Annexes

Contents

A.1. Manufacture, import and export....10
A.1.1. Manufacture, import and export of textiles and leather....10
A.1.2. Estimated volumes on of the chemicals used in textile and leather articles....12
A.2. Uses....14
A.2.1. The use of chemicals in textile and leather processing....14
A.2.1.1. Textile processing....14
A.2.1.2. Leather processing....19
A.2.1.3. Textile and leather formulations....20
A.2.1.4. Chemicals used in textile and leather....23
Annex A: Manufacture and uses....30
A.2.2. Identification of relevant chemicals in finished textile and leather products....30
A.2.2.1. Screening of substances with a possible use in textile and leather....30
A.2.2.2. Identification of substances in finished articles....31
A.3. Uses advised against by the registrants....32
Annex B: Information on hazard and risk....33
B.1. Identity of the substance(s) and physical and chemical properties....33
B.1.1. Name and other identifiers of the substance(s)....33
B.1.2. Composition of the substance(s)....36
B.1.3. Physicochemical properties....37
B.1.4. Justification for grouping....39
B.2. Manufacture and uses (summary)....39
B.3. Classification and labelling....39
B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)....39
B.3.2. Classification and labelling in classification and labelling inventory/ Industry's self classification(s) and labelling[1]....39
B.4. Environmental fate properties....39
B.5. Human health hazard assessment....39

B 5.1 Skin irritation....39
B 5.2 Skin corrosion....39
B.5.3. Skin sensitisation....39
B.5.3.1. Development of allergic contact dermatitis....40
B.5.3.2. Allergic contact dermatitis acquired from textiles and leather....40
B.5.3.3. Diagnosis of allergic contact dermatitis....41
B.5.3.4. Prevention of allergic contact dermatitis....41
B.5.3.5. Classification of skin sensitisers according to the CLP Regulation....41
B.5.3.6. The dose-response relationship of skin sensitisers....41
B.5.4. Reference dose....43
B.5.4.1. Information gathering and search strategy....43
B.5.4.2. Hazard information related to targeted substances or groups of substances 45
B.5.4.3. Default elicitation threshold dose....47
B.5.4.4 Conclusion on reference dose....48
B.6. Human health hazard assessment of physicochemical properties....49
B.6.1. Explosivity....49
B.6.2. Flammability....49
B.6.3. Oxidising potential....49
B.7. Environmental hazard assessment....49
B.8. PBT and vPvB assessment....49
B.9. Exposure assessment....49
B.9.1. General information on releases and exposure....49
B.9.1.1. Summary of the existing legal requirements....49
B.9.1.2. Summary of the effectiveness of the implemented operational conditions and risk management measures....49
B.9.2. Uses: Textile....53
B.9.2.1. General information on exposure to chemical substances from textile....53
B.9.2.2. Information gathering and search strategy....55
B.9.2.3. Exposure information related to targeted substances or groups of substances 56

B.9.2.4. Exposure assessment 64

B.9.2.5. Exposure scenario 68

B.9.2.6. Workers exposure 69

B.9.2.7. Consumer exposure 69

B 9.2.8. Indirect exposure of humans via the environment 69

B.9.2.9. Environmental exposure 69

B.9.3. Uses: Leather, hide and fur 69

B.9.3.1. General information on exposure to chemical substances in leather, hide and fur 69

B.9.3.2. Information gathering and search strategy 70

B.9.3.3. Exposure information related to targeted substances or groups of substances 71

B.9.3.4. Exposure assessment 77

B.9.3.5. Exposure scenario 81

B.9.3.6. Workers exposure 81

B.9.3.7. Consumer exposure 81

B 9.3.8. Indirect exposure of humans via the environment 81

B.9.3.9. Environmental exposure 81

B.9.4. Other sources (for example natural sources, unintentional releases) 82

B.9.5. Overall environmental exposure assessment 82

B.9.6. Combined human exposure assessment 82

B.10. Risk characterisation 82

B.10.1. Human health risk from exposure to skin sensitisers in textile 83

B.10.1.1. Equations to derive concentration limits in textile 83

B.10.1.2. Concentration limits for substances or groups of substances with information on elicitation threshold doses and migration: Quantitative, substance specific approach 84

B.10.1.3. Concentration limits for substances/groups of substances with information on elicitation threshold doses or migration: Quantitative, substance semi-specific approach 85

B.10.1.4. Concentration limits for substances/groups of substances no information on elicitation threshold doses or migration: Quantitative default approach 86

B.10.1.5. Conclusion on human health risk....87

B.10.1.6. Sensitivity analysis....88

B.10.2. Human health risk from exposure to skin sensitisers in leather, hide and fur....89

B.10.2.1. Equations to derive concentration limits in leather....89

B.10.2.2. Concentration limits for substances/groups of substances with information on elicitation threshold doses and migration: Quantitative, substance specific approach 90

B.10.2.3. Concentration limits for substances/groups of substances with information on elicitation threshold doses or migration: Quantitative, substance semi-specific approach 91

B.10.2.4. Concentration limits for substances/groups of substances with no information on elicitation threshold doses or migration: Quantitative default approach 92

B.10.2.5. Conclusion on human health risk....93

B.10.2.6. Sensitivity analysis....93

Annex C: Justification for action on a Union-wide basis....94

Annex D: Baseline....95

Annex E: Impact Assessment....99

E.1. Risk Management Options....99

E.1.1. Existing regulations on textile and leather....99

E.1.2. Existing EU and national restrictions....101

E.1.3. Labelling schemes, ecolabels and standards....105

E.2. Alternatives....107

E.2.1. Description of the use and function of the restricted substances....129

E.2.2. Identification of potential alternative substances and techniques by group of substances....133

E.2.2.1. Diisocyanates....134

E.2.2.2. Dyes....136

E.2.2.3. Intermediates....140

E.2.2.4. Plasticisers....141

E.2.2.5. Rubber accelerators....142

E.2.2.6. Rosins....144

E.2.2.7. Solvents 145
E.2.2.8. Other substances 147
E.2.2.9. Normal, good and best practice 150
E.2.3.Technical and economic feasibility, and availability of alternatives 151
E.2.3.1. Assessment of alternatives to diisocyanates 152
E.2.3.2. Assessment of alternatives to dyes 152
E.2.3.3. Assessment of alternatives to intermediates 153
E.2.3.4. Assessment of alternatives to plasticisers 153
E.2.3.5. Assessment of alternatives to rubber accelerators 156
E.2.3.6. Assessment of alternatives to rosins 157
E.2.3.7. Assessment of alternatives to solvents 158
E.2.3.8. Other substances 159
E.3. Restriction scenario(s) 162
E.4. Economic impacts 162
E.4.1. Substitution cost 162
E.4.1.1. Cost of substituting to alternative chemical substances 163
E.4.1.2 Costs related to reformulation, research and development 163
E.4.1.3 Production process changes incurred when moving towards best practice (including possible investment costs for new machinery) 164
E.4.1.4 Groups and substances where substitution has not been identified as technical feasible, or where substitution cost has not been identified 165
E.4.1.5 Total substitution cost estimates for substances where cost data are available 165
E.4.1.6. Total reformulation cost estimates for rubber accelerators 166
E.4.2. Testing and enforcement costs 167
E.4.3. Uncertainty aspects connected to the Analysis of Alternatives 173
E.5. Human health and environmental impacts 174
E.5.1. Human health impacts 174
E.5.1.1. What is an allergic contact dermatitis? 175
E.5.1.2. The disease course 176

E.5.1.3 The number of ACD cases that can be prevented by the proposed restriction: prevalence and incidence data 183
E.5.1.4 Valuation of health impacts and benefits assessment 195
E.5.1.5 HHIA: Sensitivity analysis 205
E.5.2. Environmental impacts 208
E.6. Risk reduction capacity, practicability and monitorability 208
E.7. Distributional impacts 208
E.8. Proportionality 208
E.9. Comparison of Restriction Options 208
Annex F: Assumptions, uncertainties and sensitivities 209
Annex G: Stakeholder information 216
References 220

Tables

Table 1. Number of manufacturers of textile and leather in the EEA 12
Table 2 : Functions of the typical chemical substances used in chemical formulations 25
Table 3 : Number of substances with a harmonised classification as skin sensitisers or with skin sensitising concern (included in list of concern) including biocidal substances 33
Table 4: List of substances of concern (included in the scope) 34
Table 5 : Chemical and physical properties of the substances included in the list of concern 37
Table 6 : Groups of substances or substances which were targeted for information searches. 44
Table 7: Migration factors for substances targeted for exposure information searches. 56
Table 8: Approximate (measured or estimated) levels in textile for the targeted substances. 64
Table 9: Values on migration of various chemical substances from textile to artificial sweat found in the literature. 66
Table 10: Parameters to be applied for exposure calculation from textile 68
Table 11: Approximate (measured or estimated) levels in leather of the targeted substances 78
Table 12: Parameters to be applied for exposure calculation from leather 81
Table 13: The risk assessment approach 83
Table 14: Summary table of proposed concentration limits in textile articles for substances in the restriction scope. 87

Table 15 : Effects of changes in the parameters in the formula on the concentration limit in textile. 88

Table 16: Summary table of proposed concentration limits in leather for substances in the restriction scope 93

Table 17 : Baseline scenarios on the cumulative number of prevalent and new cases of textile and leather ACD from 2019. 96

Table 18 : Restrictions on hazardous substances (Annex XVII of Regulation (EC) No 1907/2006) 101

Table 19 : Indicative Master List of chemicals relevant for the scope of the current restriction proposal and identified by the Dossier Submitter to be found today in the textile and leather articles manufacturing processes. 108

Table 20: Narrow Master List of substances that should be substituted 129

Table 21 : Chemical concentration ranges for formulations and finished articles 134

Table 22 : Diisocyanates in the finished articles above concentration limits considered safe 135

Table 23 : Acid dyes in the finished articles above concentration limits considered safe ... 137

Table 24 : Direct dyes in the finished articles above concentration limits considered safe 137

Table 25 : Disperse dyes in the finished articles in concentration above levels considered safe 138

Table 26: Additional disperse Dyes of the list of concern without available concentration and substitution information 139

Table 27 : Rubber accelerators in finished articles above concentration limits considered safe 142

Table 28 : Solvent in finished articles above concentration limits considered safe 145

Table 29: Total cost estimates of substitution between restricted rubber accelerators and alternatives (based on assumed number of reformulations) 167

Table 30: Total testing cost estimates for companies and authorities expected from the restriction 171

Table 31: Assumptions and data used for the estimates of testing costs (based on tattoo inks and permanent make-up restriction proposal) 172

Table 32 :European Baseline Series S-1000 180

Table 33 : Textile Colours & Finish Series TF-1000 180

Table 34 : Shoes Series SH-100: 181

Table 35 :Textile Dye mix (TDM) Mx30 182

Table 36 : Overview of prevalence data on contact allergies in the general population 184

Table 37 : Overview of prevalence data on contact allergies from positive patch tests to chemicals contained in textile and/or footwear in adults and children 190

Table 38 :Incidence data of contact allergy and allergic contact dermatitis 193

Table 39 : Number of individuals already sensitised in 2023 to substances in textile and leather articles (in million) 194

Table 40 : Number of annual new textile and leather ACD cases from 2023 194

Table 41 : Assumptions and diagnosis costs assessed in the restriction on Cr VI.....197

Table 42 : Assumptions and annual treatment costs assessed in the 2012 restriction proposal on Cr VI 198

Table 43 : 'Illness' B profile (chronic skin sensitisation) according to ECHA (2014) report 200

Table 44 : Economic values available to assess the disease burden of contact allergies ...201

Table 45 : Summary of the number of cases and economic values used for the HHIA.....203

Table 46 : Total annual human health benefits expected from the restriction: assuming 70% of prevalent and new cases protected. 204

Table 47: Total annual human health benefits expected from the restriction: assuming 90% of prevalent and new cases protected) 205

Table 48 : Total annual human health benefits expected from the restriction – SA 1: the average prevalence/frequency of positivity patch tests to textiles assumed to be 10% 206

Table 49 : Total annual human health benefits expected from the restriction – SA 2: the average prevalence/frequency of positivity patch tests to textiles assumed to be 0.5% ...206

Table 50 : Total annual human health benefits expected from the restriction – SA 3: the average prevalence/frequency of positivity patch tests to textiles assumed to be 1%.....206

Table 51 : Total annual human health benefits expected from the restriction – SA 4: the prevalence of contact dermatitis in the general population, all causes, assumed to be 8%-12% 206

Table 52 : Total annual human health benefits expected from the restriction – SA 5: the number of current and new cases of textile and leather ACD in the general population protected assumed to be 50%.....207

Table 53 : Total annual human health benefits expected from the restriction – SA 6: the assessment period assumed to be 30 years for both current and new cases protected/prevented (discounted until 2053 at 2.5%). 207

Table 54 : Total annual human health benefits expected from the restriction – SA 7: the assessment period assumed to be 10 years for both current and new cases protected/prevented (discounted until 2033 at 2.5%). 207

Table 55 : Total annual human health benefits expected from the restriction – SA 8: the prevalence of textile-related ACDs in the general population, assumed to be between 0.8% (the DS' calculated lower bound) and 2% (taking into account the upper bound from Bfr, 2006) 207

Table 56 : Assumptions, uncertainties and sensitivities 209

Table 57 : List of Stakeholders consulted by the Dossier Submitter in the preparation of the restriction proposal.....218

Figures

Figure 1. Global textile fibre production. Source: Tecnon Orbichem (KemI, 2019)..... 11

Figure 2 : Visual of the Textile Supply Chain. Source: KemI (2019) 18

Figure 3 : A simplified schematic picture of the textile manufacturing process (KemI, 2013) 19

Figure 4 : Visual representation of a drum of a chemical formulation used in textile and leather processing. Source: KemI (2019) 22

Figure 5 : Variation in induction potency between different disperse dyes. DB refers to Disperse Blue, DR to Disperse Red, DO denotes Disperse Orange and DG refers to Disperse Green (results from in vitro tests excluded) (BfR, 2012)..... 46

Figure 6 : Logistic dose–response curve for 16 patch test elicitation dose–response studies with methylchloroisothiazolinone/methylisothiazolinone (MCI/MI), formaldehyde, nickel, cobalt, chromium, isoeugenol, hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) (Fischer et al., 2011) 48

Figure 7 : Substances notified between 2004 and October 2017 in textile and footwear articles (RAPEX) 50

Figure 8. Examples of allergy contact dermatitis due to clothing articles.....176

Figure 9. Examples of shoes allergy contact dermatitis.....176

Figure 10. The disease course for ACD (Source: COWI, 2004).....176

Figure 11. Typical ACD course and associated medical protocol (when diagnosed) 179

A.1. Manufacture, import and export

A.1.1. Manufacture, import and export of textiles and leather

In the report "Risk to human health for chemicals in textiles" (KemI, 2014), the Swedish Chemicals Agency focused on textiles consumption in the EU. Even though this study is four years old, it allows the Dossier Submitter to quantify roughly the problem.

Textiles are produced in large quantities. They are either the main component of or included in a wide variety of consumer articles that are widely used in the society. Textiles constitute the largest surface area of the total surface area in the indoor environment, about twice as large as the combined area of flooring, ceilings and walls. As a result of this high-volume use of textile articles, a significant amount of chemical substances have the potential to be released and subsequently expose both consumers and the environment. The type of fibre is one factor influencing the release of substances from textile material. Textiles such as tops, underwear and bottoms come in close contact with the skin and these product groups are important when it comes to dermal exposure. The volumes presented in this section are therefore separated by textile article types and by fibre type.

The textiles and clothing consumption in the EU has increased rapidly during the last decade, a majority of the articles (about 80%) is imported from outside the EU. Statistics from the European Commission (2014) show that the main suppliers in 2012 were China, which stood for 33% of the imports in terms of value, followed by Turkey (14%), Bangladesh (10%) and India (7%) (EC, 2014). According to Textile & Clothing Industries' Association (TEKO), it is common that semi-finished textiles are imported from outside the EU and then finally manufactured and labelled in the Union. Even though these textiles are "made in EU" the chemical intensive process may have taken place in a non-EU country. **Based on EU statistics this would mean that more than 80% of the textile production involving chemical substances occurs outside the EU**.

Information on consumption differs depending on what statistics are used. A study performed by the European Commission's Joint Research Centre, JRC, estimated the consumption in the EU as imports plus production minus exports (EC, 2014).

The average apparent textiles consumption is estimated to correspond to 9 500 thousand tons/year or 19.1 kg/EU citizen. Clothing accounts for more than two thirds of the consumption where tops, bottoms and underwear together represented approximately 80%. Amongst household textiles bought, floor coverings (carpets) are the main articles (38%) followed by bed linens (16%) (EC, 2014).

When focusing on clothing textiles, cotton accounts for over 43% of all fibres used (in terms of mass of consumption). Polyester comes in second place with 18% of clothing textiles and viscose and acrylic make approximately 10% each. Natural fibres dominate with 54% of the clothing consumption in terms of mass (EC, 2014).

According to the Entry 47 of the REACH Annex XVII related to chromium VI in leather, the majority of articles of leather placed on the market are imported from countries outside the EU.

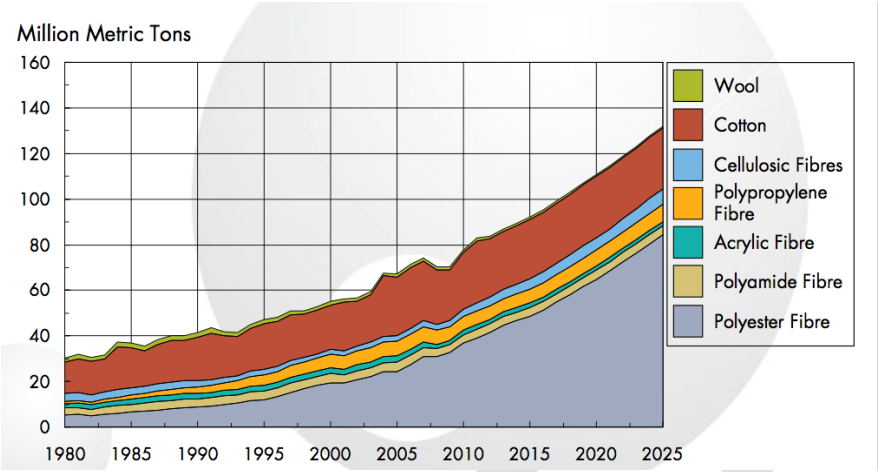

Figure 1. Global textile fibre production. Source: Tecnon Orbichem (KemI, 2019)

The information in the Figure 1 above was used in a consultancy study (referred to as "KemI (2019)" in the whole restriction proposal) initiated during the elaboration of this restriction proposal, performed by Cattermole Consulting Inc. (for further details, please see Annex G and KemI, 2019). The information provided estimates for total fibre consumption (for all end uses in all global markets) and a breakdown by fibre type. Based on this figure, the consultants stated that:

- The global market for textile fibres corresponds to approximately 100 million tons in 2018.
- 40% of the global textile fibre market is used in technical textiles, 60% is used in apparel and home textiles (source http://www.tikp.co.uk/)
- Approximately 30% of global textile sales are accounted for in the EU (source: Wazir Advisors[1]).
- The global market for leather corresponds to approximately 7 million tons. Approximately 84% is used in footwear, apparel and furniture (source www.ukleather.org).
- The EU is assumed to account for approximately 30% of global leather sales (in line with textiles)

Based on this information, the consultants deduced that about 18 million tons of the textile market and 1.76 million tons of the leather market are used for the total EU market for apparel and home (KemI, 2019).

The number of manufacturers of textile, wearing apparel and leather in the EEA30[2] is shown in Table 1 below.

[1] www.wazir.in

[2] EEA31 excluding Liechtenstein. No data for Liechtenstein available.

Table 1. Number of manufacturers of textile and leather in the EEA

Industry[3]	Manufacturers <250 employees	Manufacturers >250 employees
Manufacture of textiles	59 284	270
Manufacture of wearing apparel	123 615	380
Manufacture of leather and related products	37 182	170

Source: Eurostat 2019

A.1.2. Estimated volumes on of the chemicals used in textile and leather articles

The data provided hereunder are taken from the KemI (2019), such as described in Annex A.2.2 below and Annex G. It has to be understood that it is an impossible task to get accurate information on volumes of chemicals used in textile and leather articles without a legal requirement for chemical formulators to disclose confidential information on content of formulations and sales data. Moreover, providing volumes for all the substances included in the scope would have also been difficult and considered unnecessary for the purposes of this restriction proposal. As a result, the volumes data provided in this restriction proposal focus on the narrower list of 95 chemicals prepared by the Dossier Submitter, named the Master List, that could be used in the textiles and leather manufacturing processes today (at the time of the elaboration of this restriction proposal) such as in part identified by KemI (2019) (for more details about KemI (2019) methodology to identify these chemicals, see A.2.2 below). This list is indicative and cannot be claimed as exhaustive, since it cannot be excluded that other substances are also used today but have not been identified.

For chemical substances that can potentially be present in the finished articles such as identified by KemI (2019), the approach consisted of estimating the approximate total volume of each chemical substance used in the manufacture of textile and leather articles sold in the EU based on the volume data of textile and leather articles produced (presented above in section A.1.1) as well as the volume data of chemicals registered under REACH. Indeed, the volumes registered (can) cover other uses than for textiles and leather. However, those registration volumes do give some indication of the tonnages in circulation across all industries. Furthermore, some of the chemicals identified do not have an ECHA registration, which suggests that deliberate use or permitted import does not occur, and that the only usage is outside the EU.

To estimate the potential quantity of chemical substances used in textile and leather manufacture at the time of the elaboration of this restriction proposal, a volume ready reckoner was created and used in KemI (2019).

[3] Industry categories based on NACE R2.

The data used in the volume ready reckoner were:

A. An estimate of the total volume of textiles and leather used in the EU per annum (see section A.1.1.)

B. An estimate of the percentage of textiles and leather that can potentially be affected by the specific listed chemical (assuming e.g. all textiles and leather = 100%, acrylic = 2% of all textiles, polyester = 55% of all textiles, coated/pigment printed textiles = 15% of all textiles. In KemI (2019) it is estimated that 15% of all textiles and 30% of all leather articles are coated or pigment printed, and that 1% of all textiles and leather articles are rubber coated.

C. An estimate of the likelihood that a listed chemical substance is present in a formulation of a given type, for example:

    - Assume an in-can preservative is present in 1 of 50 formulations
    - Assume that a rubber accelerator is present in 1 of 20 rubber formulations

D. There is an assumption that 10 chemical formulations are used in a wet process – this is an average – so that if a listed chemical is assumed to be present in 1 in 50 formulations then it will be present in 1 of 5 (20%) of potentially affected articles.

E. An estimate of the percentage of a listed chemical that is deliberately applied (by weight of substrate), or the percentage of a chemical that is unintentionally applied. For functional chemicals in formulations, the amount applied is calculated by assuming that an active chemical formulation is applied at 2 g/l at a liquor ratio of 10:1. (For example, 2 g/l of the formulation applied at 10:1 liquor ratio is an intentional add-on of the total formulation of 2%. If a functional chemical is present at 1% in a formulation, the amount added is 1% of 2% = 0.02%)

A figure for the annual volume of a chemical used in the manufacture of textile or leather articles sold in the EU, in tons, is calculated by the consultants as follows (KemI, 2019):

V = A x B% x D% x E%

V = (Annual Tonnage of textiles or leather sold in the EU) x (% of articles that are potentially affected) x (% likelihood of the chemical being present in an article) x (% of chemical applied)

The Master List presenting the chemicals identified by the Dossier Submitter as being used today in the textile and leather articles manufacturing processes and the associated volumes is provided in Annex E.2. This list is not exhaustive since it cannot be excluded that other substances (not identified) are also used today or will be in the near future.

A.2. Uses

A.2.1. The use of chemicals in textile and leather processing

A.2.1.1. Textile processing

Chemicals are present in all parts of textile processing, from fibre to finished product. Here below an overview of textile manufacturing and the textile supply chain is presented. The following information is mainly based on ChemSec Guide[4] and on KemI (2019).

Textile manufacturing consists of a series of steps where chemicals are added, serve a function, and are then removed by washing and rinsing the textile, or applying heat. It takes many steps to transform a fibre or animal skin into a finished textile article or leather product. Each step in the process requires chemical substances, usually housed in chemical formulations, which are applied to the textile, usually in the presence of water.

Different chemical substances provide different functions at each step in the textile manufacturing process. For example, spinning oils lubricate the yarn so that it is easier to spin, dyes colour the fabric, and softeners ensure the finished textile article has an acceptable hand and drape.

