. Yellow 15 (2 Na)	25664-81-7	Natural fibres (especially cotton)	No
33	React. Yellow 39	70247-70-0	Natural fibres (especially cotton), garments, yarn, fabric for suit, tie, scarf	No

34	React. Yellow 57		Yarn	No
35	React. Yellow 145 (4 Na)	80157-00-2	Natural fibres (especially cotton)	No
36	React. Yellow 175	111850-27-2	Natural fibres (especially cotton)	No

Other dyes

- Skin sensitiser (H317/R34)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Acid Black 61	12269-79-3	Various fibres	No
2	Acid Black 194	57693-14-8	Yarn, nylon, garments, suit, tie, scarf	No
3	Acid Black 207	84145-95-9	Yarn	No
4	Acid Blue 185	1330-38-7	Various fibres	No
5	Acid Blue 225	70209-96-0	Various fibres, garments	No
6	Acid Blue 317	68541-71-9	Fabric for suit	No
7	Acid Brown 289	52587-68-5	Various fibres, fabric for suit	No
8	Acid Brown 298	70236-62-3	Various fibres, garments	No
9	Acid Green 111	58419-36-6	Various fibres	No
10	Acid Green	85407-92-7	Garments	No
11	Acid Red 260	52333-30-9	Various fibres	No
12	Acid Red 447 (xK xNa)	141880-36-6	Various fibres	No
13	Acid Yellow 42	6375-55-9	Various fibres	No
14	Acid Yellow 79	41741-86-0	Fabric for suit	No
15	Acid Yellow 199	70865-20-2	Various fibres	No
16	Acid Yellow 220	70851-34-2	Fabric for suit	No
17	Acid Orange 156	68555-86-2	Nylon	No
18	Acid Grey	51147-75-2	Garments	No
19	Yellow E-JD 3442	147703-65-9	Nylon	No
20	Sulphur Black 6	1327-16-8	yarn	No
21	Direct Red 243	52953-36-3	Yarn	No*
22	Direct Yellow 27	10190-68-8, 98113-29-2	Suit, tie, scarf	No*
23	Solvent Yellow 1 (CI 11 000)	60-09-3	Natural & synthetic textile incl. pigment print	Yes

24	Solvent Yellow 2 (CI 11 020)	60-11-7	Natural & synthetic textile incl. pigment print	Yes
25	Solvent Yellow 3 (CI 11 160)	97-56-3	Natural & synthetic textile incl. pigment print	Yes
26	Solvent Yellow 163	13676-91-0	Synthetic fibres	Yes

** Direct dyes have lower fastness because the binding of the dyes to the fibre is based on van der Waals force and H-bridges. It is therefore possible that they remain on the fibre.*

- Respiratory sensitiser (H334/R42)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Acid Green 111	58419-36-6	Various fibres	No
2	Sulphur Black 6	1327-16-8	Yarn	No
3	Direct Red 243	52953-36-3	Yarn	No*
4	Direct Yellow 27	10190-68-8 98113-29-2	Suit, tie, scarf	No*

** Direct dyes have lower fastness because the binding of the dyes to the fibre is based on van der Waals force and H-bridges. It is therefore possible that they remain on the fibre.*

Dyeing auxiliaries

- Skin sensitiser (H317/R34)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	3-hydroxy-2-naphthanilide	92-77-3	Natural fibres (especially cotton)	Unknown
2	5-[[4-Chloro-6-[ethyl[3-[[2-(sulfooxy)ethyl]sulfonyl] phenyl]amino]-1,3,5-triazin-2-yl]amino]-4-hydroxy-	718619-88-6	Garments	Unknown

	3-[(1-sulfo-2-naphthalenyl)azo]-2,7-naphthalenedisulfonic acid sodium salt			
3	Sodium [3-hydroxy-4-[(1-hydroxy-8-sulpho-2-naphthyl)azo]naphthalene-1-sulphonato(4-)]chromate(1-)	70942-15-3	Fabric for suit	Unknown
4	2,7-Naphthalenedisulfonic acid, 5-4-chloro-6-(ethylphenylamino)-1,3,5-triazin-2-ylamino-3-5-(2,3-dibromo-1-oxopropyl)amino-2-sulfophenylazo-4-hydroxy-, sodium salt	155522-14-8	Fabric for suit	Unknown