The chemical substances used in the manufacture of textiles can be divided into the following categories:

- Functional (or effect) chemicals: Indented to remain in the finished textile product to give the garment certain properties, e.g. dyestuffs and crease resisting agents.
- Auxiliary (or process) chemicals: Not intended to remain in the finished textile product but may remain as an impurity. These substances are necessary for the textile production process to work, e.g. solvents and softeners.
- Degradation products: No function in the finished article or in the production process, e.g. formaldehyde released from certain resins and arylamines from certain azo dyes (FIH, 2011, KemI 2013, Salute 2012).

The following sequential steps provide a high level overview of the processes that the textile article must endure as it moves through the supply chain towards its finished state.

Textile Processing[5]

Most chemicals used in wet processing are intended to serve a particular purpose during a process, after which they are theoretically removed. However, some chemicals, such as dyes and chemical finishes, are intended to stay on the finished article at point of sale.

Additionally there may be chemicals present in finishing formulations that serve no purpose on the finished article (e.g. preservatives in chemical formulations, chemicals that control pH etc.) but that will be present at point of sale unless there is a subsequent laundry process.

[4] http://textileguide.chemsec.org/find/textiles-come-with-a-toxic-footprint
[5] The order of the steps may vary, depending on the desired end state of the product. For example, for yarn dye patterns on woven fabric, the yarn is prepared and dyed prior to weaving. In some cases, even the fiber is dyed.

Step 1. Fibre production (ChemSec Guide[6]): Fibres are produced. Natural fibres such as cotton and linen are grown with the addition of pesticides, whereas synthetic fibres such as polyester and nylon are usually produced from oil.

All textiles are made up of fibres that are arranged in different ways to create the desired strength, durability, appearance and texture. The fibres can be of countless origins, but can be grouped into four main categories. Natural fibres, with the exception of silk, have a relatively short fibre length, measured in centimetres. Silk and man-made fibres have on the other hand very long fibre lengths (filaments) ranging from hundreds of metres to kilometres long.

- Plant fibres consists of cellulosic material, normally derived from cotton, linen, hemp or bamboo, but more or less any plant with extractable cellulose can be used. Cotton is by far the most commonly used plant fibre. Pesticides, insecticides, fertilisers can be used at this step.
- Animal fibres consist of proteins. Wool and silk are the most commonly used fibres from this group, but the wool can come from a number of different animals. Pesticides, insecticides, scouring chemicals are used at this stage.
- Man-made fibres such as viscose (rayon) or lyocell are based on cellulosic raw material, normally from wood pulp. They are heavily treated with chemicals before the new fibre is spun. The whole process of producing fibres from wood pulp is very resource-intensive, involving the use of several hazardous substances sur as carbon disulphide.
- Synthetic fibres are made from monomers derived from fossil oil feedstocks, which are subsequently polymerised into different fibres. Given all the possible monomers that can be made from a synthetic feedstock, the possible combinations are endless. However the most common synthetic fibre is polyester, followed by polyamide, polyacrylic and aramide. Depending on the monomer used to produce the fibre, a numerous of chemicals may be used in the process. For some of the synthetic fibres such as polyester, dyeing can be accomplished already when the fibre is manufactured. Petroleum-based feedstock, dyes, pigments, catalysts, stabilizers are usually used at this stage.

Step 2. Yarn production: The fibres are spun into yarns. (Continuous filament synthetic yarns are produced as the fibre is formed) and the yarns are either woven or knitted into a fabric (KemI, 2019).

When the fibre has been harvested or produced the next step is to spin the fibres into a yarn. In order to increase the strength of the fibre, increase fibre cohesion and reduce friction during the spinning process, spinning oils are added.

Step 3. Fabric production: The core of textile manufacture is fabric production. Fabrics can be created in many different ways, the most common being weaving, knitting or through production of non-woven fabrics. To prevent the yarn from breaking during these processes, it is important to strengthen the yarn and reduce friction. Sizing chemicals and lubricants are therefore added.

[6] http://textileguide.chemsec.org/find/textiles-come-with-a-toxic-footprint

Step 4. Pre-treatment: Pre-treatment processes can be carried out with fibres, yarns or fabrics. It enables subsequent processing of the material, which needs to be prepared to accept dyes and functional chemicals. This is done in a multi-step process. Exactly which steps the fabric goes through depends on the type, or blend of fibre, and how it will be treated afterwards. In some cases pre-treated fabrics are manufactured for later garment dyeing.
The most common steps involving chemicals for a fabric are:

- Washing, general cleaning of the fabric following previous steps and treatments. (Detergents, solvents)
- De-sizing removes the sizing chemicals (starch) from the warp yarns in the woven fabric. (Enzymes)
- Scouring removes fatty waxes and greases from natural fibres, cotton seed and husk. (Detergents, bases, solvents)
- Bleaching makes the fibres whiter and facilitates the dyeing process. It also makes the fibres more absorbent.
- Mercerizing makes cellulosic fibres swell and get stronger, more lustrous and a greater capacity to accept dye. By doing so one can reduce the amount of dyes needed (by using bases)
- Carbonizing removes vegetable residues such as seed pods from wool.

Step 5. Dyeing and printing: The fabric is prepared for dyeing. This involves scouring, bleaching and neutralizing the bleach. Then the fabric is dyed or printed. Any unfixed dye is washed off thoroughly to meet customer's colourfastness requirements.

During dyeing and printing both hazardous chemicals and dyestuffs are used. Dyes used for dyeing, can also be used for printing, but must then undergo the same fixation and washing steps as after the dyeing process. The most common way to print a fabric in full width is to use pigment prints, where the pigments stick to a surface using polymeric resin or a binder. No washing processes are needed. For garment printing, plastisol printing is very common. The PVC-based paste often contains hazardous chemicals, such as phthalates, but there are also alternatives based on acrylate or polyurethane.

Dyeing can take place in several steps of the processing of the textile. It can be done when spinning the synthetic or man-made fibres, as loose natural or regenerated fibres and in the form of yarns or fabrics. Garment dyeing is also common. For fibre blends, two types of dyed fibres can be spun together e.g. viscose and wool. Full-width printing is carried out on pre-treated fabrics, but it is also possible to put a print on a garment or manufactured textile product by screen or transfer printing. Digital printing is another method.

There are other printing techniques, such as discharge and resist print, which use dyes and chemicals. These techniques include a washing step to get rid of surplus dyes and residues.

Dyeing is a step that should be expanded upon because without a doubt, dye will be present on the finished product. The dyeing process consists of intentionally added dyes that are intended to remain on the fabric plus lots of process chemicals that are needed to make the dye react with the fabric. For example it is common to use salt and wetting agents to help attract reactive dye to cellulosic fabric followed by fixing agents, such as soda ash, to help

the dye to bond or stick to the fabric. These process chemicals serve a valuable function, but they are not designed to remain on the fabric. After the dye process, steps are taken in the form of washing and rinsing the textile so that they are adequately removed.

Almost all dyes used in textile industry are synthetic organic compounds. Colourizing with dyes is based on physic-chemical equilibrium processes, namely diffusion and sorption of the dye molecules or ions. These processes may be followed by chemical reactions in the fibres. In a well-managed dyeing process, 70 - 95% of the dyeing agents attach to the fibre and the rest are channelled to waste water treatment. Pigments are attached into the fabric using a binding agent or applied using a printing method. Approximately half of all textile printing is performed using pigment printing technology, in which the pigment has no affinity with the fibre. For this reason, a binder and fixating agent must be added to the printing paste. The type and quantity of dyes, chemicals and auxiliaries (surfactants, dispersing agents, etc.) depends on the product quality. The most common coloured articles are socks, pantyhose and wool knitwear (RIVM, 2014).

Step 6. Finishing treatments: The fabric is finished with the application of basic softeners or performance chemicals and dried at a high heat, typically 140°C for drying or 160°C+ for curing. Some products, such as denim jeans or garment washed in industrial laundries to create abrasion patterns and a “washed down" casual aesthetic.

This step of the process is all about adding special technical properties or an aesthetic appeal to the finished fabric. Depending on the properties desired, such as flame retarding properties, enhanced water resistance, antibacterial treatment, protective coatings or specific fashion treatments, a diverse range of chemicals are used. Some examples are given below.

- Handle modification
- Crease resistance (anti-wrinkling, easy care)
- Antistatic treatment
- Anti-pilling
- Antibacterial/anti-odour treatment
- Water repellence
- Oil/soil repellence
- Flame retarding properties
- (Protective) coatings
- Laminated films and membranes
- Garment treatments for fashion

The textile is then dried, using high temperatures. During this process volatile chemicals can evaporate, dramatically reducing the amounts present on the finished article. [For reference the EU uses a boiling point of 250 ^{o}C in its definition of VOC’s]

Step 7. Manufacturing, transport, sales and retail. When the fabric has the desired colour and properties, it is made into finished products. This step includes processes such as cutting, sewing and the addition of buttons and zippers, for example. In some cases dyeing and printing of the finished garments, with the fabric only pre-treated, occurs at this step. In garment dyeing there are a lot of dyestuff and chemicals used (showed in step 5). Sometimes dyestuff with quite bad wash permanence are chosen to give the clothing in fashion a worn out look. For garment printing, Plastisol prints (PVC) are very common, but there are other types available for example based on acrylate or polyurethane.

Transport preparation includes protection from mould during transportation and storage, mostly using biocides. Substances can also be added to textiles for protection during storage and transport, especially for long journeys. These substances can be directly applied to the textile or contained in separate bags with the packaging. Treatment of the container itself with substances requires labelling the container, but this does not apply if the textile in the containers is treated before loading (RIVM, 2014).

The visual below, shows the textile supply chain and all of the places where chemical formulations are added and then removed (KemI, 2019).

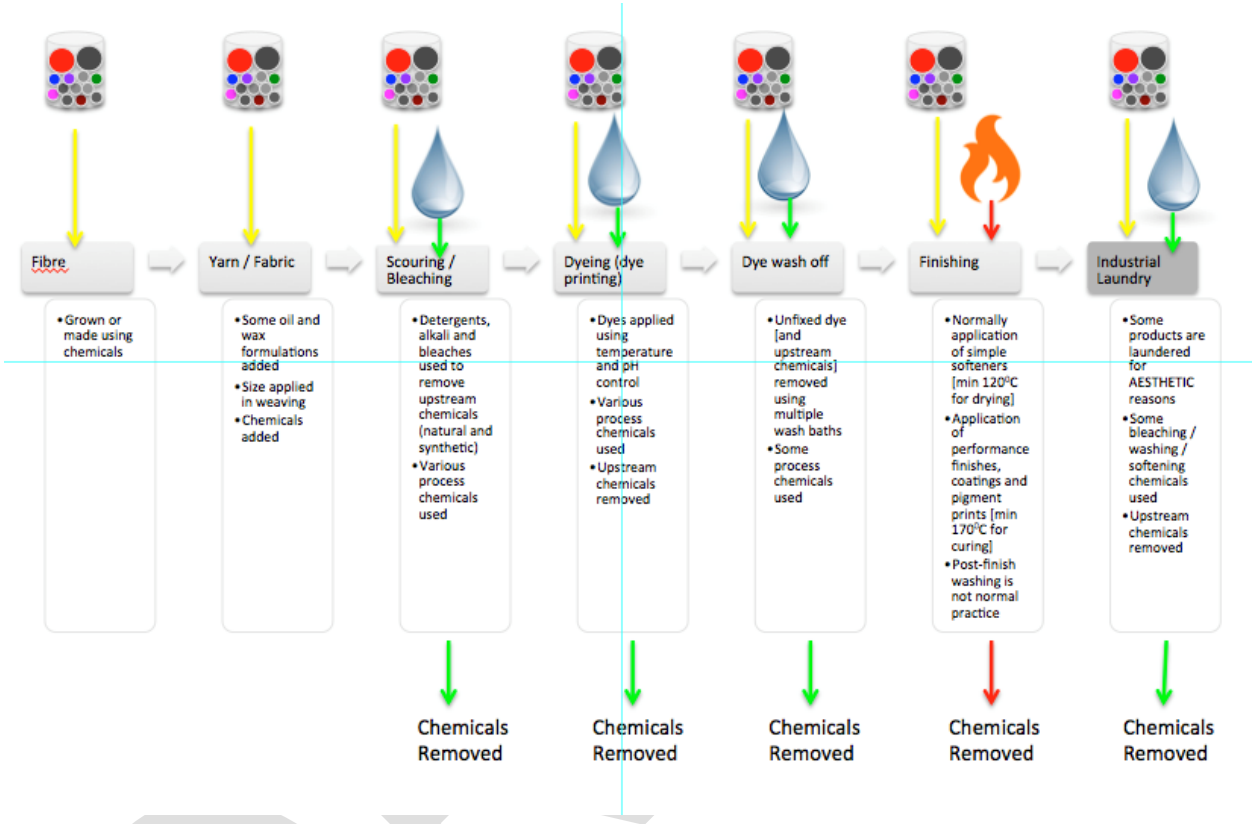

Figure 2 : Visual of the Textile Supply Chain. Source: KemI (2019)

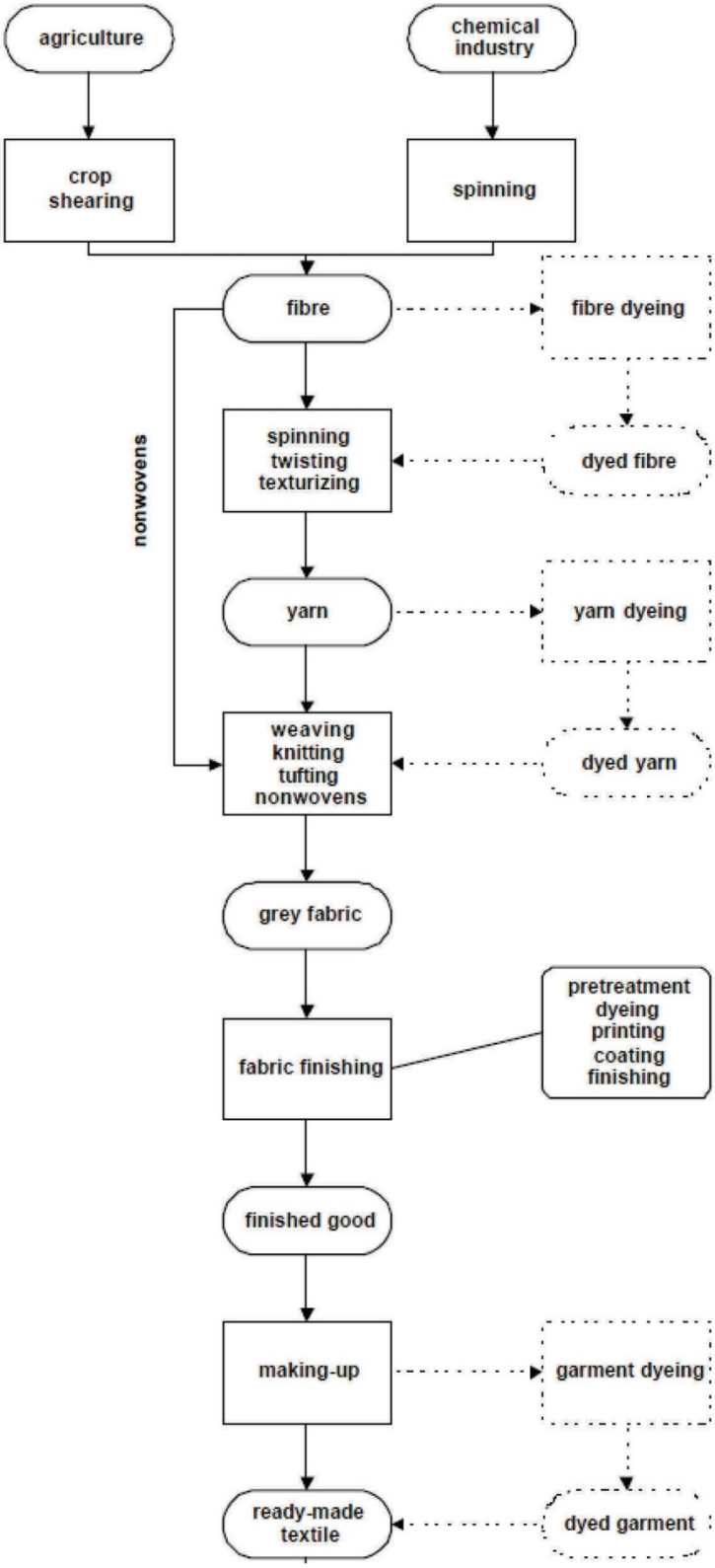

Figure 3 : A simplified schematic picture of the textile manufacturing process (KemI, 2013)

A.2.1.2. Leather processing

Chemicals are also present in all parts of leather processing, from raw animal hide to finished product. Here below is presented an overview of leather manufacturing and the leather supply

chain. The following information is mainly based on ChemSec Guide[7]and the website leatherfrance.com.

The leather supply chain also follows a series of sequential steps, however the steps are different, and the chemical substances required in those steps are also different.

The following steps occur to transform an animal skin[8], also known as a hide, into a finished leather article.

1. Soaking: the skin is rehydrated and cleaned to remove any impurities and grime.
2. Unhairing and liming, fleshing: the hide is stripped of hair, excess flesh and fatty tissue is removed.
3. Bating: this process is used to start softening the leather.
4. Pickling: at this stage, the skin is acidified to prepare it to undergo the tanning process.
5. The next step is called tanning and this is the process by which the hide is preserved and made durable. These consist of substances of various kinds (vegetable, mineral such as chromium III salts, combination tanning) that convert the skin from a putrescible substance into a rotproof material, which is resistant to hot water and has a low water content.
6. The hide is dyed and then grease, or a synthetic alternative, is added to improve the hand feel and aesthetics.
7. The hide is further treated to help prepare it for its final use (Shoes, jackets, accessories etc.)
8. Finally, the hide is finished to provide additional functionality. A significant proportion of leather has a synthetic coating applied to enhance aesthetics and / technical performance. At this stage, the leather takes on specific properties, notably in terms of its texture and appearance. These properties enable the leathers produced to be standardised. Depending on the end-uses involved, the following finishes are distinguished:
    - Aniline finish: this enhances the surface of the leather by covering it with a transparent substance. This type of leather has a fine appearance, but its upkeep requires a great deal of attention.
    - Semi-aniline finish: The leather is covered with a slightly opaque layer of pigment and another layer of translucent material, which masks minor defects.
    - Pigment finish: The leather is covered with a layer of opaque pigments only. It offers easycare properties and is not sensitive to water.

A.2.1.3. Textile and leather formulations

In addition to understanding the sequential steps involved in textile and leather wet processing, it is also important to understand what types of chemical substances may reside

[7] http://textileguide.chemsec.org/find/textiles-come-with-a-toxic-footprint
[8] Animal hides are made into leather via a series of manufacturing steps. An animal hide would not be sold directly to a consumer until it has gone through some textile processing.
For this assignment, fur can be considered as leather with hair. Examples are sheepskin and animal pelts used to make jackets and other types of apparel items. Both leather and fur need to be treated so that they become durable and can attract dyes and other performance chemicals that provide a set of functional benefits.

in the formulations that are used to process textiles and leather. The information below is taken from KemI (2019).

Upstream synthesis of chemicals (at the chemical **manufacturer**) usually involves the use of relatively simple chemical building blocks to form chemical 'intermediates'. Chemical intermediates are then reacted to form the desired chemical species –a dye or an emulsifying agent or a softener etc. Catalysts are used to speed up chemical reactions and very few reactions involve entirely pure (uncontaminated) reagents or have 100% conversion to the desired chemical species.

Chemical formulations such as dyes, softeners etc. are therefore contaminated with impurities, unreacted building blocks, unreacted chemical intermediates, by-products from unwanted side-reactions and catalysts. Removal of such contaminants is costly and unlikely given the cost conscious fashion industry.

Chemical **formulators** take the desired chemicals and create formulations for use by the wet processing industry; this involves the addition of substances to aid solubility, stability, applicability and other necessary functions.

A formulation, whether it is a dye, a detergent or a softener, always consists of a number of individual chemical substances. Some are intentionally added, whereas others may be unintentionally present.

In KemI (2019) it is concluded that it is very difficult to know exactly what substances are present in a formulation because the chemical industry is not required to disclose all intentionally added chemicals unless they are present at concentrations greater than 1%, or 0.1% for certain harmful substances.

Below is a diagram of a typical chemical formulation that shows the different functions required to give the formulation the right consistency, quality and longevity (KemI, 2019).

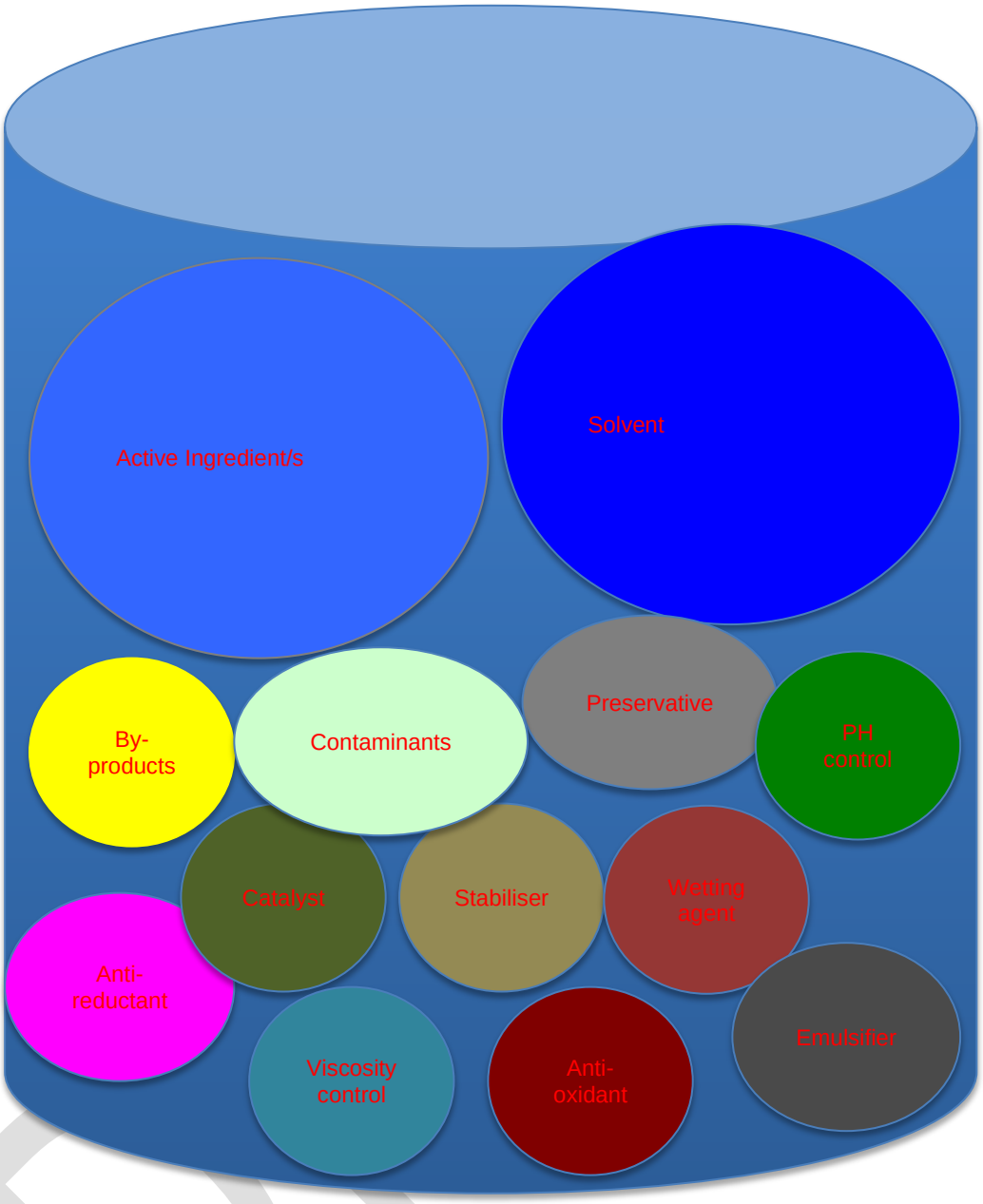

Figure 4 : Visual representation of a drum of a chemical formulation used in textile and leather processing. Source: KemI (2019)

As described in KemI (2019), each drum consists of the active ingredients and a solvent, which may or may not be water, plus lower concentrations of other chemical substances that provide much needed functions such as preserving agents, anti-oxidants, stabilizers etc. These functional chemicals play a critical role in the stability and quality of the formulation, and in some cases, these substances may be unintentionally, but foreseeably present, on finished textiles.

A.2.1.4. Chemicals used in textile and leather

A.2.1.4.1 Existing reports

European government authorities published various reports and survey regarding hazardous chemicals in textile.

In 2010, the RIVM made a list of potentially hazardous chemicals in indoor environment with a focus on inside textile products (rugs, clothing etc.). The aim was to put forward new chemicals flame retardants, phthalates in textiles that may need a new regulation (RIVM, 2010).

In 2012, the BfR wrote an opinion on substances that are in clothing and that can induce skin sensitisation allergies. This opinion is mainly focused on formaldehyde, glyoxal, flame retardants, colorants, organo-tin compounds, biocidal products, etc. (BfR, 2012). The BfR made some recommendations to stop the usage of some dyes like Disperse Blue 1, Disperse Blue 35, Disperse Blue 106, Disperse Blue 124, Disperse Yellow 3, Disperse Orange 3, Disperse Orange 37/76 and Disperse Red 1. This opinion also indicates that 1,2,4 trichlorobenzene is dangerous used as a dye vector in textiles. BfR finally recommended not to use anymore triclosan as antimicrobial in textiles (BfR, 2012).

In 2013, the Swedish Chemicals Agency investigated which chemicals with hazardous properties are used in the textile production. Furthermore, the hazardous chemicals that may be found in the final textile product were listed. A non-exhaustive list of substances falling within the chosen definition of hazardous chemicals (CMR, endocrine disruptors, skin or respiratory sensitisers), was presented as an indicator of which chemicals may be needed to be restricted (e.g. amines, formaldehyde, organo-tin compounds, chromium etc.) (KemI, 2013).

In 2014, KemI published a new report that gathered all information on textile consumption in the EU, a screening study with the aim of identifying hazardous substances/groups of substances posing a potential risk to human health and the environment. The list of substances pointed out mainly comprises flame retardants, azodyes, fragrances, plasticizers (KemI, 2014).

And finally, in 2016, KemI's report on hazardous chemicals substances in textiles with proposals for risk management measures was published (KemI, 2016). Their conclusions pointed out into three directions:

- A specific regulation about textiles in Europe which will imply necessary requirements regarding chemicals in textiles. This regulation should cover the CMR, endocrine disruptors, skin sensitisers and the substances hazardous for the environment.
- Support the possibility to introduce restriction for azo-dyes,
- Implement a study to establish the possibility of a tax for textiles.

In parallel, in 2014, RIVM published a methodology to prioritize chemicals, register under REACH and not already regulated, that could be present in textiles and trigger an adverse effect onto consumers (RIVM, 2014). The prioritization took into account the uses of the substances, their classification and their potency. The most severe substances identified were dyes and flame retardants.

In 2014, the survey of selected allergenic, disperse dyes in clothes was published by the Danish EPA (Danish EPA, 2014). This survey aimed at making a focus onto allergenic disperses dyes in synthetic textiles in Denmark. The textiles were in polyester in dark colours or luminous ones. An important list of allergenic disperse dyes were tested and none of them were found in the textiles.

The article 25 from the regulation (UE) No 1007/2011 planned that the European Commission would evaluate the hazardous chemicals present in textile and in particular the link between allergic reactions and chemicals found in textiles. Finally, if necessary, it was asked to propose some regulatory measures. In 2013, RPS completed this assessment by first defining what was an allergic reaction due to textile. Then a list of chemicals and mixtures in textiles that can trigger allergies was made. To establish this list, RPS has performed a literature review, and sent questionnaires to industry. The list of substances and mixtures contained: disperse dyes, flame retardants, preservatives and antimicrobials, softeners, fixing agents, formaldehyde, perfumes, resins, antistatic and anti-slipping substances (RPS, 2013).

RPS proposed various actions:

- New informative guidance for consumers,
- To combine voluntary actions (labels, standards) with control procedures,
- Other measures like the one to derivate and harmonise limits values for very sensitising substances based on quantitative risks assessments etc.

A.2.1.4.2. Technical functions of the formulations used

As presented mentioned in section A.2.1.1 and A.2.1.2 chemicals are thus present in all parts of textile and leather processing, from fibre to finished product. A definition of the functions is explained in the table below.

Table 2 : Functions of the typical chemical substances used in chemical formulations

Type of chemical substances	Technical function	Reference
Active ingredient	The chemical that is deliberately applied to the textile or leather [e.g. a dye, a water repellent finish or a softener]. Sometimes the formulation is 'passive' and the active ingredient is simply transferred to the leather/textile [many softeners and dyes] Sometimes the formulation is reactive and the active ingredients react to form a different chemical on the leather/textile [e.g. some resins, coatings and binders]	KemI (2019)
Solvent	A solvent is usually a liquid that is used to dissolve substances or materials, such as pigments, in a solution, the dye. Solvents are used in several stages throughout the production process. Water can often be used as a solvent, but it cannot be used for everything. Different types of organic solvents are often required. Many of them are hazardous when inhaled or when they come in contact with the skin. Solvents are often used in large quantities both in the production process as well as for cleaning of the machinery. Many solvents are also flammable and some are explosive. Careful selection of solvents can be an efficient way to reduce hazards, especially in the work place	ChemSec Guide
Contaminants/impurities	No chemicals that are used in leather/textile processes are 100% pure due to cost constraints. All formulations and process chemicals will contain impurities	KemI (2019)
By-products	No chemical process results in a 100% conversion of starting materials to the intended product – there are always unwanted side-reactions and by-products form upstream processes. Unreacted building blocks and intermediates may be present in formulations	KemI (2019)
Preservatives/_Biocides and pesticides	Preservatives are used to extend the shelf life of a formulation or perhaps the shelf life of un-dyed fabric during transportation from one mill to another, which is common. Small amounts of preservatives are used to protect chemical formulations. Biocides and pesticides are used to prevent living organisms from thriving on goods. Biocides can be used to prevent anything from bacterial growth to grazing by large animals, and are designed to be hazardous for the target organisms. Pesticides, or	ChemSec Guide

	plant protections products are used to defend crops from damage by insects, mould or weeds. Residues of pesticides may therefore be present in fibres such as cotton or linen. Biocides can also be used during manufacture, transportation or to give the end product antibacterial properties. Mould inhibitors may be used to provide protection during transportation or storage of wet goods. Biocides and pesticides are out of scope in this restriction proposal.	
pH control	Acids, alkalis and buffers are used to keep formulations at an appropriate pH for storage and application. Poor pH control can result in costly precipitation, coagulation etc.	KemI (2019)
Catalyst	Active formulations (where curing/cross linking is required) may include a catalyst and residues of catalyst from upstream manufacturing may also be present	KemI (2019)
Wetting agent	Detergents are used to ensure formulations can penetrate textiles/leather	KemI (2019)
Emulsifier	Short cut for emulsifying agent that are used in formulations that contain oils/water to stabilise the mixes	ChemSec Guide
Anti-oxidant	Some chemicals are degraded by oxidation (exposure to air) and so anti-oxidants are used to protect against costly damage	KemI (2019)
Anti-reductant	Some chemicals are degraded by reduction (exposure to reducing agents). Anti-reductants are used to protect against costly damage	KemI (2019)
Viscosity control	Some formulations contain gels or diluents to adjust viscosity for optimum application	KemI (2019)
Stabilizers	Stabilizers may be required to maintain good conditions for the formulation during storage and/or of the chemical when applied to textiles leather	KemI (2019)
Surfactants	Surfactants may act as detergents, wetting agents, emulsifiers, foaming agents, dispersants, softeners and antistatic agents and are used in many stages of the textile process. Commonly used surfactants are alkyl phenol ethoxylates, which are problematic since they are endocrine disruptors, meaning they could interfere with the hormone systems of mammals	ChemSec Guide
Water and soil repellents	Water repellence is often a desired property, especially for fabrics that are used outdoors. A popular way to achieve this is to impregnate the fabric with fluorinated or perfluorinated compounds. Some of these substances, including PFOA and PFOS (sometimes called C8 technology), have been known for many years to have hazardous properties. This has led to the increased use of other perfluorinated	ChemSec Guide

	substances. However, many of these (including those sometimes known as C6 or C4) have been shown to have problematic properties as well. And even if the perfluorinated substances give the fabric desired properties, in particular water repellence, it is important to reflect if these properties are really necessary for the specific purpose. There are available alternatives that are not based on fluorochemicals and that can be used to create a water-repellent surface. One option is to use dense cotton fabric which swell in contact with water or a dense synthetic fabric woven from microfibers yarns, both impregnated with wax based alternatives to achieve a repellent effect. In addition, it is also possible to achieve a repellent property in synthetic fabric with a variety of methods without using fluorinated/perflourinated compounds. It is of course equally important that also “refill” repellents sprays sold to consumers are free from these compounds and that the manufacturer and retailer actively promote alternative products, free from fluorocarbons	
Dye/pigments	Dyes and pigments are used to give a desired colour, or whiteness. Some frequently used dyeing methods are using dyes in excess quantities, and large amounts are hence discharged into the wastewater. Some dyes, including azo dyes, can be very toxic and are often persistent, which is a desired property on the fabric but not in the environment. Dyes may also contain heavy metals such as lead or cadmium, which are very hazardous. Optical whiteners on cotton are often only loosely bound to the fibre and hence easily washed off. From an environmental aspect, it is important to choose dyestuff of quality that binds or adheres strongly to the fibre under optimal production conditions. You should be able to reproduce the process and get the same result over and over again. This also counts for the washing fastness which is a very much wanted desired property for the consumer. Disperse dyes are used to stain synthetic fabrics made from polyester, acetate and polyamide. These types of dyes can in some cases easily rub off from the textile and migrate onto the skin of the person wearing the garment. Especially if the dying procedure is not carried out under optimal conditions or if the dye is not suited for the specific material	ChemSec Guide

Flame retardants	Flame retardants are used to make a product less flammable. Depending on national regulations, flame retardants may be required in a product. Examples of such products are protective clothing, curtains and fabrics used in furniture, to name a few. Some of the currently used flame retardants, especially halogenated versions, have been shown to have hazardous properties and some are subject to international and/or national regulations. The first choice when looking for alternatives is to investigate whether the use of a flame retardant is really required or necessary for the purpose. If it is necessary, you may want to look for an alternative, less flammable material or a combination of materials that fulfils the requirements for your product. The good news is that more and more flame retardants with improved health and environmental profiles are becoming available	ChemSec Guide
Plasticisers/ Phthalates	Plasticisers are used to soften plastics. For textile applications, such as screen printing and coating of fabrics, PVC first needs to be softened. One common group of plasticisers is phthalates which are being used in large quantities in the print, often around 30-60% of the total composition. Several phthalates have hazardous properties, such as being toxic to reproduction. Because phthalates are not chemically bound to the PVC but can leach out, users are likely to be exposed to and ingest the phthalates from the textile, for example through fibre dust. Children can get exposed when chewing on the printed textile. Alternative plasticisers exist, as well as alternatives to PVC	ChemSec Guide
Auxiliary chemicals	A range of chemicals is normally used in most steps of the production process to assist the tasks of other chemicals. Such general auxiliaries include: • Acids • Bases • Salts • Detergents • Surfactants • Sequestrants • Stabilisers • Solvents • Enzymes	ChemSec Guide

	Large quantities of chemical substances are used in the manufacture of textiles, from processing of fibres and raw materials to the final touch of the finished article. An overview of the textile production process and what kind of chemicals that are used in the different steps is illustrated in figure 1 and has been described in greater detail in several other reports (FIH, 2011; KemI, 2013; Salute, 2012)	

Annex A: Manufacture and uses

A.2.2. Identification of relevant chemicals in finished textile and leather products

This restriction proposal targets chemicals that are harmonised classified as skin sensitisers and may be present in finished textile and leather articles at point of sale to the general population as well as a list of substances of concern indicated to have skin sensitising properties. According to the ECHA CLH-inventory there are to this date 1 041 substances with a harmonised classification for skin sensitisation in Category 1/1A/1B. It should be noted that not all will be used in the production of the article, and not all will be present in the finished article at point of sale.

In order to perform a risk assessment and a socio-economic analysis, the Dossier Submitter would need specific information on substances that are used in textile and leather articles. This information could then be used to make general assumptions on all substances within the scope of this restriction proposal. In order to identify which substances are used in textile and leather articles today, the Dossier Submitter first screened chemical databases for substances with any possible indication that they may be used in textile and leather applications. Thereafter, as already mentioned above in A.1.1, a consultancy study was initiated with the purpose to confirm these indications of use and refine the list as far as possible (KemI, 2019). In the consultancy study, the concentration of the used substance in the finished articles was also estimated (for details about this consultation, please see Annex G).

Initially, substances that are harmonised classified for skin irritation as well as those classified for skin corrosion were included in the scope. Therefore, in the identification of relevant substances in finished products, also substances with those classifications were included and assessed in the consultancy study (KemI, 2019). These substances were however later on excluded from the scope by the Dossier Submitter for several reasons: i) these endpoints are considered less severe in that the effect is reversible; ii) for irritant and corrosive substances, the threshold of the induction of the adverse effect (corrosive or irritant) is not determined, making it difficult to carry out a qualitative or a quantitative assessment; iii) the Dossier Submitter finds it unlikely that these substances would be present in articles at such high concentrations that would cause harm to people wearing the articles. For more information on the scope, and substances that are covered by the restriction proposal, please see Annex E.1 and section 1.1 of the Main report.

In this restriction proposal, leather articles also include articles made of fur and hides, unless specifically specified.

A.2.2.1. Screening of substances with a possible use in textile and leather

Substances which are possibly used in textile and leather applications were identified by the Dossier Submitter by screening inventory databases available in Sweden and in other countries. Both publicly and confidentially available information were used (this information is collected in an internal database for prioritization at Swedish Chemicals Agency).

The following sources were used:

- the IUCLID database,

- the Swedish Products Register[9],
- the SIN list[10],
- Color Index database[11],
- CpCAT database (US EPAs product database)[12],
- KemI's textile list (unpublished),
- CLP database (ECHA),
- SPIN database (Nordic Product Register data)[13]

Approximately 6 000 substances were identified as potentially used in textiles, leather, furs and/or hides. In addition, another ~6 000 substances with structural similarities to these were identified.

Of these ~12 000 substances, 176 substances have a harmonised classification for skin sensitisation, 84 for skin corrosion and 137 for skin irritation (since, again, skin corrosion and skin irritation were initially endpoints included in the scope). In total, 320 substances had a harmonised classification for either of the three endpoints (or more).

In a study conducted by ANSES, 15 substances or families of substances present in actual textiles and footwear articles, and which were proven to cause allergic dermatitis or skin irritation in actual patients, were identified (ANSES, 2018). In total, 35 substances (including skin irritant substances) were identified, comprising dyes, biocides, heavy metals, etc. Of these substances, 9 were already among the 320 substances identified by the Dossier Submitter. The remaining 26 substances from the study were added to the list. Consequently, the initial list of substances of potential concern and which were considered to have a possible application in textile and leather included 346 substances. The list of substances were evaluated in a consultancy study (KemI, 2019) in order to determine which ones are used today (at the time of the elaboration of this restriction proposal) in the manufacture of textile and leather articles, see more information below in section A.2.2.2.

At the time point of preparation of the current restriction proposal, there were RAC opinions available calling for a harmonised classification for skin sensitisation, skin corrosion or skin irritation for another 10 substances. These substances were not included in the consultancy study, but they were in a Call for comments and evidence hosted by ECHA and in a questionnaire sent to selected stakeholders. The list of substances for these activities therefore comprised 356 substances.

A.2.2.2. Identification of substances in finished articles

In order to identify which of the 346 substances on the initial list prepared by the Dossier Submitter are possibly present in the finished textile and leather articles at point of sale, a consultancy study was initiated. The purpose of this study was to:

- Identify substances on the list that are used in the production textiles, leather, furs and hides, and that are likely to be present in any of the finished articles.

[9] https://www.kemi.se/en/products-register
[10] https://chemsec.org/sin-list/
[11] https://colour-index.com/
[12] https://www.epa.gov/chemical-research/chemical-and-products-database-cpdat
[13] http://spin2000.net/

- Gather information about levels in formulations, use patterns and potential consumer exposure
- Estimate approximate volumes, identify if and how the substances can be substituted, and the approximate costs of substitution.

The study showed that 116 chemicals can potentially be present on articles at point of sale in concentrations that potentially can cause harm to consumers. This list is referred to by the consultants as the IN-list (KemI, 2019), and captures chemical name and CAS number, use/function, where in the supply chain the chemical is used (deliberately or unintentionally), volumes, alternatives, costs, recommendations and suggested priorities, for each substance or group of chemical substances, where applicable. In order to develop the IN-list, it was established, for each chemical on the initial list, if it is used in the processing of textiles/leather or in the manufacture of chemicals for use in wet processing. It was also determined if the chemical may still be present in the finished article at point of sale, after going through industry standard processes, and if so, at what concentrations. In this work, several questions have been submitted to different expert groups (associations, trade organisations, companies, etc.) consulted. For further details about the consultations carried out, please see Annex G.

Further refinement of the IN-list by the Dossier Submitter

In order to obtain a list of chemicals that are relevant for the scope of the current restriction proposal, the Dossier Submitter further refined the IN-list prepared by the consultants. Chemicals without a harmonised classification for skin sensitisation were removed from the consultants' IN-list (i.e. substances with only a harmonised classification for skin irritation or skin corrosion). This resulted in a list of 70 substances, all with a harmonised classification for Skin Sens 1/1A/1B. In addition, 24 substances that presently are included in voluntary schemes for substitution because of skin sensitising properties were added to the list.

The Dossier Submitter's final Master List thus includes in total 94 substances, of which 70 have a harmonised classification for Skin Sens 1/1A/1B, and 24 substances without a harmonised classification for Skin Sens 1/1A/1B but are considered to be of concern (these 24 substances corresponds to the List of Concern, see section 1.1.4.3 of the Main report). The Master List covers substances with skin sensitising properties and which may be present in finished textile and leather articles at point of sale and is shown in Table 19 in Annex E2.

It should be noted that the consultants did not find complete information on costs and cost of alternatives for all substances in the IN-list. The Dossier Submitter has in the Master List complemented with additional information when found, but for some substances this remains one area where more information is needed in the public consultation (for more details, see Annexes E.2).

A.3. Uses advised against by the registrants

It should be noted that some of the substances classified as skin sensitisers have their uses for textile not covered by its registration dossier (textile identified as use advised against). Uses advised against by the registrants is treated as confidential information.

Annex B: Information on hazard and risk

B.1. Identity of the substance(s) and physical and chemical properties

B.1.1. Name and other identifiers of the substance(s)

More than one thousand substances fall within the scope of the restriction proposal. Table 3 below gives a breakdown of the number of these substances by category.

Table 3 : Number of substances with a harmonised classification as skin sensitisers or with skin sensitising concern (included in list of concern) including biocidal substances

Total number of substances in the scope:	
A/ Substances with an harmonised classification in the Classification, Labelling and Packaging Regulation (EC) n° 1272/2008 as Skin sensitiser 1,1A, 1B	1 030 Skin Sens 1 11 Skin Sens 1A 9 Skin Sens 1B
B/Substances without an harmonised classification but of skin sensitising concern	24

Substances of concern: These substances are known to be used in clothing and footwear, and some of them have been identified to cause allergic dermatitis in clinical tests (for more details, please refer to Annex B.5.11.1 and here below.)

The restriction proposal intends to cover substances having harmonised classifications as skin sensitisers in Category 1/1A/1B according to Annex VI of the CLP Regulation. It is important to bear in mind that skin sensitisation is not a prioritised hazard category under CLP (Article 36 of CLP regulation) and therefore, many chemical substances with allergenic properties will not yet have harmonised classifications as skin sensitisers. Hence, to limit the restriction to substances with harmonised classifications is judged insufficient to significantly reduce the risk of skin sensitising substances in textile, leather, hide and fur. The Dossier Submitter therefore suggests to add disperse dyes to the scope (see Table 4 List of substances of concern) that have been indicated to cause ACD when present in textile or leather articles. All these substances are included in voluntary labelling schemes such as the Oeko-tex standard, Bluesign, Global Organic Textile Standard, EU Ecolabel and Nordic Swan Ecolabel and on (manufacturing) restricted substances lists ((M)RSL) such as Zero Discharge of Hazardous Chemicals because of their skin sensitising properties.

Therefore, similar to the approach adopted in the tattoo inks and permanent make-up restriction proposal, it is proposed to restrict all substances with certain specific hazards so that they will no longer be present above a proposed concentration limit in the articles covered by this restriction proposal, based on the argumentation that these hazards are severe enough to justify the proposal. Thus, this restriction proposal covers all substances with a harmonised classification as skin sensitisers in Category 1/1A/1B and listed Annex VI of the CLP regulation, as well as substances considered of concern due to their sensitising properties, although not having a harmonised classification as such. By this dynamic relationship to the CLP regulation, substitution from one skin sensitising substance in textile and leather article to another skin sensitising substance will be prevented, and thereby maintaining a high risk reduction potential of the restriction.

Table 4: List of substances of concern (included in the scope)

Substance name	EC Number	CAS No.	Reason for inclusion
CI Disperse Blue 3	219-604-2	2475-46-9	Included in a Voluntary scheme due to sensitisation concern
CI Disperse Blue 7	221-666-0	3179-90-6	
CI Disperse Blue 26	223-373-3	3860-63-7	
CI Disperse Blue 35	602-260-6	12222-75-2	
CI Disperse Blue 102	602-282-6	12222-97-8	
Ci Disperse Blue 106[14]	68516-81-4	271-183-4	
CI Disperse Blue 124[15]	15141-18-1	239-206-6	
CI Disperse Blue 291	56548-64-2	260-255-0	
CI Disperse Brown 1	245-604-7	23355-64-8	
CI Disperse Orange 1	219-954-6	2581-69-3	
CI Disperse Orange 3	211-984-8	730-40-5	
CI Disperse Red 1	220-704-3	2872-52-8	
CI Disperse Red 11	220-703-8	2872-48-2	
CI Disperse Red 17	221-665-5	3179-89-3	
CI Disperse Yellow 1	204-300-4	119-15-3	
CI Disperse Yellow 9	228-919-4	6373-73-5	
CI Disperse Yellow 39	602-641-7	12236-29-2	
CI Disperse Yellow 49	611-202-9	54824-37-2	
CI Disperse Orange 149	400-340-3	85136-74-9	
CI Disperse Yellow 64	233-701-7	10319-14-9	
CI Disperse Violet 1	204-922-6	128-95-0	
CI Disperse Violet 93	2 -	268221-71-	
CI Disperse Yellow 23	228-370-0	6250-23-3	Included in a Voluntary scheme due to sensitisation concern + Anses 2018 study
CI Disperse Orange 37 /59/76	236-325-1 602-312-8	13301-61-6 12223-33-5 51811-42-8	

Some of the substances in the scope have additional harmonised classifications as CMR, and may thus be covered by the restriction of CMR substances in textile (Entry 72 of the Annex XVII of REACH). Moreover, some of the substances classified as skin sensitisers in Category 1/1A/1B according the CLP Regulation are already restricted within REACH or by other sectorial regulations such as the Biocidal Products Regulation. In case there are coexisting parallel regulations for the same substance and application, the Dossier Submitter proposes that the regulation with the stricter concentration limit applies (For more details, please refer to section 1.1.4.3 in the main report).

[14] The former CAS/EC numbers for the CI Disperse Blue 106 are 12223-01-7/602-285-2
[15] The former CAS/EC numbers for the CI Disperse Blue 124 are 61951-51-7/612-788-9

Other substances were highlighted in the Anses study because they were found multiple times in clothing and footwear and can be of concern regarding sensitising issue. Nevertheless, these chemicals were not found to be the ones that triggered sensitisation on the patient when they were quantified in the articles (Anses, 2018).

Moreover, even if these substances do not have harmonised classifications as skin sensitisers according to the CLP Regulation, they can be restricted in other regulation (eg Cosmetic Product Regulation) or they can have been notified by industrial as skin sensitisers according the CLP. That is why, the Dossier Submitter would like to underline to the reader, four substances of interest which are : benzyl benzoate, 2-phenoxy ethanol, butyl hydroxytoluene and paratertbutylphenol.

Benzyl benzoate:

Benzyl benzoate is subject to mandatory labelling in cosmetic products according to Regulation (EC) No 1223/2009. It is on the list of 26 allergenic fragrances.