- Respiratory sensitiser (H334/R42)

	Substance name	**CAS no.**	**In which type of textile products it is used and remains?**	**Whether remaining on finished textile products?**
1	Sodium [3-hydroxy-4-[(1-hydroxy-8-sulpho-2-naphthyl)azo]naphthalene-1-sulphonato(4-)]chromate(1-)	70942-15-3	Fabric for suit	Unknown

Surfactant

- Skin sensitiser (H317/R34)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	2-(2-aminoethylamino) ethanol	111-41-1	Garment, bedclothes, towels	No
2	Poly(oxy-1,2-ethanediyl),a-(2-propylheptyl)-w-hydroxy-	160875-66-1	Yarn	No
3	Alcohols, C10-14, ethoxylated	66455-15-0	Yarn	No

- Respiratory sensitiser (H334/R42)

No surfactant with respiratory sensitising characteristics which is used in textiles has been reported in the questionnaires.

Softener

- Skin sensitiser (H317/R34)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Amides, from 2-[(2-aminoethyl)amino]ethanol and hydrogenated tallow fatty acids	68155-12-4	Garments	Yes
2	Tetradecyl dimethyl (3 - (trimethoxysilyl) propyl) ammonium chloride			Yes
3	Octadecanoic acid, reaction products with diethylenetriamine, carboxymethylated	92797-51-8	Garments	Yes
4	Octadecanoic acid, reaction products with diethylenetriamine	68412-13-5	Garments	Yes
5	Amides, tallow, hydrogenated, N-[2-[(2-hydroxyethyl)amino] ethyl] , acetates (salts)	68425-52-5		Yes

- Respiratory sensitiser (H334/R42)

No softener with respiratory sensitising characteristics which is used in textiles has been reported in the questionnaires.

Flame retardant

- Skin sensitiser (H317/R34)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Organic phosphorus compound, active fiber			Yes
2	THPC-urea; Tetrakis(hydroxymethyl)phosphonium chloride, oligomeric reaction products with urea	27104-30-9	Garments	Yes
3	THPC; tetrakis(hydroxymethyl)phosphonium chloride	124-64-1		Yes
4	Aziridine, homopolymer			Yes

- Respiratory sensitiser (H334/R42)

No flame retardant with respiratory sensitising characteristics which is used in textiles has been reported in the questionnaires.

Preservative (and antimicrobial)

- Skin sensitiser (H317/R34)

Function group	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
Preservative	2-Methylisothiazol-3(2H)-one	55965-84-9	Garment, technical textiles, bands, ribbons, webbings (only in the coating paste)	No
Preservative, antimicrobial	Dimethyltetradecyl[3-(trimethoxysilyl)propyl]ammonium chloride	41591-87-1	Yarn	Yes

- Respiratory sensitiser (H334/R42)

No preservative or antimicrobial with respiratory sensitising characteristics which is used in textiles has been reported in the questionnaires.

Solvent

- Skin sensitiser (H317/R34)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	2,2'-oxydiethanol (diethylenglycol)	111-46-6	Suit, tie, scarf	unknown

- Respiratory sensitiser (H334/R42)

No solvent with respiratory sensitising characteristics which is used in textiles has been reported in the questionnaires.

Fixing agent

- Skin sensitiser (H317/R34)

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Dimethyloldihydroxyethyleneurea modified, with catalyst			Yes
2	Methanol esterified melamine resin (methoxymethyl melamine)			Yes

- Respiratory sensitiser (H334/R42)

No fixing agent with respiratory sensitising characteristics which is used in textiles has been reported in the questionnaires.

Others

- Skin sensitiser (H317/R34)

Function group	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
Others	Formaldehyde	50-00-0	Natural & synthetic textile incl. pigment print, all garment, diverse textiles, resin fabric, CO blends dyed with reactive and direct dyes, textile finish resins	Yes
Perfume for aromatizing of textiles	D-Limonene	5989-27-5	Hosiery, underwear, towels, bedclothes	Yes
Easy care resin	alkyl-modified melamine-formaldehyde derivative			Yes
Coating	1,6-diisocyanato hexane homopolymer 2-hydroxyethyl acrylate blocked	polymer		Yes
Others	Stearylaminethoxylat (2EO)	90367-28-5		Unknown
Catalyst	maleic acid	110-16-7		No
Antifoam	Maleic acid, bis(2-ethylhexyl)ester	142-16-5		No

- Respiratory sensitiser (H334/R42)

No substance with respiratory sensitising characteristics from this category which is used in textiles has been reported in the questionnaires.