Benzyl benzoate seems to be used in textiles as a dye accelerator in polyester and polyester/wool or as a substituent of chlorobenzenes and other aromatic solvents (biphenyls, phenyl oxides, etc.), all of which are classified as POPs.

This substance is not authorised in Europe under Regulation (EU) No 528/2012 (the Biocides Regulation) in PT18 (insecticides). However, a potential use outside the European Union as an anti-mite biocide in the manufacture, packaging or shipment of imported articles may be suspected.

This substance has been classified as Acute Toxicity Category 4 by the CLP Regulation. Benzyl benzoate was quantified during the Anses biomedical study in three footwear articles (Anses, 2018) and three new footwear articles (causing ACD even if it's not linked to benzyl benzoate) at concentrations ranging from 13 to 45 mg/kg (at 885 mg/kg in one sample but with suspected external contamination). It was also detected from thermal extraction in eight new textile articles and 11 samples included in the biomedical study.

Butyl hydroxy toluene :

Butylated hydroxy toluene (2,6-di-tert-butyl-4-methylphenol, BHT) is a substance notified by manufacturers under the CLP Regulation as Acute Toxicity Category 4.

BHT was detected or quantified in all the footwear articles analysed in the biomedical study (Anses, 2018). When it was quantified, the BHT concentrations were between 11 mg/kg and 71 mg/kg. BHT was detected in three new footwear articles (concentration of less than 10 mg/kg) and quantified in nine new footwear articles at concentrations ranging between 11 and 57 mg/kg (causing ACD even if it's not linked to butyl hydroxy toluene) .

BHT was thermally extracted from four textile articles from the biomedical study (maximum concentration of 2 mg/kg) and eleven new textile articles (maximum concentration of 165 mg/kg).

This substance is not currently classified but according to the RMOA conducted by France in 2014, in the framework of the REACH Regulation, this substance is suspected of having an endocrine-disrupting effect on the thyroid.

2-phenoxyethanol :

2-phenoxyethanol was detected and/or quantified in all the footwear from the ANSES study. When it was quantified, the concentrations were between 11.30 and 68 mg/kg. It was also detected in seven new footwear articles (concentrations below 10 mg/kg) but in none of the new textile articles (Anses, 2018).

This substance was quantified seven times in textile articles from the biomedical study using thermo-desorption (maximum concentration of 1.70 mg/kg) (causing ACD even if it's not linked to 2-phenoxyethanol).

This substance, mainly used as a solvent in the dyeing or finishing of footwear and textile articles, is regulated as an eye irritant (Eye irrit. 2) and Acute Tox 4. under the CLP Regulation.

It cannot be used at a concentration of more than 1% in cosmetic products, as a preservative, according to the Cosmetics Regulation (EC) No 1223/2009.

Para-tert-butylphenol:

Para-tert-butylphenol was quantified in six articles of footwear from the biomedical study (at concentrations ranging up to 152 mg/kg) and in six new footwear articles (at concentrations ranging up to 80 mg/kg). These articles caused ACD even if it is not linked to para-tert-butylphenol. Para-tert-butylphenol is prohibited in cosmetic products and is classified as a Category 2 skin irritant and Category 2 reprotoxic substance. The presence of formaldehyde in the analyses, in conjunction with the presence of para-tert-butylphenol, can be an indicator of the presence of para-tert-butylphenol formaldehyde resin in footwear.

Formaldehyde was quantified ten times in footwear (up to 425 mg/kg) and five times in new footwear (up to 22 mg/kg) in the ANSES study (Anses, 2018).

Other substances of interest:

The Dossier Submitter has identified chromium III substances that do not presently have harmonised classifications as skin sensitisers according to the CLP Regulation, but that may be of concern according to a consulted leather expert [16] . The Dossier Submitter would like to raise attention to these substances as well and encourage the Member States to oversee the possibility to propose harmonised classification according to the CLP regulation.

B.1.2. Composition of the substance(s)

Not relevant for this restriction proposal due to the high number of substances included in the scope. A focus could be done for the substances on the list of concern. Indeed, the substances included in the list of concern are only disperse dyes. These dyes do not have specific composition however compared to the disperse dyes already classified as skin sensitiser 1/1A/1B and are used in the same way as the already classified ones (please see A.2).

[16] Dossier submitter's personal communication 2019

B.1.3. Physicochemical properties

Physical and chemical properties are not included in this report due to the high number of substances included in scope except for the substances of the list of concern (see Table 5).

Table 5 : Chemical and physical properties of the substances included in the list of concern

Substances (CAS number)	EC Number	Classification under CLP	Melting point	Boiling point	Relative density	Vapour pressure	Water solubility	Log Kow
CI Disperse Blue 3 (2475-46-9)	219-604-2	Not classified	187°C	437°C	1.14	ND	Insoluble	3.28
CI Disperse Blue 7(3179-90-6)	221-666-0	Not classified	215-220°C	491°C	1.607	ND	ND	ND
CI Disperse Blue 26 (3860-63-7)	223-373-3	Not classified	217°C	439°C	1.34 - 1.53	ND	0.0203 mg/L	4.7
CI Disperse Blue 35 (12222-75-2)	602-260-6	Not classified	ND					
CI Disperse Blue 102 (12222-97-8)	602-282-6	Not classified	ND					
CI Disperse Blue 106 (68516-81-4)	271-183-4	Not classified	ND			ND	ND	ND
CI Disperse Blue 124 (15141-18-1)	239-203-6	Not classified	ND			ND	ND	ND
CI Disperse Brown 1 (23355-64-8)	245-604-7	Not classified	ND	647.5°C	1.543	ND	ND	ND
CI Disperse Orange 1(2581-69-3)	219-954-6	Not classified	151-158°C	ND	1.24	$4.69.10^{-9}$ mmHg	Insoluble (10^{-4}g/L)	5.8
CI Disperse Orange 3 (730-40-5)	211-984-8	Not classified	215°C	460.2°C	1.34	ND	0.34 mg/L	3.59
CI Disperse Red 1 (2872-52-8)	220-704-3	Not classified	160-162°C	522.5	1.23	ND	0.16 mg/L	N4.3
CI Disperse Red 11 (2872-48-2)	220-703-8	Not classified	N242°C	575.6°C	1.429	$1.95.10^{-9}$ mmHg	0.482 mg/L	3.5
CI Disperse Red 17 (3179-89-3)	221-665-5	Not classified	160°C	586.5°C	1.283	$2.07.10^{-13}$ mmHg	0.757 mg/L	3.69
CI Disperse Yellow 1 (119-15-3)	204-300-4	Not classified	191 -196°C	443.8°C	1.549	ND	Practically insoluble (0.02 g/L)	2.67
CI Disperse Yellow 9 (6373-73-5)	228-919-4	Not classified	187-190°C	466°C	1.511	ND	315 mg/L	2.04
CI Disperse Yellow 39 (12236-29-2)	602-641-7	Not classified	ND	465.9°C	1.219	ND	ND	ND
CI Disperse Yellow 49 (54824-37-2)	611-202-9	Not classified	ND	ND	1.62	ND	ND	ND
CI Disperse Orange 149 (85136-74-9)	400-340-3	C 1B H 350 Aquatic Chronic 4 H 413	158.5°C	>250°C	1.28	ND	< 0.01 mg/L	4.6

Substances (CAS number)	EC Number	Classification under CLP	Melting point	Boiling point	Relative density	Vapour pressure	Water solubility	Log Kow
CI Disperse Violet 1 (128-95-0)	204-922-6	Not classified	265-269°C	544.2°C	1.456	ND	0.33 mg/L	3
CI Disperse Violet 93 (268221-71-2)		Not classified	172 – 180°C	680.8 - 695.2°C	1.42 - 1.64	0 Pa	20 - 33.3 µg/L @ 20 °C	5.7 – 5.8
CI Disperse Yellow 64 (10319-14-9)	233-701-7	Not classified	ND	505.4°C	1.691	ND	Miscible	ND
CI Disperse Blue 291 (56548-64-2)	260-255-0	Not classified	173 - 203 °C	700.4-686.4	1.42 - 1.58	0.001 Pa @ 20 °C	52.2 µg/L - 10 mg/L@ 20 °C	1.543 - 6.9
CI Disperse Yellow 23 (6250-23-3)	228-370-0	Not classified	ND	ND	ND	$2.41.10^{-9}$ mm Hg	$6.04.10^{-5}$ mg/L	5.75
CI Disperse Orange 37/76/59 (13301-61-6 or 12223-33-5 or 51811-42-8)	236-325-1 602-312-8	Not classified	No data					

ND: not determined

B.1.4. Justification for grouping

The justification for targeting the substances in this restriction proposal is explained under 1.1 Introduction and 1.1.4 Scope.

B.2. Manufacture and uses (summary)

Data about manufacture and uses are provided in details in Annex A.

B.3. Classification and labelling

B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

The classifications of the substances in the scope are included in Appendix B.1 and in section 1.2.2 of the main report.

B.3.2. Classification and labelling in classification and labelling inventory/ Industry's self classification(s) and labelling[1]

Due to the large number of substances in the scope of the restriction proposal, the notified classification and labelling in the classification and labelling inventory (Industry's self-classification(s) and labelling is not included in appendix B.1.

B.4. Environmental fate properties

Not relevant.

B.5. Human health hazard assessment

B 5.1 Skin irritation

The substances with harmonised classification as Skin irritation in Category 2 have the potential to cause reversible damage to the skin, such as erythema, oedema or limited scaling.

B 5.2 Skin corrosion

The substances with harmonised classification as Skin corrosion in Category 1/1A/1B/1C have the potential to cause destruction of skin tissue, such as necrosis, ulcers and scars.

B.5.3. Skin sensitisation

The chemical substances in the scope of the proposed restriction either have harmonised classifications as skin sensitisers in Category 1/1A/1B or have been indicated to have skin allergenic properties.

The substances with harmonised classifications as skin sensitisers in Category 1/1A/1B have the potential to cause allergic contact dermatitis (ACD) in individuals that are exposed to the substances *via* the skin.

The chemical substances in the scope of the proposed restriction which are contained in the list of concern (see section 1.1.4.3) are considered to have skin sensitising properties, although not having a harmonised classification as such. The disperse dyes on the list of concern are included in several voluntary schemes such as Oeko-tex standard, Bluesign, Global Organic Textile Standard, Zero Discharge of Hazardous Chemicals, EU Ecolabel and Nordic Swan Ecolabel because they are considered as allergenic dyestuffs. They are also mentioned in scientific literature, through patch testing results and in Anses study performed in 2018. In addition, the EU Commission lists Disperse Blue 26, Disperse Blue 102, Disperse Orange 37, Disperse Orange 149, Disperse Yellow 23 and Disperse Yellow 49 as skin allergens (Malinauskiene, 2012). In September 2019, German authority BAuA submitted a proposal for harmonised classification of Disperse Blue 124 as Skin Sens. 1A with a SCL of 0.001%.

B.5.3.1. Development of allergic contact dermatitis

ACD is a type IV or delayed type hypersensitivity reaction, which means that it is an allergic response that is mediated by T cells. The Dossier Submitter acknowledges that the definition of the term skin sensitisation may differ slightly between regulatory frameworks such as the CLP Regulation and the Cosmetic Products Regulation and scientists in the dermatology and allergy field. In this restriction proposal, sensitisation and skin sensitisation is defined as in the CLP Regulation, where it is stated that the development of skin sensitisation includes two phases. The first phase is the induction phase in which the immune system is primed. After penetrating the skin, the chemical binds to proteins and hapten-carrier complexes are formed, which are recognized and processed by Langerhans cells that migrate to the draining lymph nodes. In the lymph nodes, Langerhans cells present the hapten-carrier complex to T-cells, which in turn are activated and start to proliferate and generate so-called memory T-cells. These T-cells recirculate and gain access to the skin. This is an asymptomatic event which may occur instantaneously or take place over months or years of exposure to the allergen. After induction, re-exposure to the allergen leads to the second phase (elicitation) in which the hapten complex is processed again by Langerhans cells and presented to the memory T-cells present in the skin. The activation of these T-cells causes a rapid release of cytokines and other inflammatory mediators, leading to an inflammatory response in the skin, the ACD. Currently in humans, the only detectable and measurable health effect of skin sensitisation is the elicitation phase, or the ACD. Prevalence and incidence are therefore related to the ACD.

The clinical features of ACD include eczema, oedema, rash and itching, pruritis and vesicles. Symptoms can range from mild to severe, and they can appear within a few hours up to 10 days after the moment of contact with the allergen. The inflammatory response typically develops at the site of allergen contact. Symptoms are maximal within 2–3 days and, without further exposure to the allergen, they decline.

B.5.3.2. Allergic contact dermatitis acquired from textiles and leather

ACD from textiles has been described in clinical studies and case reports and reviewed in many scientific publications and authority reports (Coman et al., 2014; RSP, 2013; KemI, 2014; Lisi et al., 2014; Mobolaji-Lawal & Nedorost, 2015; Moreau et al., 2005; Nygaard et al., 2013; Pacheco et al., 2013; Salute, 2012; Uzuncakmak et al., 2015; Vandevenne et al., 2015). ACD is manifested as inflammation of the skin typically characterised by redness, rash

and oedematous and/or scaly skin lesions (Salute, 2012). The lesions are primarily located on the chest, abdomen and thighs but can involve all parts of the body. The clinical picture may vary considerably and be difficult to diagnose. The condition is mainly associated with synthetic materials, and the garments include trousers, skirts, underwear, shirts, nylon stockings and sportswear (Lisi et al., 2014). For more detail, see Annex C.

B.5.3.3. Diagnosis of allergic contact dermatitis

The diagnosis of ACD is made through patch testing. It involves standardised application of small doses of a set of potential or individually suspected skin sensitisers for a period of 1-2 days. Normally a standard set of allergens are used. Examples are given in Annex E.5.1.2.1. In the following days, typically up to 48 hours, exposed skin sites are checked for the occurrence of allergic reactions. International guidelines for the application, reading and interpretation of the patch test exist (SCCS 2012).

B.5.3.4. Prevention of allergic contact dermatitis

Primary prevention aims at preventing induction, whereas secondary and tertiary prevention deals with avoiding elicitation (the manifestation of ACD).

B.5.3.5. Classification of skin sensitisers according to the CLP Regulation

Evidence that a substance can lead to sensitisation by skin contact in either humans or animals will normally justify classification as a skin sensitiser. Most of the substances in the scope of the proposed restriction have harmonised classifications as skin sensitisers (Skin Sens. 1). Sub-categorisation into category 1A (strong and extreme skin sensitisers) and 1B (medium or weak skin sensitisers) could be made based on sufficient evidence of potency. The generic classification limits for skin sensitisers in mixtures are 1 and 0.1 % for substances in Category 1/1B and 1A, respectively. The labelling limit for skin sensitisers on Annex VI of the CLP-legislation are set to one tenth of the classification limit. It should be noted that textiles and leather articles are not covered by CLP, and therefore does not require labelling according to chemical content.

Most substances included in the scope of this restriction proposal are classified as Skin Sens. 1, thus lacking sub-categorisation according to potency. The decision on harmonised classification was for many of those substances made prior to the introduction of sub-categorisation, and the majority of the skin sensitisers on Annex VI have therefore not been evaluated according to potency.

B.5.3.6. The dose-response relationship of skin sensitisers

The induction and elicitation of skin sensitisation in humans is generally regarded to be threshold phenomena (i.e. there is an exposure threshold, µg/cm^2, below which sensitisation either does not occur or is not observed clinically). However, the dose-response relationship between skin contact with sensitisers and the actual induction and/or elicitation is complex and the thresholds are therefore often difficult to identify, in particular at a population level. It has been found that the risk for skin sensitisation is not only dependent on the dose of allergen per unit area of skin but also on the number of exposures, or accumulated dose (SCCS, 2012). Other important factors are the duration of skin exposure, the presence of skin irritants and/or of other sensitisers (combination effects), the anatomical sites of exposure, condition of the skin, the level of occlusion and individual susceptibility.

The sensitisation or induction threshold is determined by the potency of the chemical and the dose. Potency can be defined as the relative ability of a chemical to induce sensitisation. Potency determination is typically based on results from animal studies, such as the local lymph node assay (LLNA), in which chemicals are tested in mice in order to define the sensitisation potential. It may also be inferred from historical data from Human Repeated Insult Patch Test (HRIPT). The sensitisation threshold may be used to set limits in products that may prevent individuals from becoming sensitised to skin allergens (primary prevention).

The elicitation threshold dose can be identified by experimental dose–response studies performed on allergic individuals. This dose is likely to be lower than the threshold dose for the induction of sensitisation (Allenby et al., 1989, 1993; Andersen et al., 2001; Frosch et al., 1995; Johansen et al., 1996; McFadden et al., 1998; Menné, 1994) however it is unclear whether induction threshold doses of sensitisers can be readily extrapolated to elicitation thresholds. The complexity is that elicitation thresholds not only depend on the intrinsic properties of the chemical but also on the exposure dose that induced sensitisation, and the strength of the sensitisation. Studies in human volunteers have demonstrated that an inverse relationship exists between the strength of sensitisation and the elicitation threshold dose (Boukhman et al., 2001; Friedmann, 2007; Friedmann et al., 1983). This means that at a higher sensitisation dose, a lower dose is needed for elicitation responses (Scott et al., 2002). Hence, although it is expected that the dose needed to induce skin allergy will be higher than the dose needed to elicit an allergic reaction, it is not given that an allergen with low sensitisation potency will also require a high dose to elicit an allergic reaction in already sensitised individuals. Fischer et al. (2011) found a rather small variation in the elicitation doses between allergens, for the most sensitive part of the allergic population, and no clear relationship between induction potency and elicitation threshold for a range of allergens. Griem et al. (2003) have shown that in humans no correlation could be shown between sensitisation and elicitation thresholds, hence, thresholds for sensitisation can currently not be used to predict elicitation thresholds.

Elicitation threshold doses may originate from patch testing with dilution series of skin sensitisers or from repeated open application tests (ROAT). The ROAT mimicks day-to-day exposure conditions to the product containing the allergen, and typically uses single dosings which are a small fraction of the patch test dose. (SCCS, 2012) From these two types of studies, the dose that give reactions in 10 % of the most sensitive individuals may be identified (ED10 or $MET_{10\%}$, see below), and be used to set limit values in various products, in order to protect consumers from manifestations of allergy (secondary or tertiary prevention). However, dose-response studies of elicitation of contact allergy to determine reliable limit values are rare (NEG, 2018).

MET (Minimal Elicitation Threshold): The $MET_{10\%}$ value represents the concentration at which 10% of sensitised individuals elicit a reaction. The $MET_{10\%}$ is derived from one occluded exposure to a dose of allergen at 0.5 cm^2 area for 48 hours. (Johansen et al., 2011).

ED (Elicitation Dose): The $ED_{10\%}$ is the dose required to elicit a reaction in 10% of sensitised individuals. Values available in the literature are not necessarily derived from occluded patch testing and therefore may differ from $MET_{10\%}$ values. However, the ED10 values given in the present restriction proposal are all derived from patch testing with dilution series, under occlusion during 48 hours.

B.5.3.6.1. Individual susceptibility

Data show that children are not more susceptible to skin sensitisation than adults (Cassimos et al., 1980; Epstein, 1961). Experimental evidence shows that young children are less easy to sensitise, meaning that a risk assessment for adults is enough conservative for children. The risk for skin sensitisation has primarily been linked to the exposure and the inherent properties of the chemical, i.e. its potency. A review on developmental immunotoxicology and risk assessment by Holsapple et al. (2004) concluded that current risk practices have generally proved to be sufficiently protective for children (> 6 months old) and an additional safety factor is not needed for additional protection. Another review by Militello et al. (2006) finds that the risk of sensitisation appears to increase with age, which may be linked to an increase in exposure. It exists some exception for the skin for premies (born before 37 weeks). For more details, please refer to Annex E.5.1

B.5.4. Reference dose

The threshold dose for elicitation reactions is usually lower than that of induction. This means that in general, a dose per skin area derived to protect already sensitised individuals from manifestation of the ACD (elicitation) will also protect naïve subjects from induction, but not the reverse.

Based on the experience of the nickel regulation, it has been shown that the dose that elicits ACD in 10% of already sensitised individuals will not only protect 90% from developing ACD, but will also prevent induction of skin sensitisation and thus decrease the incidence of allergy globally (Jensen et al., 2002; Johansen et al. 2000; Schnuch et al., 2003). In order to protect the general population from the manifestation of allergy, the ACD, as well as induction of skin sensitisation, the Dossier Submitter therefore proposes to use a threshold dose which aims to protect consumers from the elicitation of skin allergy when exposed to chemicals in textile and leather.

For a number of recognised contact allergens in humans, dose-elicitation studies on sensitised individuals are available. These studies indicate that it is in principle possible to derive exposure levels that the majority of sensitised individuals will tolerate. However, for the majority of skin allergens in the scope such data was not found. A general elicitation threshold dose is therefore suggested for those substances. This dose is based on results from a meta-analysis of dose response relationships for 8 different skin allergens (see section B.5.4.2.2. below).

B.5.4.1. Information gathering and search strategy

The skin sensitising properties of substances with a harmonised classification has been agreed upon at the EU level. No detailed hazard assessment is therefore needed. Elicitation threshold doses (ED10 or $MET_{10\%}$-values) was however searched for in the literature. To efficiently and effectively deal with the large amount of substances with a harmonised classification as skin sensitisers included in the scope, the Dossier Submitter used the Master list (see Annex E) as a starting point for information searches. The Master list contains a number of substances that potentially are used in the production of textile and leather. Of the substances in the Master list, a number of substances were further targeted for information searches based on a criteria defined by the Dossier submitter:

- Groups of chemicals with a structural similarity or same toxic entity (eg. diisocyanates, (meth) acrylates, chromium VI compounds)
- Substances for which there is potential for high exposure (deliberate use in textile or leather, substance intended to stay on article and high[17] levels of substance in textile or leather) and
- Substances that are well-known skin sensitisers (e.g. rosin, formaldehyde, nickel and cobalt compounds)

For the substances on the list of concern, a more detailed hazard assessment was performed.

In general, the Dossier Submitter had difficulties to find public data on elicitation threshold doses for most chemicals. The Dossier Submitter search strategy included mainly the internet and the search engine PubMed. Search terms used were chemical names, CAS numbers and chemical group names. Furthermore, the Dossier Submitter looked for information in the Call for Evidence responses and *via* personal communication with researchers in the field. For some targeted substances/groups of substances such as allergenic disperse dyes, chromium and formaldehyde, sparse data was found (Table 6). Detailed information can be found in section B.5.4.2.

Table 6 : Groups of substances or substances which were targeted for information searches.

Group / Substance	**Number of substances**	**Group or substance specific elicitation threshold dose (ED_{10} or $MET_{10\%}$)**	**Source of the ED10 or MET $_{10\%}$**
Diisocyanates	7	-	-
(Meth)acrylates	4	-	-
Chromium VI compounds	8	0.02 µg/cm^2	Cr (VI) Restriction proposal, 2012
Nickel compounds	1	0.74 µg/cm^2	Flyvholm et al. 1997 as reviewed in Fischer et al. 2011
Dyes	2 direct dyes,	-	-
	2 acid dyes	-	-
	8 disperse dyes[18]	0.0003 µg/cm^2	Ryberg et al., 2009
DCHP	1	-	-
Rosin	2	-	-
Formaldehyde	1	20.1 µg/cm^2	Fischer et al. 2011
Cobalt compounds		0.44 µg/cm^2	Fischer et al. 2011
1,4 paraphenylene diamine	1	1.5 µg/cm^2	Sosted et al. 2006
Glutaraldehyde	1	-	-

[17] The term high level refer to assumptions and estimated amounts in the consultancy report (KemI, 2019) where "high" corresponded to ≥10 000 ppm or 30% (DCHP).

[18] The disperse dyes with harmonised classifications as skin sensitisers were assessed as members of the larger group of disperse dyes included in the list of concern.

B.5.4.2. Hazard information related to targeted substances or groups of substances

Allergenic disperse dyes

Eight disperse dyes are included within the list of substances with harmonised classification as Skin Sens 1 according to CLP, likely to be present in textiles (KemI, 2019) and 24 disperse dyes are additional included in the scope *via* the list of concern. The disperse dyes on the list of concern were included based on a hazard and potential risk for skin sensitisation agreed upon by procedures and voluntary schemes such as Oeko-tex standard, Bluesign, Global Organic Textile Standard, Zero Discharge of Hazardous Chemicals, EU Ecolabel and Nordic Swan Ecolabel.

Disperse dyes have been linked to textile-induced contact allergies (see for example Brookstein 2009; Mobolaji-Lawal and Nedorost 2015). Patients that seek medical care for contact allergy are diagnosed with the use of patch tests containing a series of allergenic substances. The European Baseline Series is the most common patch test series in the EU and is routinely used to diagnose patients at dermatology clinics. Included in the textile dye mix are Disperse Blue 35, Disperse Blue 106, Disperse Blue 124, Disperse Orange 1, Disperse Orange 3, Disperse Red 1 and Disperse Red 17, and Disperse Yellow 3. The prevalence of contact allergy to disperse dyes has been investigated in several publications, with varying results. In short, the prevalence of allergic textile dermatitis to disperse dyes among consecutive patients at dermatology clinics is typically around 3% (Isaksson et al., 2015a; Isaksson et al, 2015b; Ryberg et al., 2006, 2010, 2011, 2014; Hatch et al, 2000; Malinauskiene et al, 2012; KemI, 2016). More information on prevalence data on disperse dyes can be found in detail in Annex E.5.

The relative importance of individual dyes within the group of allergenic disperse dyes as culprit agents of ACD is difficult to assess since only a few of them has been examined by epicuteaneous testing in clinical trials. In addition, there are frequent reports of cross-reactions with other dyes and with 1,4-phenylene diamine (PPD).

The sensitising potential of some disperse dyes has been investigated in mice using the local lymph node assay (LLNA). Disperse Blue 106 and Disperse Blue 124 have been identified as strong allergens in several studies (Seidenari et al. 1991; Betts et al. 2005; Kimber et al. 2005). The sensitisation potential of Disperse Blue 106 (the lowest EC3 value was 0.003% for disperse Blue 124, which corresponds to an area dose of 0.75 µg/cm^2) was estimated as being similar to 2,4-dinitrochloro-benzene (Betts et al, 2005). Other disperse dyes have been found to have a higher sensitisation threshold. The suggested relative variation in induction potency between different disperse dyes are depicted in Figure 5. It should be noted that the data on the sensitising potential of the disperse dyes in Figure 5 were generated using a non-guideline modified version of the LLNA (Ahuja et al, 2010). In the modified LLNA, ear thickness, ear punch weight, lymph node weight, lymph node cell count and the proportion of various lymphocyte subpopulations (determined by flow cytometry) was used as endpoints.

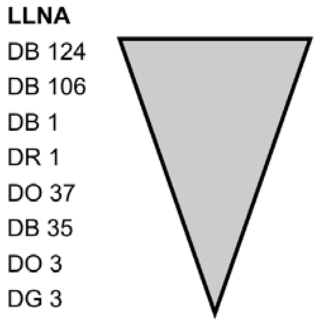

Figure 5 : Variation in induction potency between different disperse dyes. DB refers to Disperse Blue, DR to Disperse Red, DO denotes Disperse Orange and DG refers to Disperse Green (results from in vitro tests excluded) (BfR, 2012).

Elicitation threshold doses based on patch testing with dilution series have been studied with purified dyes Disperse Blue 106 and 124. Two out of 21 patients (10%) tested positively to concentrations corresponding to 0.00030 µg/cm^2 (lowest dose tested) of the purified Disperse Blue 106, and one of them also to the corresponding dose per square centimeter of the purified Disperse Blue 124 (Ryberg and al., 2009). This skin area dose is comparable to the lowest doses reported to give positive reactions in sensitised subjects, such as some phenol formaldehyde resins (Bruze et al, 1986; Zimmerson et al., 2000) and the perfume contact allergen chloroatranol (Johansen et al, 2003), all regarded as very potent sensitisers. Disperse Orange 1 have also been indicated to have the same low threshold as Disperse Blue 106 and Disperse Blue 124 (Malinauskiene et al., 2011).

The value of 0.0003 µg/cm^2 was used as a threshold dose to calculate concentration limits in textiles and leather for all allergenic disperse dyes included in the scope.

Chromium VI compounds

The estimated minimal elicitation threshold for 10% of sensitised individuals, MET10% values have been reported to be between 0.02 - 0.9 µg/cm^2. In the restriction dossier for chromium VI compounds in leather (ECHA 2012b), the lower value was used in the overall risk assessment. This value of 0.02 µg/cm^2 was used as the reference dose in the present restriction proposal.

Diisocyanates

No information on elicitation threshold doses for diisocyanates has been found.

(Meth)acrylates

Although skin allergy to (meth)acrylates seems to be an overall increasing problem in society, no information on elicitation thresholds doses have been found in the literature.

Formaldehyde

An ED10-value of 20.1 µg/cm^2 was reported in Fischer et al., 2011. This value of 20.1 µg/cm^2 was used as the reference dose in this restriction proposal to calculate the concentration limit in textile and leather articles for formaldehyde.

Nickel compounds

5 different ED10-values for nickel were reported in Fischer et al., 2011. The lowest value of 0.74 µg/cm^2 was used as the reference dose in this restriction proposal to calculate the concentration limit in textile and leather articles for nickel.

Cobalt compounds

An ED10-value of 0.44 µg/cm^2 was reported in Fischer et al., 2011. This value of 0.44 µg/cm^2 was used as the reference dose in this restriction proposal to calculate the concentration limit in textile and leather articles.

1,4 paraphenylene diamine

An ED10 value of 1.5 µg/cm^2 was reported in Sosted et al., 2006. This value of 1.5 µg/cm^2 was used as the reference dose in this restriction proposal to calculate the concentration limit for 1,4 paraphenylene diamine in textile and leather articles.

Direct dyes

No ED10 or $Met_{10\%}$ value has been found in the literature.

Acid dyes

No ED10 or $Met_{10\%}$ value has been found in the literature.

Rosin

No ED10 or $Met_{10\%}$ value has been found in the literature.

DCHP

No ED10 or $Met_{10\%}$ values has been found in the literature.

B.5.4.3. Default elicitation threshold dose

Fischer et *al.* (2011) gathered 16 patch test dose-elicitation studies for eight well known skin sensitisers (i.e. methylchloroisothiazolinone/ methylisothiazolinone, formaldehyde, nickel, cobalt, chromium, isoeugenol, hydroxyisohexyl 3-cyclohexene carboxaldehyde, and methyldibromo glutaronitrile) from the scientific literature, according to pre-determined quality criteria. The data was used to fit dose-response curves to identify the doses that will elicit an allergic response in 10% of allergic individuals under patch test conditions (ED10) for the different allergens (Figure 6). The median ED10 value was 0.835 µg/cm^2. The authors found a rather small variation in the ED10 value between the various allergens (within a factor of 7 from the lowest to the highest value, leaving out three outliers).

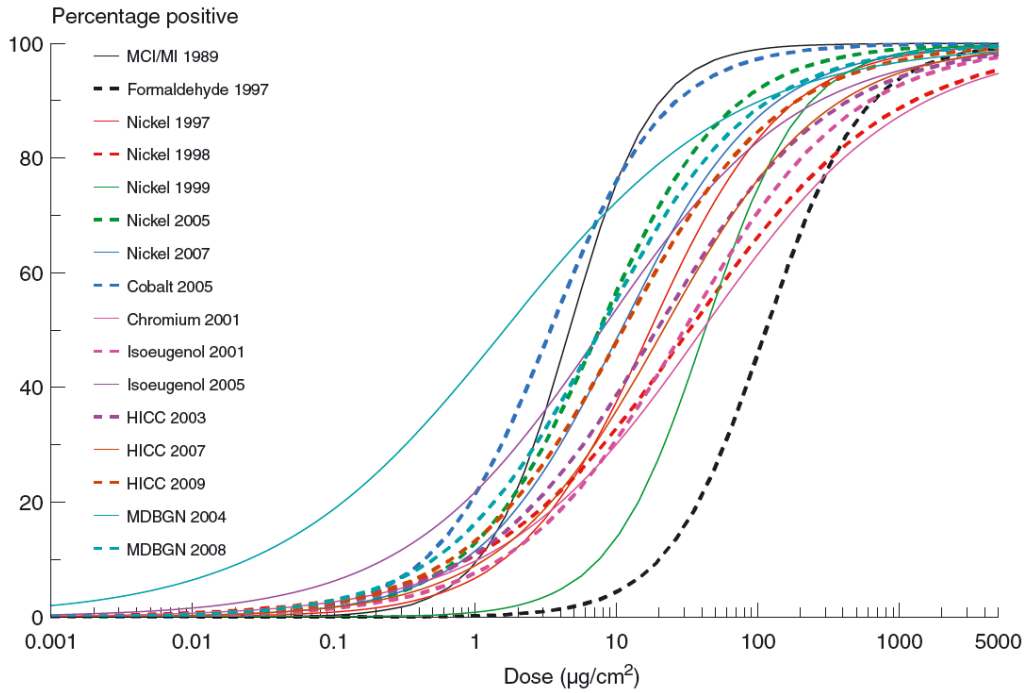

Figure 6 : Logistic dose–response curve for 16 patch test elicitation dose–response studies with methylchloroisothiazolinone/methylisothiazolinone (MCI/MI), formaldehyde, nickel, cobalt, chromium, isoeugenol, hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) (Fischer et al., 2011)

The results from the Fischer et al. study stimulated thoughts on the possibility of introducing a generic limit in exposure to allergens for regulatory purposes, in cases when there is a lack of data for establishing chemical specific thresholds. For example, a generic elicitation limit of 0.8 µg/cm^2 has been used to derive the 0.01% (100 mg/kg) limit for potent fragrance allergens in cosmetic products indicative for safe use (SCCS, 2012). The SCCS comments that the suggested limit value may hold for weak to strong allergens, but that some strong and extreme sensitisers may require lower individual thresholds. On the other hand, for very weak sensitisers, this generic threshold may be overly conservative. An elicitation threshold dose of 0.8 µg/cm^2 has also been considered by the Risk Assessment Committee (RAC), in the derivation of reference dose for skin sensitisation in the restriction of tattoo inks and permanent make-up restriction proposal.

B.5.4.4 Conclusion on reference dose

The Dossier Submitter proposes to use available elicitation threshold doses (ED10 or MET$_{10\%}$) as reference dose for substances or groups of substances for which such information has been found in the literature (e.g. disperse dyes, formaldehyde, chromium VI compounds). Elicitation threshold doses have served as the basis of several regulatory decisions regarding allergens (Johansen et al., 2011). Moreover, since there seems not to exist a clear link between the potency of a skin sensitiser and its elicitation threshold, the potential influence of difference in potency on elicitation limits within groups is disregarded in the proposal. The Dossier Submitter also proposes to use the default elicitation threshold dose of 0.8 µg/cm^2

proposed by Fischer et al. (2011), as the reference dose for the substances or groups or substances for which no specific elicitation threshold dose has been found.

B.6. Human health hazard assessment of physicochemical properties

B.6.1. Explosivity

Not relevant

B.6.2. Flammability

Not relevant

B.6.3. Oxidising potential

Not relevant

B.7. Environmental hazard assessment

Not relevant.

B.8. PBT and vPvB assessment

Not relevant.

B.9. Exposure assessment

B.9.1. General information on releases and exposure

B.9.1.1. Summary of the existing legal requirements

The existing legal requirements are presented in Annex E.1.

B.9.1.2. Summary of the effectiveness of the implemented operational conditions and risk management measures

Different risk management measures exist at European level or country based, that could re-inforce the necessity of this restriction proposal. To this respect, three measures are of interest: RAPEX system, the French poison center information system and the French studies from the DGCCRF.

RAPEX:

The European Commission set up the Rapid Alert System for dangerous non-food products (RAPEX) to facilitate exchanges between the national authorities of the 31 European countries and the European Commission on dangerous products/articles placed on the market. Every

week, since 2004, the Commission publishes alerts reported by the national authorities. These alerts include:

- Information on the dangerous products found;
- The risks identified;
- The measures taken by the notifying country, with the aim of preventing or restricting their use. The measures can be imposed by the national authorities (compulsory measures) or taken directly by the producers/distributors (voluntary measures).
- All the countries where the same products can be found.

A survey was carried out from 2004 to 2016 on the "Clothing, textiles and fashion items" product category, for the chemical risk and for all countries combined. From this survey, the information below could be noted.

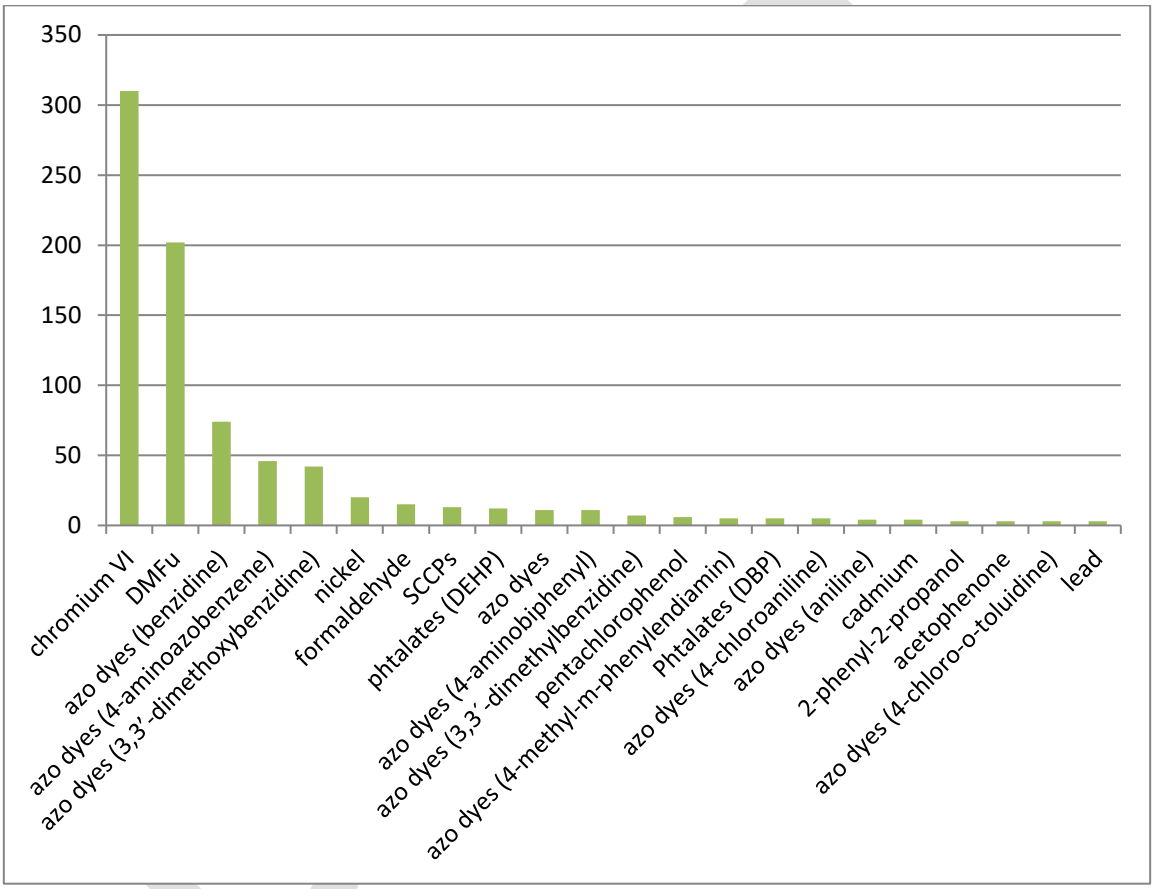

Figure 7 : Substances notified between 2004 and October 2017 in textile and footwear articles (RAPEX)

This graph only shows the substances for which the most notifications were received from 2004 until October 2017. Chromium VI, formaldehydenickel are substances that are the most frequently reported to cause a chemical risk. Because chromium VI and dyes are the substances the most reported in the RAPEX reports due their measures taken by the notifying country and to the risks identified, the Dossier Submitter would like to point out that these information re-inforce the necessity of this restriction proposal.

French Poison centre information system

The aim of toxicovigilance is to monitor the acute or chronic toxic effects for humans of exposure to a natural or synthetic mixture or substance available on the market or found in

the environment, for the purpose of undertaking alert and prevention actions. Toxicovigilance covers products that do not fall within the scope of other regulated national vigilance systems. The toxicovigilance network is based on all eight CAPs in metropolitan France and two toxicovigilance schemes (DTVs) in the overseas territories.

In 2008, DMFu was recognised as responsible for allergic and irritation contact dermatitis in furnitures and textiles in several countries of the European Union. In France, three successive studies, in 2009, 2011 and then 2013, reviewed the cases recorded by the poison control centres (CAPs) and the dermato-allergology vigilance network (Revidal-GERDA). Following the restriction of DMFu in May 2012 under the REACH Regulation, which prohibited its use and placing on the market in articles at concentrations above 0.1 mg/kg, a weekly extraction of cases was performed to enable the CAPs to monitor symptomatic cases. Anses decided it needed a new retrospective study of cases recorded by the CAPs in 2015.

An extraction of the cases was carried out based from the national database on products and compositions (BNPC). In total, 25 cases corresponded to exposure to textiles or footwear responsible for a skin manifestation, with a predominance in women. For 20 cases, the agents in question were footwear, most often purchased from public retailers. All the cases were symptomatic, with localised skin manifestations (erythema, pruritus, localised oedema) and always a favourable outcome once identified. Accountability was determined with regard to the article (shoes or clothing) and the substance (DMFu or another irritant/allergen). Accountability of the article was unlikely in three cases, possible in 21 and likely in one. Accountability of the substance on the other hand could not be determined in most cases.

An analysis of the article was only performed on three occasions indicating the absence of DMFu and in one case the presence of isopropylaniline. However, the list of chemical substances screened for is unknown. In parallel, patch tests were only performed on four patients, as most abandoned after they had recovered. The tests in a patient without any prior history of allergies proved positive for DMFu. In a patient known to be allergic to DMFu, the tests were also positive for chromium, nickel and PTBPF resin. Again, the substances screened for were not precisely indicated in the dossiers.

Even though the number of cases reported to the CAPs has decreased over the years, this compilation shows the persistence of cases of skin allergies or irritation resulting from the wearing of textile articles or footwear.

DGCCRF studies on textile clothing:

In 2013, the DGCCRF carried out a survey with an objective that enforced this restriction proposal: to screen for other substances (in addition to prohibited or restricted substances – azo dyes, DMFu) in textiles in direct contact with the skin (underwear, tight-fitting sport clothing, etc.) liable to cause allergic skin reactions. Ninety-eight samples were taken. Of these, 33% of the textiles tested were non-compliant for composition analyses (with regard to either the CLP Regulation, the nickel restriction or the REACH Regulation). Regarding the survey's primary objective, the DGCCRF emphasised the fact that:

- Many allergenic aromatic amines were found in numerous dark-coloured polyesters and polyamides.
- Compounds derived from diisocyanates and polyurethane monomers were found in a significant proportion of elasthanes.
- The presence of allergenic biocides was observed in some textiles.

- Anthraquinone dyes were found (Disperse Blue 14, Solvent Red 146), especially in cellulose fibres.
- Several anti-UV compounds of the class of phenolic benzotriazoles were detected (2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol and drometrizole).

In 2014, the French Joint Laboratory Service (SCL) conducted analyses in response to complaints about textiles, footwear and protective sport gear. The complaints relating to these articles mainly concerned allergic reactions developed by consumers.

- In 25% of the analyses, formaldehyde was detected at concentrations above the limit set for textiles in direct contact with the skin by the European Ecolabel for textile products, i.e. 16 mg/kg. Formaldehyde was detected in several types of materials (cotton, viscose, wool, leather and polymeric materials).
- Four articles containing leather parts in contact with the skin had chromium VI concentrations above the maximum value of the REACH restriction (3 mg/kg). Furthermore, three articles containing leather parts in contact with the skin contained chromium VI, but at levels below the maximum value of the restriction.
- In 20% of the articles tested, aromatic amine[19] were found
- In 15% of the articles, diisocyanates were detected.
- Rosin, used in adhesives, was found in 40% of footwear.
- Benzyl benzoate was detected in 15% of the analyses. This substance is used as a plasticiser for certain polymers.
- Several other substances were found like plasticisers in footwear[20]; diacrylates and dimethacrylates, a priori from the adhesives[21]; anti-UV agents (oxybenzone, drometrizole); monomers used in the synthesis of polyamide (caprolactam).

DGCCRF study on textiles for children[22] (2015)

In 2015, the DGCCRF carried out a survey on 96 textiles for children in France to verify the mechanical and chemical safety of clothing for children, and in particular the compliance with the REACH Regulation (azo dyes, nickel and DMFu, in particular).

Out of the 96 samples analysed, only one sample was declared non-compliant and dangerous by the laboratory with regard to substances prohibited by the REACH Regulation (namely due to the presence of benzidine and dimethoxybenzidine).
Even though the vast majority of textiles were compliant with the REACH Regulation, the DGCCRF also screened for other chemicals in these textiles: formaldehyde, phenol, free amines and anthraquinone dyes. It was found that a number of substances were quantified at varying concentrations, namely:

- Free amines,
- Free haloamines and nitrosamines are regularly found in dark-coloured polyester textiles. These substances, which are not currently regulated, are becoming more and more

[19] : 2-bromo-4,6-dinitroaniline (CAS 1817-73-8/ EC 217-329-2); 2-chloro-4,6-dinitroaniline (CAS 3531-19-9/ EC 222- 564-9); 2-bromo-6-chloro-4-nitroaniline (CAS 99-29-6/ EC 202-745-9); 2,6-dichloro-4-nitroaniline (CAS 99-30-9/ EC 202-746-4); 2,6-dibromo-4-nitroaniline (CAS 827-94-1/ EC 212-577-8).
[20] diethyl maleate (CAS 141-05-9/ EC 205-451-9), dibutyl fumarate (CAS 105-75-9/ EC 203-327-9), bis(2-ethylhexyl)fumarate (CAS 141-02-6/ EC 205-448-2).
[21] 1,4-butylene glycol dimethacrylate (CAS 2082-81-7/ EC 218-218-1), tri(propylene glycol) diacrylate (CAS 42978-66-5/ EC 256-032-2).
[22] https://www.economie.gouv.fr/dgccrf/enquete-sur-loyaute-et-securite-des-textiles-habillement

widespread, since the DGCCRF found them in 70% of polyester samples analysed. In 40% of cases, concentrations above 100 mg/kg were estimated,
- Dyes: several anthraquinone dyes were quantified in the samples, in particular Solvent red 146 (CAS 17418-58-5/EC 241-442-6), Solvent violet 13 (CAS 81-48-1/ EC 201- 353-5).

These dyes can be found at high concentrations (levels exceeding around a gram per kg) in textiles, both in synthetic (polyester) and natural (cotton) fibres and for several different colours, but generally bright ones.

All these studies show the persistence of allergy related to textiles, footwear and re-inforce the necessity of this restriction proposal.

B.9.2. Uses: Textile

B.9.2.1. General information on exposure to chemical substances from textile

The use of textiles is particularly difficult to avoid in modern society. The frequent everyday use may lead to exposure of people of all ages to skin sensitisers. The level of exposure varies however according to the end-use of the textile. This means that uses with close bodily contact such as clothes, shoes and bed linen will lead to the highest exposures (Danish EPA, 2003). Most of such articles are also used for prolonged periods of time and exposure occurs under occlusion, which increases the likelihood for substances to deposit on skin and trigger skin allergy. Exposure from textiles and leather articles not used in direct contact with skin, or for shorter periods of time, is by the Dossier Submitter estimated to be lower.

The Dossier Submitter developed an exposure scenario exploring the exposure from the use of articles made of textile materials. Hence, information on exposure parameters used for the risk assessment decribed below are given for textile.