Irritating substances which are not sensitising

Disperse dyes

- Skin Irritant (H315/R38) which is not skin sensitiser

Disp. Blue 1 and 291 are skin irritants reported in the questionnaires. However, they are also reported as skin sensitisers.

- Respiratory Irritant (H335/R37) which is not respiratory irritant

No disperse dye with respiratory irritating characteristics which is used in textiles has been reported in the questionnaires.

Reactive dyes

- Skin Irritant (H315/R38) which is not skin sensitiser

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	React. Red	129651-19-0	Natural fibres (especially cotton)	No
2	React. Red (x Na)	321912-24-7	Natural fibres (especially cotton), yarn	No
3	React. Yellow 81		Yarn	No
4	React. Yellow 138:1		Yarn	No

- Respiratory Irritant (H335/R37) which is not respiratory irritant

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	React. Yellow 81		Yarn	No

Other dyes

- Skin Irritant (H315/R38) which is not skin sensitiser

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Acid Brown 289	12219-72-6	Yarn	No
2	Acid Brown 413	75199-05-2	Yarn	No
3	Acid Green 84	97375-18-3	Yarn	No
4	Acid Red 26 (CI 16 150)	3761-53-3	Yarn	No
5	Acid Red 131	12234-99-0	Yarn	No
6	Acid Black 107	79920-42-6	Yarn	No
7	Basic Red 15	72208-20-9	Yarn	No
8	Basic Red 46	89959-98-8	Nylon	No
9	Basic Yellow 13	25717-55-9	Yarn	No
10	Basic Yellow 21	6359-50-8	Yarn	No
11	Basic Yellow 28	54060-92-3	Yarn	No
12	Basic Violet 14 (CI 45 510)	632-99-5	Nylon	No
13	Direct Violet 66	4-3-6798	Suit, tie, scarf	No
14	Direct Red 80	8-10-2610		No
15	Vat Brown 1	2475-33-4	Suit, tie, scarf	No

- Respiratory Irritant (H335/R37) which is not respiratory irritant

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Direct Red 80	8-10-2610	Yarn	No
2	Acid Orange 51	8003-88-1	Suit, tie, scarf	No

Dyeing auxiliaries

- Skin Irritant (H315/R38) which is not skin sensitiser

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Sodium hydrogen N,N-dibutyl-10-(sulphonatooxy)octadecanamidate	62093-93-0	Yarn	Unknown
2	Adipic acid, compound with 1,4-bis(3-aminopropyl)piperazine (1:1)	5423-61-0	Yarn	Unknown

- Respiratory Irritant (H335/R37) which is not respiratory irritant

No dye related substance with respiratory irritating characteristics which is used in textiles has been reported in the questionnaires.

Surfactant

- Skin Irritant (H315/R38) which is not skin sensitiser

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Alcohols, C12-15, ethoxylated; cetyl alcohol	68131-39-5	Garment	No
2	Isotridecanol, ethoxylated	9043-30-5	Garment	No
3	Sulfonic acids, C14-16-alkane hydroxy and C14-16-alkene, sodium salts	68439-57-6	Yarn	No
4	Sodium etasulfate (sodium 2-ethylhexyl sulfate)	126-92-1	Yarn	No
5	Tridecyl alcohol ethoxylates	24938-91-8	Garment	No
6	Sodium dodecyl sulphate	151-21-3	Yarn	No
7	Sodium lauryl polyoxyethylene ether sulfate	9004-82-4	Yarn	No
8	Polyethoxylated (5) tallow alkylamines	6179-26-2	Yarn	No
9	Propan-2-ol	67-63-0	Fabric for suit	No
10	Isotridecanol, ethoxylated	69011-36-5	Fabric for suit	No

11	Alcohols, C12-13, ethoxylated	66455-14-9		No

- Respiratory Irritant (H335/R37) which is not respiratory irritant

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Sulfonic acids, C13-17-sec-alkane, sodium salts	85711-69-9	Yarn	No
2	Propan-2-ol	67-63-0	Fabric for suit	No

Softener

- Skin Irritant (H315/R38) which is not skin sensitiser

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Siloxanes and Silicones	102782-92-3 75718-16-0	Garment	Yes
2	Dimetyl polysiloxane		Sheeting and garments	Yes
3	Octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol	68815-50-9	Suit, tie, scarf	Yes
4	Amino-functional Silicone		Different types of textile products	Yes

- Respiratory Irritant (H335/R37) which is not respiratory irritant

No softener with respiratory irritating characteristics which is used in textiles has been reported in the questionnaires.