As described in the main report in section 1.1.4.1. on articles covered by the restriction, other articles and/or materials included in the scope coming into contact with the skin to an extent similar to clothing, such as latex, rubber, neoprene, synthetic leather, prints, coatings and disposable articles (napkins, tissues and nappies) are included in the scope of the restriction. These are assimilated to the textile exposure scenario for risk assessment purposes, the reason being that these articles are typically made of materials either resembling a textile material, and/or that they have similar use patterns as textiles. Synthetic leather is produced by applying a polymer coating, for example polyurethane or polyvinyl chloride (with protective stabilizers, softening plasticizers and lubricants), to a textile base material (e.g. polyester, cotton, nylon or rayon). Rubber materials can contain rubber vulcanization accelerators and antioxidant agents (e.g. thiurams, carbamates, mercaptobenzothiazoles) or other additives (e.g. para-tert-butylphenol-formaldehyde), raising a concern for these articles. Articles made of other polymer materials can also include skin sensitising plasticisers (e.g. DCHP or (meth)acrylates). Disposable articles, like nappies or sanitary towels may be treated during the manufacturing with for example dyes, solvents or softeners. Therefore, the risk related to skin sensitising substances in such articles cannot be excluded. Prolonged skin contact with disposable sanitary towels or nappies is expected over the day. In addition, direct contact with damaged skin may increase the skin sensitisation concern. Migration of skin sensitising substances from inner layers to outer parts of such articles cannot be formally excluded. In

addition, a tearing of the outer parts of the nappies may occur, leading to skin contact with the inner parts of the article. Regarding disposable napkins or tissues, a prolonged exposure is unlikely. A single short exposure is expected but repeated exposures to the similar article may occur over the day. In conclusion, the risk related to sensitising chemical substances in such materials cannot be excluded.

Hazardous chemical substances can intentionally or unintentionally remain in the material following the manufacture and finishing of textiles. They can be released through several mechanisms, resulting in exposures of the general population: from direct release of the substance from the articles, or from fibres released from textile during normal wear and tear. Indirect exposures may also occur when textile articles are used and washed, and ultimately are disposed of as waste (KemI, 2014).

The most relevant exposure pathway in the context of skin sensitisation is direct release of substances to skin by migration from the textile. Hence, the assessment of the exposure to chemical substances released from the material would ideally be based on presence in textileand information on migration of the skin sensitising substance to skin during use. However, for most substances included in the scope of the restriction proposal, such information is not available.

The Dossier Submitter has therefore, for most substances in the scope made qualitative exposure assessments based on justified assumptions on the presence of the skin sensitiser in textile and migration of the substance from the material to skin. (Semi-)quantitative assessments have been attempted for a limited number of substances for which sufficient information was considered available. In addition, to efficiently and effectively deal with the large amount of substances included in the scope, the substances have primarily been assessed as part of a group, or family of substances with similar properties and function.

The level of exposure that consumers will be subjected to from chemicals in textile depends on several factors, including the type of material, the chemical bonding to the material and the amount of substance present in the material, the physicochemical properties of the substance, and the presence of other chemicals (e.g. irritants) in the material. Other factors affecting the exposure are related to the use and handling, such as frequency or conditions like sweat or heat. The technique used to produce the articles, including the quality of the manufacturing and treatments such as fixation of dyestuffs could also affect the migration and thus the exposure.

Migration of chemical substances from textile

Migration may occur to the moisture on skin or sweat and to the sebum - the oily or waxy matter that lubricate and waterproof the skin. Migration to oil-based leave on cosmetics products used on skin may also be relevant. Direct release and migration of chemical substances from textiles are dependent on a number of factors (KemI, 2014; BfR 2012):

- the inherent chemical/physical properties of the substance
- how the substance is incorporated into the textile
- the type of fibre the substance is incorporated in
- the handling of the textile (by the consumer)
- the quality of the manufacturing process

The chemical/physical properties of the substances that influence release are medium to high vapour pressure and water/lipid solubility (ECHA, 2012). Substances with a high vapour pressure are prone to evaporate to the air (and thereby be deposited on skin) and it is likely that water-soluble substances migrate to sweat. In addition, lipid solubility can influence the migration to skin (KemI, 2014).

The mechanism by which a chemical is incorporated into the textile will also influence how it is released. Substances which bind loosely to the material (e.g. plasticisers, stabilising agents, direct dyes) are likely to have high releases during use, while strongly bound substances, e.g. reactive dyes, will have fibre-mediated releases. The binding affinity can also vary for different fibre types and textile materials. Other factors that can trigger release include high humidity, high temperature, outdoor use (UV-radiation) and high physical stress (wear and tear) (KemI, 2014). The quality of the manufacturing process is also an important factor to consider. For example, residues of process chemical substances, excess dyes, unreacted monomers, impurities and contaminants are often loosely bound to the material. If such substances are not removed properly (e.g. by not using best practises) during the production they may be deposited on the skin during use of the textile article.

Several other factors have been shown to increase the release of substances from textile, such as dry- and wet rubbing, occlusion and heat.

B.9.2.2. Information gathering and search strategy

To deal with the large amount of substances with a harmonised classification as skin sensitisers included in the scope, the Dossier Submitter used the Master list (see Annex E) as a starting point for information searches. The Master list contains a number of substances that potentially are used in the production of textile. Of the substances in the Master list, a number of substances were further targeted for exposure information searches based on a criteria defined by the Dossier submitter:

- Groups of chemicals with a structural similarity or same toxic entity (eg. diisocyanates, (meth)acrylates, chromium VI compounds)
- Substances for which there is potential for high exposure (deliberate use in textile or leather, substance intended to stay on article and high levels[23] of substance in textile or leather, and
- Substances that are well-known skin sensitisers (e.g. rosin, formaldehyde, nickel and cobalt compounds)

In addition, the substances in the list of concern were specifically targeted for information searches.

In the Dossier Submitter search strategy, mainly the internet and the search engine PubMed were used. Search terms used were chemical names, CAS numbers and chemical group names. Furthermore, the Dossier Submitter looked for information in the call for evidence responses and *via* personal communication with researchers in the field. The available information on migration is summarised in the table below (Table 7: Migration factors for substances targeted for exposure information searches.). Detailed information can be found in section B.9.2.4.

[23] The term high level refer to assumptions and estimated amounts in the consultancy report (KemI, 2019) where "high" corresponded to ≥10 000 ppm or 30% (DCHP).

Table 7: Migration factors for substances targeted for exposure information searches.

Group / Substance	Number of substances	Migration factor (%)	Reference
Diisocyanates	7	-	-
(Meth)acrylates	4	-	-
Chromium VI compounds	8	30	ECHA 2012b
Nickel compounds	1	-	-
Dyes	2 direct dyes	0.5[1]	BfR 2012
	2 acid dyes	0.5[1]	BfR 2012
	8 disperse dyes[24]	0.5[1]	BfR 2012
Dicyclohexyl phthalate (DCHP)	1	-	-
Rosin	2	-	-
Formaldehyde	1	-	-
Cobalt compounds	1	-	-
1,4 paraphenylene diamine	1	-	-
Glutaraldehyde	1	-	-

[1] Recommendation of the BfR (2012) is 0.5 % for dyes in general based on migration experiments with textiles dyed according to state-of-the-art technology.

B.9.2.3. Exposure information related to targeted substances or groups of substances

Allergenic disperse dyes

Disperse dyes are used to dye polyester and acetate fibers (Dossier Submitter's communication, 2018). They are lipophilic substances which are dissolved in the chemical fibre (BfR, 2012, KemI, 2017).

Eight disperse dyes are included within the list of substances with harmonised classification as Skin Sens 1 according to CLP, that may be present in textiles (KemI, 2019). Two of these substances (Disperse Blue 1 and Disperse Yellow 3) are included in the CMRs restriction in textile (entry 72 of REACH Annex XVII), due to their carcinogenic properties. The 24 disperse dyes in the list of concern are not classified with regard to skin sensitisation but have been included in the scope based on sufficient evidence on their allergenic properties. These allergenic dyes are contained in the list of the Oekotex Standard 100 and other eco-labels (GOTS, ZDHC, BlueSign). In addition, the EU Commission lists Disperse Blue 26, Disperse Blue 102, Disperse Orange 37, Disperse Orange 149, Disperse Yellow 23 and Disperse Yellow 49 as allergens (Malinauskiene, 2012).

The Dossier Submitter would like to add that 2 disperse dyes in the list of concern (Disperse Orange 27 and Disperse Yellow 23), were identified in a study done by Anses (2018) as responsible for cases of skin sensitisation reported by patients to physicians after wearing

[24] The disperse dyes with harmonised classifications as skin sensitisers were assessed as members of the larger group of allergenic disperse dyes included in the list of concern.

clothing articles or footwear. The cases re-inforce the relevance of including the 2 disperse dyes in the list of concern.

Presence of substances in articles
Dyeing is performed with the intention for the dye to remain in the fabric at point of sale. There is evidence that disperse dyes are used or have been used historically in the production of textiles and textile articles. These are reported to be rarely used to dye textiles nowadays (Malinauskiene et al., 2012). A possible explanation could be that serious actors in the textile sector have voluntarily chosen to phase out these substances. However, these voluntary schemes or agreements are not followed by the entire sector worldwide. Hence, it cannot be excluded that these dyes are contained in textile articles produced by other actors and put on the EU market.

Approximate levels in textile
Levels of disperse dyes in synthetic textile materials have been indicated to be up to 10 000 (KemI, 2019) and to range between approximately 1 and 10% (10 000-100 000 mg/kg), based on extraction with solvent based techniques (Dossier Submitter's personal communication, 2018). In Anses, 2018, the amount of disperse dye are reported to be between 10 to 600 mg/kg in textile articles.

Information on exposure from textile articles
It can be concluded from the many reported cases of contact allergy to disperse dyes that sufficient exposure may occur *via* textiles to trigger ACD in consumers (see for example Malinauskiene et al., 2013; Brookstein, 2009).

The level of exposure to disperse dyes depends not only on the colour intensity (dye content) but also on the fastness of the dye in the textile material. The fastness may vary considerably between different textile materials. It has been reported that textiles with a dye fastness ≥4-5 will result in a dose per cm^2 of skin of <1 µg/cm^2 (ETAD, 1983). This is well above the elicitation threshold for disperse dyes (see section 1.2.4 hazard assessment). Where poor dyeing techniques have been used, release rates may be considerably higher, however no quantitative data is available (BfR, 2012).

Migration from textile to skin
A small number of research projects have investigated the release, or migration of dyes from textiles under various conditions. A project by the *Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers* (ETAD) [ETAD, 1983] determined the release of dyes from garments to artificial sweat during 4 hours. The samples consisted of textiles which had been dyed using the latest technologies available, at the time of the analysis. Between 0.1 and 300 µg dye were extracted from 500 cm^2 of textile sample, depending on the colour fastness. The highest release rate measured was 0.4 mg per simulated wear event (corresponding to a migration factor of 0.18%). The authors state that there may be higher release rates from poorly dyed textiles. Other projects (Heine et al, 1996, 2000 as reported in BfR, 2012), investigated the release of textile dyes under simulated dynamic conditions of use (friction). During the first extractions a maximal migration factor of 0.26 % to 0.43% was reported. No time frame for the extractions was however reported.

Based on studies cited in the BfR report (2012), the BfR recommended that a migration factor of 0.5 should be used as a default worst-case assumption in the risk assessment for dyes migrating from textiles. The voluntary scheme Bluesign's risk assessment approach for

chronic dermal exposure[25] including colorants with allergenic potential, uses a default migration factor of 1-5% seemingly taking additional uncertainty into account as compared to BfR (2012). However, the basis and the assumptions underlying the Bluesign range are not available to the Dossier Submitter. The actual value used in the calculations is according to Bluesign influenced by the usage range (e.g. use next to skin and baby articles, occasional or no skin contact) and the usage during wearing of an article (e.g. sweat management). A migration study on disperse dyes (Disperse Blue 291, Disperse Blue 291:1, Disperse Yellow 64, Disperse Violet 93:1 and Disperse Red 1) was submitted in the Public Consultation, reporting values at the limit of detection, LOD, i.e. below 0.0005% wt for most disperse dyes. For Disperse Red 1 the migration was 0.0013% and 0.0024% to hydrophilic and hydrofobic extraction, respectively. The Dossier Submitter notes that these migration factors are well below those previously reported by BfR (2012). In addition, that the degree of coloration in the study (1-2%) is in the lower range of the reported levels in textile (1 to 10%, see Table 8) and that the study uses the latest techniques for dyeing. In the Public Consultation, another stakeholder states that the migration of disperse dyes from textile with a high fastness (note 4-5) seem to be very low (<<0.1%) based on own measurements.

As discussed by the BfR (2012), the conditions of use and the manufacturing techniques may influence the migration of dyes, leading to uncertainties about the real release of dyes from textile to the skin. In addition, some dyes (e.g. disperse dyes) are lipophilic substances (BfR, 2012, KemI, 2017), and migration to sebum or other oil-based matter on the skin may be higher that what has been reported using artificial sweat extraction tests. Taking into consideration the availability of poor quality (low fastness) textile products on the market, the Dossier Submitter proposes a migration factor of 10% for dyes in general in textile. Information on disperse dyes submitted in the Public Consultation indicate low migration for disperse dyes, thus the Dossier Submitter consider 5% to be sufficient to cover the uncertainties described above.

Chromium compounds (Cr VI)

Presence of substances in articles
Chromium salts are used in the manufacturing of textile as a catalyst in the dyeing process and as a dye for wool (chrome dyes). Chromium VI compounds are restricted in textile article with a concentration limit of 1 mg/kg (Entry 72 of REACH Annex XVII).

Approximate levels in textile
Estimated amount on article may be up to 100 mg/kg (KemI, 2019). Chromium has been quantified twice in the Anses study (2018) at amounts around 1.4 mg/kg. (Anses, 2018).

Information on exposure from textile articles
No information has been found.

Migration from textile to skin
Literature on transfer or migration of chromium VI from textile are scarce. However, information on migration of chromium VI from leather is available and may be used as a proxy for migration from textile. However, there are likely some differences in how chromium is incorporated into the different materials and therefore also on how it is released. A migration

[25] https://www.bluesign.com/downloads/criteria/bluesign_criteria_for_chemical_assessment_homologation_v2_0.pdf

factor of 30% was used for risk assessment in the restriction of chromium VI in leather (ECHA, 2012b).

Diisocyanates

Presence of substances in articles
Diisocyanates are used in the production of mock leather, coated textiles and pigment printed textiles. They can also be found in adhesives.

Approximate levels in articles
The levels of diisocyanates can be above 1 000 mg/kg (KemI, 2019). It is unclear if this number refers to cured or uncured forms. According to comments received during the Public Consultation, the level of diisocyanates in consumer articles estimated in KemI (2019) is based on results from the use of inappropriate analytical techniques. The actual concentration levels in articles within the scope of the proposed restriction are claimed to be considerably lower than 1000 ppm, and should not be found in concentration above 100 ppm. The Dossier submitter does not have information to further challenge these comments.

Information on exposure from textile articles
No information has been found.

Migration from textile to skin
No information has been found.

Meth(acrylates)

Low levels of residual monomers and process chemicals can migrate from acrylic polymers during handling and use of consumer products (Pemberton and Lohmann, 2014). Residues in textiles can be found in acrylic binders or coatings. (Meth)acrylates are also used in emulsions for impregnating textiles, and in adhesive applications (KemI, 2019).

Presence of substances in articles
(Meth)acrylates are used in coated and pigment printed textile and leather articles (KemI, 2019).

Approximate levels in articles
Levels may be up to 10 mg/kg (KemI, 2019). In the Public Consultation, stakeholders stated estimated levels <10 mg/kg.

Information on exposure from textile articles
No information has been found.

Migration from textile to skin
No information has been found.

Formaldehyde

Formaldehyde can be used in finishing processes such as shrinkage resistance, wrinkle-resistance, dirt-repellence antistatic treatment and in dyeing and printing.(KemI, 2017).

Presence of substance in articles
The substance can be used in easy care/non iron-products and in other articles with coated, laminated pigment printed (KemI, 2019).

Approximate levels in articles
Estimated amount may be between 100 and 1 000 mg/kg and around 75 mg/kg on unwashed easy care/non iron resins and other finishes (KemI, 2019). In a study carried out by Anses (2018) levels between 6 and 160 mg/kg were reported.

Information on exposure from textile articles
Formaldehyde is a known skin sensitiser and there are many reports on skin allergy related to formaldehyde in textile articles. This is considered as evidence that exposure of formaldehyde from textiles can take place and thus that there is migration potential.

Migration from textile to skin
This substance has properties that are relevant for migration, e.g. high water solubility, thus it can be dissolved from the article by e.g. sweat (KemI, 2017). Since formaldehyde is a known skin sensitiser, and skin allergy from formaldehyde in textiles has been reported, this is considered as evidence for migration potential of formaldehyde from textiles.

Nickel compounds

Nickel can be present in dyes and pigments (RPS, 2013, KemI, 2013). Nickel can also be present in metallic parts such as buttons and zippers but such non-textile parts are not intended to be covered but the restriction proposal. These articles are covered by entry 27 of Annex XVII of the REACH Regulation.

Presence of substance in articles
Nickel can be used in dye chromophores (KemI, 2019).

Approximate levels in articles
Nickel was quantified in four textile articles in a study at concentrations between 2.3 and 23.5 mg/kg, in the non-metal parts of the textile articles (Anses, 2018).

Information on exposure from textile articles
No information available.

Migration from textile to skin
Nickel has been reported to be 'tied in' the material and not extractable to sweat (KemI, 2019). It has low water solubility, which indicates low ability to be dissolved from the article by e.g. sweat (KemI, 2017). However, migration and exposure cannot be excluded.

Cobalt compounds

The substance is used in colorants for textiles and can be found as an impurity in dyes and pigments (KemI, 2017; KemI, 2019).

Presence of substance in articles
A few pre-metallised dyes have cobalt present. The substance can be found in nylon and wool (KemI, 2019).

Approximate levels in articles
Levels of cobalt in textile are reported to be in the region of 100 mg/kg. A comment received in the Public consultation pointed out that the presence of cobalt in leather articles can originate from metal-complex dyes, which typically have strong metal-ligand binding. Skin sensitising properties however are mainly related to the free metals.

Information on exposure from textile articles
No information has been found.

Migration from textile to skin
Cobalt has been reported to be 'tied' in textile in the dye chromophore and not extractable to sweat (KemI 2019). Furthermore, it has low water solubility, which thus indicates low ability to be dissolved from the article by e.g. sweat (KemI, 2017). However, the Dossier Submitter assumes that migration cannot be ruled out in any event.

<u>Direct dyes</u>
Direct dyes are used to dye cellulose fibres, such as cotton, linen, viscose, lyocell, silk and wool (KemI, 2014).

At least two direct dyes have been identified from the Master list for which there is potential for high exposure. These are Direct Blue 301 (CAS 124605-82-9/ EC 408-210-8) and Direct Yellow 162 (CAS 81898-60-4/ EC 400-010-9).

Presence of substance in articles
Dyeing is performed with the intention for the dye to remain in the fabric at point of sale. Loose, unfixed direct dye may be present in the article (KemI, 2019).

Approximate levels in articles
Direct dyes are typically applied at 0 - 4% (40 000 mg/kg) (KemI, 2019).

Information on exposure from textile articles
These dyes are held on the fibre by weak forces and are generally regarded as low fastness dyes (KemI, 2019). Information received in the call for evidence states that skin penetration is not expected, since the substance has a molecular weight >700 g/mol (Call for evidence). However, since Direct Blue 301 and Direct Yellow 162 have harmonised classifications as Skin Sens. 1, the Dossier Submitter assumes that skin penetration can occur as skin absorption is a pre-requisite for sensitisation to occur.

Migration from textile to skin
No data available. The substance has high water solubility, which indicates a high ability of this substance to migrate and be dissolved from the article by e.g. sweat or saliva (KemI, 2017).

<u>Acid dyes</u>

Acid dyes are mainly used to dye the textile materials polyamide, silk and wool (KemI, 2014; KemI, 2019).

At least two acid dyes have been identified with a high probability for exposure. These are Acid Red 447 (CAS 141880-36-6/ 410-070-8) and Acid Dye "Yellow E-JD 3442" (CAS 147703-65-9/ EC 410-150-2) (KemI, 2019).

Presence of substance in articles
Dyeing is performed with the intention for the dye to remain in the fabric at point of sale. Loose, unfixed dye is present in low concentrations (in the regions of 20 mg/kg) (KemI, 2019).

Approximate levels in articles
Acid dyes are typically applied at 0 - 6% (60 000 mg/kg) (KemI, 2019).

Information on exposure from textile articles
The acid dyes are held on the fibre by electrostatic interaction between the anionic groups in the dyes and cationic groups in the fibre (KemI, 2019). Unfixed dyes are removed. Acid dyes include both azo and anthraquinone compounds. Comments received in the Public Consultation states that acid dyes are chemically bound within the fibre. This process implies a chemical reaction which modifies the dye molecule and binds it to the fibre with covalent bonds or strong ionic bonds respectively. The stability of the dyes on fibre is additionally enhanced through appropriate treatments. The respondants do therefore not expect exposure to consumers.

Migration from textile to skin
No migration data has been found. The substances have high water solubility, which indicates a high ability of this substance to migrate and be dissolved from the article by e.g. sweat or saliva (KemI, 2017).

<u>Rosin</u>

Rosins are mixture of chemicals extracted from trees.

At least two rosins have been identified with harmonised classifications as skin sensitisers. These are tall-oil rosin (CAS 8052-10-6/ EC 232-484-6) and rosin (CAS 8050-09-7/ EC 232-475-7) (KemI, 2019).

Presence of substance in articles
These rosins can be used in print inks and coatings.

Approximate levels in articles
The estimated amount on articles may be up to 1 000 mg/kg (KemI, 2019). In the Anses study, rosin has been qualitatively detected in 10 footwear (Anses, 2018).

Information on exposure from textile articles
No data has been found.

Migration from textile to skin
No data has been found.

Dicyclohexyl phthalate, DCHP

1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester or dicyclohexyl phthalate (DCHP) (CAS 84-61-7/ EC 201-545-9) is a plasticiser that could be present in coated and pigment printed textiles (KemI, 2019).

DCHP has been identified as a substance with potential for high exposure and harmonised classification as skin sensitiser.

Presence of substance in articles

DCHP can be used as a plasticiser for nitrocellulose, ethyl cellulose, chlorinated rubber, polyvinyl acetate, polyvinyl chloride, and other polymers (KemI, 2019).

Approximate levels in articles

The estimated amount on articles is 0-30%, e.g. as plastisol prints[26] (KemI, 2019).

Information on exposure from textile articles

No data has been found.

Migration from textile to skin

No data has been found.

1,4 paraphenylene diamine

Presence of substance in articles

1,4 paraphenylene diamine is used as a textile dye or in azo dyes manufacturing.

Approximate levels in articles

1,4 paraphenylene diamine was quantified in eight textile articles in a study at concentrations between 16 and 40 mg/kg (Anses, 2018).

Information on exposure from textile articles

No information has been found.

Migration from textile to skin

No information has been found.

Glutaraldehyde

Glutaraldehyde has been evaluated and found suitable as a non-formaldehyde durable press finish for cotton fabrics (Yang et al., 2000).Glutaraldehyde has a harmonised classification as skin sensitiser 1A.

Presence of substance in textile articles

The Dossier Submitter has not found much information indicating the use of glutaraldehyde in textiles..

[26] As in line with entry 72 of REACH Annex XVII and the Explanatory guide to the entry (endorsed by CARACAL on 27 June 2018 [CA/44/2018]), where it is stated that “Prints and coatings applied directly on textile article surfaces (such as decorations or logos) are covered by the restriction.”

Approximate levels in articles
No data has been found.

Information on exposure from textile articles
No data has been found. In the Public Consultation, stakeholders stated that glutaraldehyde is only relevant for leather.

Migration from textile to skin
No data has been found.

B.9.2.4. Exposure assessment

Levels of skin sensitising substances in textile
The Dossier submitter has not found much published data on measured levels of skin sensitising substances in textile. Valuable information has been received through through experts *via* a consultancy study (KemI, 2019) and the Anses opinion collective expert appraisal report (questionnaire and a consultancy study (KemI, 2019; Anses, 2018). The available information on approximate levels of the targeted substances in textile is summarised in the table below (Table 8: Approximate (measured or estimated) levels in textile for the targeted substances.).

Table 8: Approximate (measured or estimated [27]) levels in textile for the targeted substances.

Group / Substance	Approximate levels in textile	Reference
Allergenic disperse dyes	Estimated levels in certain textiles around 10000 mg/kg (KemI, 2019). Measured levels range between 1 and 10% (10 000 - 100 000 mg/kg) in textile.	Dossier Submitter's communication, 2018; KemI, 2019
Chromium VI compounds	Estimated amount are some hundred mg/kg in textile.	KemI, 2019
Diisocyanates	Estimated levels above 1 000 mg/kg in textile. It is unclear if this number refers to cured or uncured forms. In the Public Consultation, stakeholders stated estimated amounts <10 mg/kg.	KemI, 2019
(Meth)acrylates	Estimated levels up to 10 mg/kg.	KemI, 2019
Formaldehyde	Estimated amount between 100 and 1 000 mg/kg and 75 ppm on unwashed easy care / non iron resins and other	KemI, 2019; Anses, 2018

[27] The estimated amount in textile presented in KemI (2019), is a worst case scenario which is largely the consultants' educated guesswork unless there is knowledge of Restricted Substance List test data (e.g. chromium VI, isocyanates etc).

	finishes (KemI 2019). In a study carried out by Anses levels between 6 and 160 mg/kg were reported.	
Nickel compounds	Nickel was quantified in four textile articles in a study at concentrations between 2.3 and 23.5 mg/kg, in the non-metal parts of the textile articles.	Anses, 2018
Cobalt compounds	Levels of cobalt in textile are estimated to be 100 mg/kg.	KemI, 2019
Direct dyes	Estimated to be applied at 0 - 4% (40 000 mg/kg).	KemI, 2019
Acid dyes	Estimated to be applied at 0 - 6% (60 000 mg/kg).	KemI, 2019
Rosin	The estimated amount on textile is 1 000 mg/kg (KemI, 2019). Rosin has been qualitatively detected in footwear (Anses, 2018).	KemI, 2019; Anses, 2018
Phthalate (DCHP)	The estimated amount in for example plastisol prints[28] on textile articles is 30%.	KemI, 2019
1,4 paraphenylene diamine	Quantified in textile articles at concentrations between 16 and 40 mg/kg.	Anses, 2018

It should be noted that the information on the levels of skin sensitising substances in textile are approximations based on either amount applied, or on few measurements of levels in finished articles of which not all were new, and was therefore not considered appropriate for use in the exposure assessment.

Migration of skin sensitising substances from textile

In general, the Dossier Submitter had difficulties to find public data on migration factors from textile for most targeted chemical substances. Summary data has been found on migration to artificial sweat for textile dyes (BfR 2012), but data is generally lacking with regards migration of individual substances from textiles (Table 7). In addition, migration data to other types of vehicles than sweat, such as sebum and cosmetics is lacking.

The available migration data is typically expressed as a percentage of the total content of the substance in the tested textile or textile article (migration factor). As migration to artificial sweat is normally measured over only a few hours, the Dossier Submitter interprets these

[28] As in line with entry 72 of REACH Annex XVII and the Explanatory guide to the entry (endorsed by CARACAL on 27 June 2018 [CA/44/2018]), where it is stated that "Prints and coatings applied directly on textile article surfaces (such as decorations or logos) are covered by the restriction."

numbers as the amount of chemical that can be released to sweat during the first use of the article. Washing and wear and tear will reduce, for some chemicals, the amount of chemical released from the textile over time, thus the exposure assessment performed below is based on first use.

Default migration factor

Since many unknown factors collectively contribute to the migration of chemical substances from textiles, the Dossier Submitter uses a precautionary approach. It is assumed that substances in the scope for which migration information is lacking, have the potential to migrate from the textile to skin if the substance is present in the textile.

Hence, for the targeted substances which lack information on migration from textile, as well as for the substances in the scope which were not targeted for information searches, a default migration factor of 10% was assumed. This value is in the upper range of the migration factor values found in the literature for any substance, which range between 0.5 - 30%, see Table 9. In addition, Bluesign uses a default value of 1-5% migration factor for various substances in their risk assessment approach. However, the basis and the assumptions underlying the Bluesign range are not available to the Dossier Submitter. The actual value used in the calculations is according to Bluesign influenced by the usage range (e.g. use next to skin and baby articles, occasional or no skin contact) and the usage during wearing of an article (e.g. sweat management).

Table 9: Values on migration of various chemical substances from textile to artificial sweat found in the literature.

Group of substance	**Migration factor (%)**	**Material**	**Reference**
Dyes, high fastness	0.5[1]	Garment textiles	Bfr, 2012
Hydrophilic textile auxiliaries	2[1]	Textile	Bfr, 2012
Hydrophobic textile auxiliaries	0.1[1]	Textile	Bfr, 2012
Flame retardants	1-30	Textile in car seats for children	MST, 2015

[1] Recommendation of the BfR (2012) based on migration experiments with textiles dyed according to state-of-the-art technology.

A migration study on disperse dyes was submitted in the Public Consultation, reporting values below 0.0005% wt for most disperse dyes. The Dossier Submitter notes that these migration factors are well below those previously reported by BfR (2012). In addition, that the degree of coloration in the study is in the lower range of the reported levels in textile (1 to 10%, see Table 8) and that the study uses the latest techniques for dyeing. In the Public Consultation, another stakeholder states that the migration of disperse dyes from textile with a high fastness seem to be very low (<<0.1%), based on own measurements.

Several comments received in the Public Consultation did not support the use of 10% as a default migration factor given that the previous studies summarised by the BfR (2012) indicated values between 0.5 and 2%. It should however be noted that the Dossier Submitter has included additional values of migration for other substances than dyes compared to the recommendation from BfR to derive the default value proposed herein. Comments was also received in the Public Consultation that supported the precautionary approach taken by the Dossier Submitter.

Contact between textiles and skin

The dose per skin surface area is considered to be the most relevant dose metric for risk assessment of skin sensitisers. Therefore, the area of the exposed skin is typically an important parameter to consider in such calculations. However, in a textile exposure scenario the relationship between the textile surface and surface of the exposed skin is 1:1, i.e. the exposed skin area is 100% covered by fabric. The exposure assessment can therefore be performed per surface area of skin, and the overall exposed skin area could be neglected.

Exposure duration

It is generally agreed that it is not only the dose per skin area that is the determinant of elicitation of skin allergy but also that the duration of the exposure, i.e. the accumulated dose per skin area is important. 24 hours was selected as an appropriate time frame/observation time for accumulated dose given that once an individual is induced, manifestations of allergy normally develop within 1-2 days after (re-) exposure to the allergen. Indeed, derivations of safe levels of allergens in cosmetics are typically made based on a 24-hour basis when repeated applications are assumed (SCCS, 2012).

Exposure frequency

Textiles that come into close contact with skin may be changed 3 times per 24 hours, i.e. clothes may change into leisure or sportswear and finally into night wear and/or contact with bedding textiles. This means that re-exposure to the same substance *via* newly purchased textile may occur up to 3 times per day, which may be considered a worst case scenario.

During Public Consultation, stakeholders expressed that the Dossier Submitter assumptions on use frequency per day are very conservative. One stakeholder proposed that a reasonable worst case for textile would be 1 new garment in any 24-hour period since most regular exposure will be to repeatedly laundered textiles.

Surface weights

The level of chemical content in textile is typically expressed as substance weight in grams per kilogram article. However, the thickness of the material will have a large influence on how much of the chemical is deposited on the skin. Assuming that the chemical is evenly distributed in the article, the thicker the textile the more chemical is contained per surface area.

The surface weight of textiles range between approximately 0.07 kg/m^2 (silk) to 0.4 kg/m^2 (blanket) (Dossier Submitter's personal communication, 2018). A surface weight of 0.1 kg/m^2 has been used in the BfR report (2012) for risk assessment purposes. In the present restriction proposal, a value of 0.2 kg/m^2 was chosen as a reasonable worst case for textiles used close to skin.

A comment recieved in the Public Consultaion questioned the assumption that heavier weight textiles result in higher levels of skin exposure. Moreover, that it could be argued that a heavier weight textile has a smaller surface to volume ratio (i.e. less surface area per volume) and hence a lower percentage of an evenly distributed substance will be in contact with the skin during wear.

Conclusion on exposure to skin sensitisers in textile

Dermal exposure can be assessed by actual measurements of the chemical deposited onto the skin or by using various exposure models. This exposure concentration is then compared to a presumed safe exposure level (reference dose, derived no effect level, DNEL) to conclude on the risk.

For most substances in the scope of this restriction proposal, information on specific concentrations in textile and/or migration factor is lacking. This makes it difficult to perform quantitative substance-specific exposure assessments.

A precautionary qualitative approach for exposure assessment is thus proposed in the present restriction dossier, where exposure of the skin is assumed to occur if the skin sensitising substance is present in the textile and if it has the potential to migrate.

For some substances, information on migration factors and other exposure parameters are available, and for the other substances remaining in the scope it has not been possible to draw conclusions on the absence of migration in any event. Thus in the restriction proposal, unless there is specific migration data showing no migration or a valid scientific justification as to why migration does not occur , the Dossier Submitter assumes that substances in the scope that are present in textile have the potential to migrate from the material,.The available exposure information is used to derive substance specific concentration limits in textile by reverse dosimetry assuming the elicitation threshold dose as the safe dose on skin, according to equations given in section B.9.

B.9.2.5. Exposure scenario

A worst-case exposure scenario describing exposure to skin sensitising substances via textile has been developed in the present restriction proposal. It describes the potential exposure of the general population to chemical substances in textile that are used close to skin.

The exposure scenario is considered relevant for all substances in the scope which are present in textile, given that they have the potential to migrate. As described in Annex B.9.2.1 and in the main report in section 1.1.4.1. on articles covered by the restriction, other articles and/or materials included in the scope coming into contact with the skin to an extent similar to textile, such as latex, rubber, neoprene, synthetic leather, prints, coatings and disposable articles (napkins, tissues and nappies) are included in the scope of the restriction. These are assimilated to the textile exposure scenario for risk assessment purposes, the reason being that these articles are typically made of materials either resembling a textile material, and/or that they have similar use patterns as textiles.

In the table below (Table 10), the assumptions and short explanations for the textile exposure scenario has been summarised. Justifications and uncertainties are discussed in Annex F.

Table 10: Parameters to be applied for exposure calculation from textile

Parameter	Assumption	Explanation
Exposure duration (h)	24	The dose on skin is assumed to accumulate for 24 hours.
Exposure frequency (n)	3	Overall, 3 changes to occur during 24 hours (e.g. sleep wear, clothes, workout wear)
Surface weight of textile (kg/m^2)	0.2	The mean value in the range of textile surface weights, 0.07 kg/m^2 (silk) to 0.4 kg/m^2 (blanket).

Surface contact	1	A 1:1 contact surface between the textile and skin is assumed

Several comments made in the Public Consultation on the overall exposure assessment expressed concerns related to the use of several precautionary assumptions in combination, which may over-estimate the potential exposure of the consumers.

B.9.2.6. Workers exposure

Not in the scope of this restriction proposal

B.9.2.7. Consumer exposure

Please see sections B.9.2.1 to B.9.2.5.

B 9.2.8. Indirect exposure of humans via the environment

Not relevant.

B.9.2.9. Environmental exposure

Not relevant.

B.9.3. Uses: Leather, hide and fur

In the text below, leather also include fur and hides, unless specifically specified.

B.9.3.1. General information on exposure to chemical substances in leather, hide and fur

Leather[29] is also a common material in articles that are used close to skin. The frequent everyday use may lead to exposure of people of all ages to skin sensitisers. The level of exposure varies however according to the end-use of the leather. This means that uses with close bodily contact will lead to the highest exposures (Danish EPA, 2003). Most of such articles are also used for prolonged periods of time and exposure occurs under occlusion, which increases the likelihood for substances to deposit on skin and trigger skin allergy. Exposure from leather not used in direct contact with skin, or for shorter periods of time, is by the Dossier Submitter estimated to be lower.

The Dossier Submitter developed a scenario exploring the exposure from the use of leather. Hence, information on exposure parameters used for the risk assessment decribed below are given for leather.

[29] In this restriction proposal, leather articles also includes articles made of fur and hides, unless specifically specified.

Hazardous chemical substances can intentionally or unintentionally remain in the final product following the manufacture and finishing of leather. They can be released and result in exposure of the general population.

The most relevant exposure pathway in the context of skin sensitisation is direct release of substances to skin by migration from leather. Hence, the assessment of the exposure to chemical substances released from leather would ideally be based on presence in leather and information on migration or release of the skin sensitising substance to skin during use. However, for most substances included in the scope of the restriction proposal such data is lacking.

Migration of chemical substances from leather

There is a general lack of information on the factors that influence the migration of substances from leather. When it comes to the release of substances from leather, the Dossier Submitter assumes that they will behave similar to what is described for textile. However, there are likely differences in how substances are incorporated into the different materials that will influence the release. Additionally, the migration from leather articles seems to be affected by material aging. For leather and other types of material that are not frequently washed, the release of chemicals will likely also decrease at a slower rate.

Due to the general lack of information on exposure to chemical substances from leather, the Dossier Submitter assumes that the migration from such materials in most aspects is similar to that from textiles (see B.9.2), unless data is available to indicate otherwise. Such data is given in the following sections.

B.9.3.2. Information gathering and search strategy

To deal with the large amount of substances with a harmonised classification as skin sensitisers included in the scope, the Dossier Submitter used the Master list (see Annex E) as a starting point for information searches. The Master list contains a number of substances that potentially are used in the production of leather. Of the substances in the Master list, a number of substances were further targeted for exposure information searches based on a criteria defined by the Dossier submitter:

- Groups of chemicals with a structural similarity or same toxic entity (eg. diisocyanates, (meth)acrylates, chromium VI compounds)
- Substances for which there is potential for high exposure (deliberate use in leather, substance intended to stay on article and high levels[30] of substance in leather, and
- Substances that are well-known skin sensitisers (e.g. rosin, formaldehyde, nickel and cobalt compounds)

In addition, the substances in the list of concern were specifically targeted for information searches.

In the Dossier Submitter search strategy, mainly the internet and the search engine PubMed were used. Search terms used were chemical names, CAS numbers and chemical group

[30] The term high level refer to assumptions and estimated amounts in the consultancy report (KemI, 2019) where "high" corresponded to ≥10 000 ppm eller 30% (DCHP).

names. Furthermore, the Dossier Submitter looked for information in the call for evidence responses and via personal communication with researchers in the field.

B.9.3.3. Exposure information related to targeted substances or groups of substances

Allergenic disperse dyes

Eight disperse dyes are included within the list of substances with harmonised classification as Skin Sens 1 according to CLP, which may be present in textile and leather (KemI, 2019). The 24 disperse dyes in the list of concern are not classified with regard to skin sensitisation but have been included in the scope based on sufficient evidence on their allergenic properties.

Presence of substances in leather articles
Disperse dyes can be used to colour leather (Dossier Submitter's communication, 2018) and are included in the voluntary scheme Oeko-Tex leather standard[31]. Colouring is performed with the intention for the dye to remain in the leather at point of sale, hence the dyes may be present in leather at point of sale. In the Public Consultation comments were received that disperse dyes are not used to colour leather.

Approximate levels in leather
No information has been found.

Information on exposure from leather articles
No information has been found.

Migration from leather to skin
In the absence of information on migration of disperse dyes from leather, the migration factor proposed for disperse dyes in textile (5%) is assumed to be relevant also for leather.

Chromium VI compounds
At least 8 chromium VI compounds have harmonised classifications as Skin Sens. 1, and may be formed during production of leather (KemI, 2019). As noted by several stakeholders presence of chromium VI in leather products is incidental, due to oxidation of chromium III compounds that are used in leather manufacture at a high concentration.

Presence of substances in leather articles
Hexavalent chromium may form during processing. Under controlled conditions, chromium tanned leather and articles of chromium tanned leather can be produced in which chromium (VI) does not form.

Approximate levels in leather articles
Measured amounts in leather articles are between 1-7 mg/kg (Anses, 2018). Estimated amount on article is up to 100 mg/kg (KemI, 2019). In the Public Consultation, stakeholders provided comments indication an estimated amount <10 mg/kg.

Information on exposure from leather articles

[31] https://www.oeko-tex.com/media/init_data/downloads/LEATHER%20STANDARD%20by%20OEKO-TEX%C2%AE%20-%20Standard.pdf

As specific exposure values in relation to consumers are not available, the potential for exposure was described by data in relation to the chromium (VI) content of various consumer articles in the risk assessment of chromium VI in leather articles (ECHA 2012b). Based on market surveys in Denmark and Germany examining the chromium (VI) content in leather consumer articles, presented in the risk assessment of chromium VI in leather articles (ECHA 2012b), the Risk Assessment Committee (RAC) concluded that it was reasonable to assume the value of 10 mg/kg for the content of chromium (VI) in leather for the exposure scenario. The Dossier Submitter had originally used a value of 3 mg/kg in their Annex XV report. It should, however, be remembered that Cr (VI) levels up to 137 mg/kg have been found in footwear, so 10 mg/kg is not a worst-case situation.

Migration from leather to skin
Literature on transfer or migration rates of chromium (VI) from leather is scarce; usually the value of the total amount of extracted chromium (VI) is taken for the amount capable of migration. The underlying supposition that all of the determined hexavalent chromium will leach out from leather during use (Hansen 2002) is a worst case assumption that might be well overestimating the migration of chromium (VI) from leather to human skin or sweat. In a study carried out by the German BGFA (Berufsgenossenschaftliches Forschungsinstitut fur Arbeitsmedizin) on the influence of the pH on the leaching of chromium (VI) from leather into artificial sweat it was found that the migration at pH 5.5 was at the most 30% of the concentrations determined at pH 7.5 to 8.0, which is the usual pH of sampling buffers according to ISO 17075 (or DIN 53314) (Korn et al, 2003).

A comment provided in the Public Consultation considers the value of 30% for migration of chromium VI to be an extreme worst-case assumption since the test conditions applied in the laboratory does not apply to a real-life exposure scenario. Confidential data on experimental release of chromium from tanned leather, using a method that was developed to be comparable to real life exposure conditions was provided in the Public Consultation. This study reported no release of CrVI after 6h Given the uncertainties regarding the test conditions in the new study compared to the previous one, the Dossier submitter proposes to use a migration factor of 30% for chromium VI from leather in the present restriction proposal.

<u>Acid dyes</u>

At least 2 acid dyes have harmonised classifications as skin sensitisers and may be used in the production of textile and leather (KemI, 2019).

Presence of substance in leatherr articles
Acid dyes are used to colour leather (KemI, 2014; KemI, 2019). Dyeing is performed with the intention for the dye to remain in the leather at point of sale.

Approximate levels in leather articles
Acid dyes are typically applied at 0 - 6% (60 000 mg/kg) (KemI, 2019). Loose, unfixed dye is present in low mg/kg levels (maybe 20 mg/kg) (KemI, 2019).

Information on exposure from leather articles
Binding to the leather is attributed to salt formation between the anionic groups in the dyes and cationic groups in the material. Acid dyes include both azo and anthraquinone compounds. Comments received in the Public Consultation states that acid dyes are chemically bound within the fibre. This process implies a chemical reaction which modifies the

dye molecule and binds it to the fibre with covalent bonds or strong ionic bonds respectively. The stability of the dyes on fibre is additionally enhanced through appropriate treatments. The respondants do therefore not expect exposure to consumers. It unclear from the response if the chemical bond with the dye and the material matrix relates to both textile and leather.

Migration from leather to skin
No migration data has been found. These substances have high water solubility, which indicates a high ability of these substances to migrate and be dissolved from the article by e.g. sweat or saliva (KemI, 2017).

Direct dyes
At least 2 direct dyes have harmonised classifications as skin sensitisers and may be used in the production of leather.

Presence of substance in leather articles
Direct dyes may be used to colour leather. Dyeing is performed with the intention for the dye to remain in the leather at point of sale.

Approximate levels in leather articles
No information has been found.

Information on exposure from leather articles
No information.

Migration from leather to skin
No migration data has been found. The substances have high water solubility, which indicates a high ability of this substance to migrate and be dissolved from the article by e.g. sweat or saliva (KemI, 2017).

Diisocyanates

At least 7 diisocyanates have harmonised classifications as skin sensitisers and are likely to be used in the production leather (KemI, 2019).

Presence of substances in leather articles
Diisocyanates may be used in the production leather (KemI, 2019).

Approximate levels in leather
The levels of diisocyanates can be up to 1 000 mg/kg (KemI, 2019). It is unclear if this number refers to cured or uncured forms. According to comments received during the Public Consultation, the level of diisocyanates in consumer articles estimated in KemI (2019) is based on results from the use of inappropriate analytical techniques. The actual concentration levels in articles within the scope of the proposed restriction are claimed to be considerably lower than 1000 ppm, and should not be found in concentration above 100 ppm. The Dossier submitter have no further information to challenge these comments.

Information on exposure from leather articles
No information has been found.

Migration from leather to skin
No information has been found.

Meth(acrylates)

At least 4 meth(acrylates) have harmonised classifications as skin sensitisers and are likely to be used in the production of leather (KemI, 2019).

Low levels of residual monomers and process chemicals can migrate from acrylic polymers during handling and use of consumer products (Pemberton and Lohmann, 2014). Residues can be found in acrylic binders or coatings. (Meth)acrylates are also used in adhesive applications (KemI, 2019).

Presence of substances in articles
(Meth)acrylates are used in coated and pigment printed leather (KemI, 2019).

Approximate levels in articles
Levels can be up to 10 mg/kg (KemI, 2019).

Information on exposure from leather articles
No information has been found.

Migration from leather to skin
No information has been found.

Formaldehyde

Formaldehyde has a harmonised classification as a skin sensitiser and may be used in the production of leather (KemI, 2019).

Presence of substance in leather articles
Formaldehyde can be used in leather tanning (KemI, 2017).

Approximate levels in leather articles
Estimated amounts between 100 and 1 000 mg/kg and 75 mg/kg on unwashed resins and other finishes. In a study carried out by Anses (2018) levels between 3 -400 mg/kg were reported.

Information on exposure from leather articles
Formaldehyde is a known skin sensitiser and there are many reports on skin allergy related to formaldehyde in textiles. Exposure to formaldehyde from leather is considered to be a problem of equal magnitude as exposure from textile (Dossier Submitter's personal communication, 2019). This is considered as evidence that exposure of formaldehyde from leather can take place (and thus there is migration potential).

Migration from leather to skin
This substance has properties that are relevant for migration, e.g. high water solubility, thus it can be dissolved from the article by e.g. sweat (KemI, 2017). Since formaldehyde is a known skin sensitiser, and skin allergy from formaldehyde in textiles has been reported, this

is considered as evidence for migration potential of formaldehyde also from leather. However, no migration data has been found.

Rosin

At least 2 rosins have harmonised classifications as skin sensitisers and may be used in the production of leather (KemI, 2019). These are tall-oil rosin (CAS 8052-10-6/ EC 232-484-6) and rosin (CAS 8050-09-7/ EC 232-475-7) (KemI, 2019).

Presence of substance in leather articles
These rosins can be used in the finishing stage of leather production (KemI, 2019).

Approximate levels in leather articles
The estimated amount on articles are 1 000 mg/kg (KemI, 2019). In the Anses study, rosin has been qualitatively detected in leather footwear (Anses 2018).

Information on exposure from leather articles
No data has been found.

Migration from leather to skin
No data has been found.

Nickel compounds

Several nickel compounds have harmonised classifications as a skin sensitisers and may be used in the production of leather (KemI, 2019).

Presence of substance in articles
The Dossier Submitter has not found data indicating the use of nickel in leather. However, the Dossier Submitter argues that it could potentially be used and the derivation of a concentration limit could be relevant as a preventive measure. Nickel can be present in metallic parts such as buttons and zippers but such non-leather parts are not intended to be covered by the restriction proposal. These articles are covered by entry 27 of Annex XVII of the REACH Regulation.

Approximate levels in articles
No data has been found.

Information on exposure from leather articles
No data has been found.

Migration from leather to skin
No data has been found.

Cobalt compounds

Several cobalt compounds have harmonised classifications as a skin sensitisers and may be used in the production of leather (KemI, 2019).

Presence of substance in articles
Cobalt is used in the so-called pre-metallized dyeing of leather products. Cobalt has been found in leather furniture upholstery, shoes and gloves (Hamann et al., 2018).

Approximate levels in articles
Cobalt was reported in levels >400 mg/kg in leather articles (Hamann et al. 2018). A comment received in the Public consultation pointed out that the presence of cobalt in leather articles can originate from metal-complex dyes, which typically have strong metal-ligand binding. Skin sensitising properties however are mainly related to the free metals.

Information on exposure from leather articles
No information has been found.

Migration from textile to skin
Cobalt has low water solubility, which thus indicates low ability to be dissolved from the article by e.g. sweat (KemI, 2017). However, the Dossier Submitter assumes that migration cannot be ruled out in any event.

<u>1,4 paraphenylene diamine</u>

1,4 paraphenylene diamine has a harmonised classification as a skin sensitiser and may be used in the production of leather (Anses, 2018).

Presence of substance in articles
1,4 paraphenylene diamine can be used to dye leather or in azo dyes manufacturing.

Approximate levels in articles
No information has been found.

Information on exposure from leather articles
No information has been found.