Flame retardant

- Skin Irritant (H315/R38) which is not skin sensitiser

Tetrakis(hydroxymethyl)phosphonium chloride is reported at a skin irritant. However, it has been also reported as a skin sensitiser.

- Respiratory Irritant (H335/R37) which is not respiratory irritant

No flame retardant with respiratory irritating characteristics which is used in textiles has been reported in the questionnaires.

Preservative and/or antimicrobial

- Skin Irritant (H315/R38) which is not skin sensitiser

Function group	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
Preservative, antimicrobial	O-Phenylphenol (OPP)	90-43-7	Natural & synthetic textiles incl. pigment print	Yes
Antimicrobial	Docusate Sodium	577-11-7	Different Types of textile products	Yes

- Respiratory Irritant (H335/R37) which is not respiratory irritant

No preservative or antimicrobial with respiratory irritating characteristics which is used in textiles has been reported in the questionnaires.

Solvent

- Skin Irritant (H315/R38) which is not skin sensitiser

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	1-methyl-2-pyrrolidone	872-50-4	Fabric for suit	No
2	2-butoxyethanol	111-76-2		No

- Respiratory Irritant (H335/R37) which is not respiratory irritant

No solvent with respiratory irritating characteristics which is used in textiles has been reported in the questionnaires.

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- Skin Irritant (H315/R38) which is not skin sensitiser

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Formic acid	64-18-6	Fabric for suit	No
2	Potassium carbonate	584-08-7	Suit, tie, scarf	No

- Respiratory Irritant (H335/R37) which is not respiratory irritant

	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
1	Potassium carbonate	584-08-7	Suit, tie, scarf	No
2	Acetic acid	64-19-7		No

Others

- Skin Irritant (H315/R38) which is not skin sensitiser

Function group	Substance name	CAS no.	In which type of textile products it is used and remains?	Whether remaining on finished textile products?
Phenols	2,3,4,6-tetrachlorophenol	58-90-2	Natural & synthetic textile incl. pigment print	Unknown
Unknown	2-methylpentane-2,4-diol	107-41-5	Ironing board cover fabric, sheeting and garments	Unknown
Complexing agent	E.D.T.A.		All types of textile products	No
Others	sodium bromate	7789-38-0	Mercerizing fabric	No

Thickener	Naphthalenesulfonate - formaldehyde condensate, sodium salt	9084-06-4	Yarn	Yes
Bleaching auxiliary	hydrogen peroxide	7722-84-1	Yarn	No
Others	sodium fluoride	7681-49-4	Garments	No
Wetting agent	Poly(oxy-1,2-ethanediyl),a-isodecyl-w-hydroxy-	61827-42-7	Fabric for suit	No
Chlorine resistance	Mixure of 4-4' diidroxyphenil sulphone condensed, bondtite 345, 655, diethylene glycol 2,2'-oxybisethanol	102958-53-2, 1401-55-4, 111-46-6	Swimming suit	Yes
Others	•-caprolactam	105-60-2	Suit, tie, scarf	Unknown
Antistatics	Phosphoric acid C3-9 Alkyl Ester Sodium Salts	68516-00-7	Different types of textile products	Yes
others	Phenolsulfonic acid	53817-89-3	apparel	no

- Respiratory Irritant (H335/R37) which is not respiratory irritant

Function group	**Substance name**	**CAS no.**	**In which type of textile products it is used and remains?**	**Whether remaining on finished textile products?**
Others	Ammonia, aqueous solution	1336-21-6	Garment, bags, parasols, sunblind, technical camouflage fabric, ironing board cover fabric, bulletproof vests	No
Bleaching auxiliary	Hydrogen peroxide	7722-84-1	Yarn	No
Others	•-caprolactam	105-60-2	Suit, tie, scarf	Unknown
Antislip Agents	Aluminium chlorohydrate	12042-91-0	Garments made from rayon and viscose	Yes
Others	Alkylamine	124-09-4		No

7. CORRELATION BETWEEN ALLERGIC REACTIONS AND CHEMICALS USED IN TEXTILE PRODUCTS

Some substances and mixtures used in textile industry are classified as sensitisers and irritants based on OECD standard tests and using the criteria contained in the CLP Regulation. The classification is based on the intrinsic properties of the substances and mixtures themselves before they are applied to textiles and not based on the properties of those after applied to textiles (together with textile fibres). There are no tests for textile fabrics and fibres based on OECD standards. Nevertheless, information on the chemicals used and remaining on the finished textile materials is especially important, for instance for allergic consumers.

It is difficult to determine the prevalence of contact dermatitis from textiles. It is partly because the studies published in literature refer almost exclusively to contact dermatitis from textile dyes. It is also because that the major part of the available data is not recent. That the patients in the conducted studies were selected with various criteria makes the results from different studies difficult to compare.

According to the report from the German Federal Institute for Risk Assessment (BfR), textile-related contact allergies account for around 1-2 % of cases. Given that everyone has close skin contact with textiles 24 hours a day, the documented cases of contact allergies triggered by textiles are rare. The evidence on textile-associated dermatitis, the potential causes and allergens, and clinical patterns, have been reviewed in 2000[100]: The evidence on textiles as a cause of skin disease was compiled by Hatch et al in 2003[153]. In this book, Hatch has summarized and discussed available prevalence data and status of knowledge about dyes as allergic contact allergens and Fowler[153] has provided a chapter on formaldehydes as a textile allergen. In summary, from the findings presented in the current report and the quoted references, the following statements can be made:

- Some disperse dyes in textiles can result in allergic contact dermatitis in sensitised individuals. These dyes include Disperse Orange 1, Disperse Orange 3, Disperse Red 1, Disperse Red 17, Disperse Blue 3, Disperse Blue 35, Disperse Blue 85, Disperse Blue 106, Disperse Blue 124, Disperse Yellow 3, Disperse Red 1, Disperse Red 17, Disperse Brown 1.

- Around 2/3 of all textile related cases of allergy are attributed to disperse dyes. The prevalence of allergic contact dermatitis (ACD) due to disperse dyes in the general population is a few percentage (less than 5.7%).

- Reactive dyes do not have a sensitising potential as they will react with fibres during the dyeing processes

- Some textile finish resins may release formaldehyde causing permanent-press finish clothing dermatitis in sensitised individuals. Most of these persons are also allergic to formaldehyde itself. Some persons may be allergic to formaldehyde resin clothing fabric finish and not to formaldehyde itself.

- The prevalence of allergic contact dermatitis due to formaldehyde resins in textiles in sensitised persons is of the order of a few percent (5.9%) and seems to have less aetiological importance compared to the past.

- Many textile additives and auxiliaries are rare sensitisers.

The prevalence of contact dermatitis from textiles, and other consumer products, is also indicated in various documents and reports from studies carried out, e.g. in the NL, the UK and Italy, which concur with the findings of the BfR report. An epidemiological study referenced by the Italian Health and Textile Association[58], found that, for the five year period 1994-1998, clothing represented an important

cause of non-occupational contact dermatitis (8.5% of the cases), after cosmetics, metal accessories and pharmaceuticals, and ranking before shoes.

However, the fact that the concentrations of sensitising and irritating chemical substances used and remaining on the finished textile product are lacking from the textile industries also makes it very difficult to draw a conclusion on whether there is a link between these substances at the levels of remaining on finished textiles and contact dermatitis (allergy).

8. PRIORITISATION AND POSSIBLE (NON-)REGULATORY ACTION

8.1 Prioritisation of the substances in textiles

We suggest that three categories can be used to prioritise the substances used in textile products, taking into account harmonised classification and self-notification under the Classification, Labelling and Packaging (CLP) Regulation, sensitising potency, and whether (or not) any alternative or substitute is available. The prioritisation categories and criteria are summarised below:

Category 1: Substances with classification of sensitisers included in the classification and labelling (C&L) Inventory (under CLP and self-notified by industry) and intended to remain on finished textile products

Category 2: Substances with harmonised classification of sensitiser under CLP and not intended to remain but remaining on finished textile products and cause textile allergies (e.g. impurity or component in formulation)

Category 3: Substances with harmonised classification of irritant under CLP and intended to remain on finished textile products

Based on the criteria above, the prioritisation categories have been applied to the allergenic chemical substances which were reported in the questionnaires. Table 31 below gives an overview on the functions, classifications and prioritisation categories of these substances, as well as the EU legislation or standard which covers these substances.

For example, Disperse Blue 1, Disperse Yellow 3, Solvent Yellow 3 and D-Limonene belong to category 1 since they have harmonised classification as sensitisers, are intended to remain on finished textile products and, for the time being, no alternative is available. The sensitising potency (1A or 1B) of these substances is known. Other disperse dyes are also in category 1 even though they do not have harmonised classification under CLP but have been self-notified by industry as a sensitiser.

For category 2 substances, an example is formaldehyde. Formaldehyde is used as an ingredient of many formulations with various functions in textiles. It is not intended to remain on finished textile products. However, formaldehyde often remains on finished textile products as a by-product. Under the EU Ecolabel Regulation, the criteria specify that the amount of free and partly hydrolysable formaldehyde in the final fabric shall not exceed 20 ppm in products for babies and young children under 3 years old, 30 ppm for products that come into direct contact with the skin, and 75 ppm for all other products. For assessment and verification, the applicant shall either provide a declaration that formaldehyde containing products have not been applied or provide a test report using the standard test method: EN ISO 14184-1.

Category 3 substances are the substances which have the harmonised classification of irritant under CLP and intended to remain on finished textile products.

Table 31 Example of priority categories suggested for potential allergenic substances

Function group	**Classification in C&L Inventory**		**Priority category in finished textile products**	**Covered by EU legislation or international standards**
	Harmonised under CLP	**Self-notified**		
Disperse dyes	Skin Sens. 1 or Skin Irrit. 2	Skin Sens. 1, Skin Irrit. 2 or Resp. Sens. 1	1 or 3	REACH; EU Ecolabel; Oeko-Tex Standard 100
Other dyes		Skin Sens. 1	1	REACH
Softener		Skin Sens. 1 or Skin Irrit. 2	1 or 3	
Flame retardant		Skin Sens. 1, Resp. Sens. 1 or Skin Irrit. 2	1 or 3	REACH
Preservative, antimicrobial		Skin Sens. 1	1	REACH
Perfume for aromatizing of textiles	Skin Sens. 1 or Skin Irrit. 2		1 or 3	Cosmetics Regulation; Toys Directive; Detergents Regulations
Dyeing auxiliaries		Skin Sens. 1, Resp. Sens. 1 or Skin Irrit. 2	2 or 3	REACH
Others (formaldehyde)	Skin Sens. 1		2	EU Ecolabel; Oeko-Tex Standard 100

8.2 Suggested regulatory and non-regulatory actions

Three different types of actions are suggested, namely aimed at providing further information to consumers, and combining non-regulatory and regulatory tools, e.g. to control and check the presence of sensitisers against the information disclosed. The suggestions hereafter shall be regarded as exploratory within the existing regulatory framework and it should be noted that further analysis is deemed necessary.

1) Propose new information requirements for consumers under relevant existing legislation

2) Propose to combine non-regulatory voluntary action (e.g. codes of conduct, standards) and further harmonization of control procedures of the presence of sensitisers against the information on the label.

3) Other measures
   - Derivation and harmonization of limit values for strong sensitisers based on quantitative risk assessment (QRA) method. This will ensure the sufficient protection of the consumers from allergy as currently the limit values for sensitisers are arbitrarily chosen in most of the cases.
   - Further analysis in view of possible regulatory actions, for the substances in category 2
   - Further investigation on exposure and risk assessment
     This measure applies to both sensitizing and irritating substances. However, for the irritating substances in category 3, more research needs to be done to investigate the link between irritating substances used in textiles and allergic reactions.
   - Promote research and voluntary actions
     The research on alternatives for the potential allergenic substances should be promoted; industry-led voluntary actions could also be promoted.

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