Migration from textile to skin
No information has been found.

<u>Dicyclohexyl phthalate (DCHP)</u>

1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester or dicyclohexyl phthalate (DCHP) (CAS 84-61-7/ EC 201-545-9) has a harmonised classification as a skin sensitiser and may be used in the production of leather (KemI, 2019).

Presence of substance in articles
The Dossier Submitter has not found further information indicating the use of DCHP in leather. However, the Dossier Submitter argues that it could potentially be used and the derivation of a concentration limit could be relevant as a preventive measure.

Approximate levels in articles
No information has been found.

Information on exposure from leather articles
No information has been found.

Migration from leather to skin
No information has been found.

Glutaraldehyde

Glutaraldehyde has a harmonised classification as a skin sensitiser and is likely to be used in the production of leather (KemI, 2019). It is used as a reactive tanning agent in chromium-free tanning of leather (KemI, 2019).

Presence of substance in leather articles
Glutaraldehyde is used for pre-tanning and re-tanning. It is also used as a tanning agent to produce leather with distinct properties (very soft and full, yellowish with high wash and sweat resistance) for special purposes, e.g. golf gloves or woolskin bedspreads for hospitals (BREF, 2013).

Approximate levels in leather articles
No data has been found. In the Public Consultation, four stakeholders submitted information about concentration levels of glutaraldehyde in leather articles. All of them indicate concentration levels below 20 ppm, and three of them indicate levels well below 10 ppm.

Information on exposure from leather articles
In leather, glutaraldehyde is bound irreversibly to the collagen molecule and severe acid hydrolysis is required to release it by breaking the peptide bonds within the collagen rather than the actual glutaraldehyde binding site (NICHAS, 1995). Unfixed residues are washed out (KemI, 2019).

Migration from leather to skin
No data has been found. Although glutaraldehyde is bound irreversibly to the collagen molecule, the Dossier Submitter assumes that exposure can occur (e.g. via residues), unless data indicate otherwise.

B.9.3.4. Exposure assessment

Levels of skin sensitising substances in leather
The Dossier submitter has not found much published data on measured levels of skin sensitising substances in leather. Valuable information has been received through experts *via* the Call for evidence, a questionnaire, a consultancy study (KemI, 2019) and the Anses opinion collective expert appraisal report (Anses, 2018). The available information on approximate levels of the targeted substances in leather is summarised in the table below (Table 11).

Table 11: Approximate (measured or estimated[32]) levels in leather of the targeted substances

Group / Substance	Approximate levels in leather	Reference
Allergenic disperse dyes	No information available	-
Chromium VI compounds	Estimated amount are some hundred mg/kg in leather. Measured amounts in leather articles are between 1-7 mg/kg. In the Public Consultation, stakeholders stated estimated amounts < 10 mg/kg.	KemI, 2019; Anses, 2018
Diisocyanates	Estimated levels above 1000 mg/kg. It is unclear if this number refers to cured or uncured forms. In the Public Consultation, stakeholders stated estimated amounts <10 mg/kg.	KemI, 2019
(Meth)acrylates	Estimated levels around 10 mg/kg in leather.	KemI, 2019
Formaldehyde	Estimated levels between 100 and 1000 mg/kg and around 75 mg/kg in leather (KemI 2019). In a study carried out by Anses (2018) levels between 3 - 400 mg/kg were reported.	KemI, 2019; Anses, 2018
Nickel compounds	No information	-
Cobalt compounds	Levels >400 mg/kg and >50 000 mg/kg in leather has been reported.	Hamann, 2018
Direct dyes	No information	-
Acid dyes	Estimated to be applied at 0 - 6% (60 000 mg/kg).	KemI, 2019
Rosin	The estimated amount is 1 000 mg/kg. In Anses, 2018, rosin has been qualitatively detected in leather footwear.	KemI, 2019; Anses, 2018
1,4 paraphenylene diamine	No information	-
Dicyclohexyl phthalate (DCHP)	No information	-
Glutaraldehyde	In the Public Consultation, stakeholders indicated	-

[32] The estimated amount in leather presented in KemI (2019), is a worst case scenario which is largely the consultants' educated guesswork unless there is knowledge of Restricted Substance List test data (e.g. chromium VI, isocyanates etc).

	concentration levels below 20 ppm, or well below 10 ppm.	

It should be noted that the information on the levels of skin sensitising substances in leather are approximations based on either amount applied, or on few measurements of levels in finished articles, and was therefore not considered appropriate for use in calculations of exposure levels.

Migration of skin sensitising substances from leather

The available migration data is expressed as a percentage of the total content of the substance in the tested leather article (migration factor). As migration to artificial sweat is normally measured over only a few hours, the Dossier Submitter interprets these numbers as the amount of chemical that can be released to sweat during the first use of the leather article. Thus the exposure assessment is based on first use of the leather article.

In general, the Dossier Submitter had difficulties to find public data on migration factors from leather for most targeted chemicals. Data has been found on migration from leather to artificial sweat for chromium VI (ECHA, 2012b), but data is generally lacking with regards migration of other individual substances (Table 7) from leather. In addition, migration data to other types of vehicles than sweat, such as sebum and cosmetics was lacking.

Default migration factor

Since many unknown factors collectively contribute to the migration of chemical substances from leather, the Dossier Submitter uses a precautionary approach in which it is assumed that substances in the scope for which migration information is lacking have the potential to migrate to skin if the substance is present in the leather or leather article. Hence, for the targeted substances which lack information on migration from leather, as well as for the substances in the scope which were not targeted for information searches, the default migration factor of 10% as assumed for textiles was applied for leather (see details in B.9.2).

Contact between leather and skin

The dose per skin surface area is considered to be the most relevant dose metric for risk assessment of skin sensitisers. Therefore, the area of the exposed skin is typically an important parameter to consider in such calculations. However, in a leather exposure scenario the relationship between the leather surface and surface of the exposed skin is 1:1, i.e. the exposed skin area is 100% covered by leather. The exposure assessment can therefore be performed per surface area of skin, and the overall exposed skin area could be neglected.

Exposure duration

It is generally agreed that it is not only the dose per skin area that is the determinant of elicitation of skin allergy but also that the duration of the exposure, i.e. the accumulated dose per skin area is important. 24 hours was selected as an appropriate time frame for accumulated dose given that once an individual is induced, manifestations of allergy normally develop within 1-2 days after (re-) exposure to the allergen. Indeed, derivations of safe levels of allergens in cosmetics are typically made based on a 24-hour basis when repeated applications are assumed (SCCS, 2012).

Exposure frequency

The probability for re-exposure to the same substance over a day from the use of leather products was considered to be smaller compared to textiles. It was assumed to occur at most 2 times in 24 hours (leisure shoes are changed into sports shoes), which may be considered a worst case scenario.

Surface weights

The level of chemical content in leather is typically expressed as substance weight in grams per kilogram article. However, the thickness of the leather will have a large influence how much of the chemical is deposited on the skin. Assuming that the chemical is evenly distributed in the article, the thicker the article the more chemical is contained per surface area. In an exposure scenario for chromium-tanned leather articles in the restriction on chromium (VI) compounds in leather, it was assumed that the density of leather is 1 500 kg/m^3 and that the weight of 1 cm^2 leather of 1 mm weights 0.00015 kg (ECHA, 2012b). This translates into a surface weight of 1.5 kg/m^2. During the Public Consultation of the present restriction proposal, stakeholders submitted information regarding density, thickness and surface weight of different leather articles. Based on the submitted data, the range for leather surface weight is estimated to be 0.4-1 kg/m^2 for footwear, 0.3-0.8 kg/m^2 for garments and gloves, 0.6-0.9 kg/m^2 for upholstery and 0.6-1.2 kg/m^2 for automotive. A value of 0.9 kg/m^2 (corresponding to the surface weight of the most representative type of leather used in contact with the skin, i.e. bovine leather for footwear, leather goods and furniture with a thickness of 1.2 mm) was chosen for risk assessment purposes.

Conclusion on exposure to skin sensitisers in leather

Dermal exposure can be assessed by actual measurements of the chemical deposited onto the skin or by using various exposure models. This exposure concentration is then compared to a presumed safe exposure level (reference dose, derived no effect level, DNEL) to conclude on the risk.

For most substances in the scope of this restriction proposal, information on specific concentrations in articles and/or migration factor is lacking. This makes it difficult to perform quantitative substance-specific exposure assessments.

A precautionary qualitative approach for exposure assessment is thus proposed in the present restriction dossier, where exposure of the skin is assumed to occur if the skin sensitising substance is present in the textile and leather articles and if it has the potential to migrate.

For some substances, information on migration factors and other exposure parameters are available, and for the other remaining substances in the scope it has not been possible to draw conclusions on the absence of migration in any event. Thus in the restriction proposal, unless there is specific migration data showing no migration or a valid scientific justification as to why migration does not occur, the Dossier Submitter assumes that substances in the scope that are present in leather have the potential to migrate from the material,.

The available exposure information is used to derive substance specific concentration limits in leather by assuming the elicitation threshold dose as the safe dose on skin, according to equations given in section B.9.

B.9.3.5. Exposure scenario

A realistic worst-case exposure scenario describing exposure to skin sensitising substances in leather has been developed in the present restriction proposal. It describes the potential exposure of consumers to chemical substances in leather and leather articles that are used close to skin.

The exposure scenario is considered relevant for all substances in the scope which are present in leather, given that they have the potential to migrate.

In the table below (Table 12) the assumptions and short explanations for the leather exposure scenario has been summarised. Uncertainties are addressed in Annex F.

Table 12: Parameters to be applied for exposure calculation from leather

Parameter	Assumption	Explanation
Exposure duration (h)	24	The dose on skin is assumed to accumulate for 24 h
Exposure frequency (n)	2	Overall, 2 changes to occur during 24 hours (e.g. leisure shoes changed into sports shoes)
Surface weight (kg/m^2)	0.9	The surface weight of the most representative type of leather (ie bovine leather for footwear, leather goods and furniture with a thickness of 1.2 mm), with a typical leather surface weight of 0.4-1 kg/m^2 for footwear, 0.3-0.8 kg/m^2 for garments and gloves, 0.6-0.9 kg/m^2 for upholstery and 0.6-1.2 kg/m^2 for automotive.
Contact surface	1	A 1:1 contact between leather and skin is assumed

Several comments made in the Public Consultation on the overall exposure assessment expressed concerns related to the use of several precautionary assumptions in combination, which may over-estimate the potential exposure of the consumers.

B.9.3.6. Workers exposure

Not in the scope of this restriction proposal

B.9.3.7. Consumer exposure

Please see sections B.9.3.1 to B.9.3.5.

B 9.3.8. Indirect exposure of humans via the environment

Not relevant.

B.9.3.9. Environmental exposure

Not relevant.

B.9.4. Other sources (for example natural sources, unintentional releases)

Not relevant.

B.9.5. Overall environmental exposure assessment

Not in the scope of this restriction proposal.

B.9.6. Combined human exposure assessment

Not relevant.

B.10. Risk characterisation

The Dossier Submitter proposes that skin sensitising substances should be restricted in clothing, footwear and other articles with similar skin contact made of textile, leather, fur, hide and synthetic leather as well as disposable sanitary towels, napkins, tissues and nappies based on the risk from exposure to substances classified with regard to skin sensitisation, or to substances that have been indicated to cause allergic contact dermatitis, with consideration to the exposure assessment as described in section 1.2.4 of the main report and Annex B.9. The purpose of the risk characterisation is to assess the likelihood that elicitation of skin allergy is avoided when wearing or using clothing, footwear and other articles with similar skin contact made of textile, leather, fur, hide and synthetic leather.

The risk management option analysis (RMOA, now called Regulatory management option analysis by ECHA), finalised by KemI in 2016, concluded that an EU wide ban of placing textile articles that contain skin sensitising substances on the market was the most appropriate RMO. A total ban of sensitising substances in textiles is not realistic, as this would seriously hamper the production of textile and leather articles. Instead, the risk is proposed to be managed by setting concentration limits for the skin sensitising chemicals in textiles and leather. However, a detailed proposal on concentration limits was not provided in the RMOA as available analytical methods and appropriate concentration limits were considered needing further investigation. Hence, the output of the (semi-)quantitative exposure and hazard assessment is a proposal for setting concentration limits for skin sensitisers in textile and leather articles.

Skin sensitisation is regarded as a threshold effect (Kimber et al., 1999, Robinson et al., 2000). This, in principle, enables a quantitative approach for the risk assessment. Such an approach, based on induction thresholds, has been developed for fragrance ingredients in consumer products (Api and al. 2008), but can also be applied to other substances. Moreover, the risk assessment for the restriction of chromium VI in leather articles (ECHA, 2012b) and substances in tattoo inks and permanent make up was based on elicitation thresholds.

The lack of substance specific exposure information makes it difficult to perform quantitative exposure assessments and risk characterisation ratios can therefore not easily be calculated. The Dossier Submitter has instead used the elicitation threshold dose as a reference dose, and combined it with available information and/or justified assumptions on exposure and migration, to derive concentration limits of skin sensitisers in textile and leather considered to be safe as regards skin sensitisation. If the level of the skin sensitising substance in the textile and/or leather at point of sale exceeds the derived concentration limit, it may be of concern and should be lowered. Approximations of the concentrations of the skin sensitisers

targeted for information search that may be present in textile and leather at point of sale are given in Table 8 and Table 11 (and in section 1.2.4 of the main report).

The amount of available information on elicitation threshold doses (ED10 or $MET_{10\%}$) and migration factors varies among the sensitising substances in the scope. Risk characterisation based on such data will therefore be associated with various level of uncertainty. The Dossier Submitter approach is to use the available data as broadly as possible, but at the same time be transparent about the uncertainty. To reflect the various levels of uncertainty, and to enable the incorporation of substance specific information if such becomes available during the public consultation, the derivation of concentration limits in textile and leather for the sensitising substances in the scope is divided in three sections (see also Table 13 below);

I. Quantitative, substance specific approach. Substances or groups of substances for which substance specific elicitation threshold doses and migration data are available. The level of certainty regarding the derived concentration limits in textile and leather is considered higher as compared to section II and III.

II. Quantitative, substance semi-specific approach. Substances or groups of substances for which substance specific migration data or substance specific elicitation threshold doses are available. Medium certainty.

III. Quantitative default approach. For substances for which no substance specific migration factor or elicitation threshold dose were found. The use of generic values is associated with considerable uncertainty.

When the approximated levels of skin sensitising substances in textile and leather is below the proposed concentration limits (described below), the risk from the exposure as described in the exposure scenario for textile and leather is considered to be controlled for.

Table 13: The risk assessment approach

Available substance specific migration data I	**Available substance specific elicitation threshold doses**	**I) Substance specific concentration limit**	**II) Substance semi-specific concentration limit**	**III) Generic concentration limit**
Yes	Yes	X	-	-
Yes	No	-	x	-
No	Yes	-	x	-
No	No	-	-	x

B.10.1. Human health risk from exposure to skin sensitisers in textile

To reduce the risk for the general population from exposure to skin sensitising substances in textile, the exposure to a chemical substance migrated from the material should not exceed the elicitation threshold dose (ED10 or $MET_{10\%}$), considered as the safe dose on skin over 24 hours.

B.10.1.1. Equations to derive concentration limits in textile

The limit in textile per surface area was calculated using the following equation:

*Limit in textile (**µg/cm²**) = elicitation threshold dose/(migration factor * contact surface * frequency of exposure)*

To convert the limit in textile per surface area to mg/kg the following equation was used:

*Limit in textile (**mg/kg**) = Limit in textile (µg/cm²)*10 000 (conversion factor cm² to m²) /(1 000 (conversion factor µg to mg)* surface weight in* kg/m²*)*

Changes in any of the parameters in the above formula will affect the proposed concentration limit in textile. For more information see Table 15, section B.10.1.5.

B.10.1.2. Concentration limits for substances or groups of substances with information on elicitation threshold doses and migration: Quantitative, substance specific approach

Allergenic disperse dyes

Disperse dyes are used to dye synthetic textile materials. An elicitation threshold dose of 0.0003 µg/cm² (Ryberg et al., 2009) was used in combination with a substance specific migration factor of 5% and the exposure scenario for textile to derive a concentration limit for allergenic disperse dyes in textile.

The concentration limit of allergenic disperse dyes in textile ensuring that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm²) = 0.0003/(0.05*1*3) = 0.002*
Limit in textile (mg/kg)** = 0.002*10 000/(1 000*0.2)* **= 0.1 mg/kg

The Dossier Submitter would like to point out, that the concentration limits are relevant for all disperse dyes included in the scope whether the substances have a harmonised classification as a skin sensitiser according to the CLP regulation or are included in the scope through the list of concern. Since the derived limits are below the current quantification limit for disperse dyes (30-50 mg/kg), the Dossier Submitter proposes a ban of allergenic disperse dyes in textile articles. By proposing a ban, the Dossier Submitter intends a limit not exceeding the limit of detection. The limit of detection should be below the concentration limit calculated here above. This restriction proposal calls for a revision of the current restriction (entry 72 of REACH Annex XVII) for the Disperse Blue 1.

Chromium VI compounds

Chromium VI is restricted to 1 mg/kg in textiles due to CMR properties (entry 72 of REACH Annex XVII). In the present proposal, an elicitation threshold dose of 0.02 µg/cm² and a migration factor of 30% (ECHA 2012b) was used in the calculations, assuming that the amount of chromium VI which migrate from leather is similar to migration from textile. This information was used in combination with the exposure scenario for textile to derive a concentration limit in textile.

The limit of chromium VI in textile articles to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm²) = 0.02/(0.30 *1* 3) = 0.02*
Limit in textile (mg/kg)** = 0.02*10 000/(1 000*0.2)* **= 1.1 mg/kg

Since 1.1 mg/kg is higher than the concentration limit for chromium VI of 1 mg/kg in entry 72 of REACH Annex XVII, the existing concentration limit is assumed to also protect from elicitation of allergic contact dermatitis by chromium VI in textile. Hence, for regulatory consistency, the lowest concentration limit for chromium VI compounds in textile applies. The proposed concentration limit is expressed as CrVI that can be extracted from the material.

B.10.1.3. Concentration limits for substances/groups of substances with information on elicitation threshold doses or migration: Quantitative, substance semi-specific approach

Formaldehyde

Formaldehyde is included in entry 72 of REACH Annex XVII with a 75 mg/kg concentration limit for textiles, based on its CMR properties. In November 2019, Commission Directive (EU) 2019/1929 amending Appendix C to Annex II to Directive 2009/48/EC (the Toy Safety Directive), adopting the specific limit values for formaldehyde of 30 mg/kg (content limit) in textile toy material, among other limit values. The specific limit values is for formaldehyde used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. According to a report from the Organisation for Economic Cooperation and Development (OECD) published in 2002, the lowest threshold concentration for allergic contact dermatitis from formaldehyde is 30 mg/kg. On that basis and in order to protect also the most sensitised individuals, the Commission's Working group on Chemicals in Toys (subgroup Chemicals) recommended a formaldehyde content limit of 30 mg/kg when the content of formaldehyde is determined in accordance with the water extraction method in standard EN ISO 14184-1:2011.An ED10-value of 20.1 µg/cm² (Fischer *et al.*, 2011) was initally used to calculate the limit concentration in textile articles for formaldehyde. No information on migration/emission from textile has been found in the literature. Hence, the Dossier Submitter uses the default migration factor of 10% in the calculations.

The limit in textile, to ensure that the elicitation threshold dose is not exceeded would then be:

*Limit in textile (µg/cm²) = 20.1/(0.1*1*3) = 67*
Limit in textile (mg/kg)** = 67*10 000/(1 000*0.2)* **= 3350 mg/kg

The Dossier Submitter's derived concentration limit of 3350 mg/kg is higher than the concentration limit of 30 mg/kg for formaldehyde in textile as toy material, as stated in Appendix C to Annex II to the Toy Safety Directive. Since the concentration limit in the Toy Safety Directive is based on risk for contact allergy, the Dossier Submitter proposes to align the concentration limit with the Toy Safety Directive. Thus, a concentration limit of 30 mg/kg for formaldehyde in textile in the present proposal is proposed.

Nickel compounds

Nickel is used in some dye chromophores (KemI, 2019). Nickel can also be present in metallic parts such as buttons and zippers but such non-textile parts are not intended to be covered by the restriction proposal. These articles are covered by entry 27 of Annex XVII of the REACH

Regulation. An ED10 value of 0.74 µg/cm^2, the lowest of 5 ED10-values reported in Fischer et al. (2011) was used in combination with the default migration factor of 10% and the exposure scenario for textile to derive concentration limit in textile.

The limit in textile to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm^2) = 0.74/(0.1*1*3) = 2.47*
***Limit in textile (mg/kg)** = 2.47*10 000/(1 000*0.2)* **= 123 mg/kg**

For simplicity, the Dossier Submitter proposes a concentration limit of **120 mg/kg** for nickel in textile.

The concentration limit for nickel in textile is proposed to cover both nickel and the nickel compounds which are in the scope. The concentration limits are expressed as nickel metal that can be extracted from the material.

Cobalt compounds

Cobalt is used in some dye chromophores, to dye nylon and wool (KemI, 2019). An ED10-value of 0.44 µg/cm^2 (Fischer et al. 2011), the default migration factor of 10% and the exposure scenario for textile have been applied in the calculations.

The limit in textile to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm^2) = 0.44/(0.1*1*3) = 1.47*
***Limit in textile (mg/kg)** = 1.47*10 000/(1 000*0.2)* **= 73 mg/kg**

For simplicity, the Dossier Submitter proposes a concentration limit of **70 mg/kg** for cobalt in textiles.

The concentration limit for cobalt in textiles is proposed to cover both cobalt and the cobalt compounds which are in the scope. The concentration limit are expressed as cobalt metal that can be extracted from the material.

1,4 paraphenylene diamine

1,4 paraphenylene diamine is used as a textile dye or in azo dyes manufacturing. An ED10 value of 1.5 µg/cm^2 (Sosted et al., 2006) and the default migration factor of 10%, in combination with the exposure scenario for textile have been used in the calculations.

The limit in textile to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm^2) = 1.5/(0.1*1*3) = 5*
***Limit in textile (mg/kg)** = 5*10 000/(1 000*0.2)* **= 250 mg/kg**

B.10.1.4. Concentration limits for substances/groups of substances no information on elicitation threshold doses or migration: Quantitative default approach

The default elicitation threshold dose of 0.8 µg/cm^2 of skin and the default migration factor of 10% was used in combination with the exposure scenario for textile, to derive a concentration limit for textile.

The limit in textile to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm²) = 0.8/(0.1*1*3) = 2.66*
Limit in textile (mg/kg)** = 2.66*10 000/(1 000*0.2) = **133 mg/kg

For simplicity, the Dossier Submitter proposes a concentration limit of **130 mg/kg** for these substances in textile.

The calculated limits in textile are proposed for all substances in the scope which are not specifically mentioned in section B.10.1.2 and B.10.1.3 above.

B.10.1.5. Conclusion on human health risk

For most of the skin sensitisers in the scope of this restriction proposal, the concentration limits suggested for textile articles are below the approximated concentrations in textile and leather at point of sale (as indicated by Table 8, and in section 1.2.4 of the main report). Hence, lowering the concentrations of the skin sensitising substance in clothing, footwear and other articles with similar skin contact made of textile, leather, fur, hide and synthetic leather as well as disposable sanitary towels, tissues, napkins and nappiesto the ones proposed above, is considered to significantly reduce the risk for skin sensitisation in consumers. The concentration limits proposed are thus considered to adequately protect consumers against skin sensitisation. The proposed concentration limits in textile for the substances in the scope are given below (Table 14).

Table 14: Summary table of proposed concentration limits in textile articles for substances in the restriction scope.

Substance / group of substances	**Proposed concentration limit in textile[1] (mg/kg)**
Disperse dyes	Ban[1]
Chromium VI compounds	1[2]
Nickel compounds	120
Cobalt compounds	70
Formaldehyde	30
1,4 paraphenylene diamine	250
Other substances in scope	130

[1]Any concentration limit proposed for textile also applies for materials such as synthetic leather, rubber materials and polymer materials, prints and coatings included in the scope coming into contact with the skin to an extent similar to clothing. The concentration limits applies also to disposable sanitary towels, napkins, tissues and nappies.
[2]The ban refers to the limit of detection (that should be below the calculated concentration limits of 0.15 mg/kg in textile and 0.03 mg/kg in leather).

Some voluntary labelling schemes and/or standards (such as Oeko Tex BlueSign, etc) may have established more restrictive concentration limits for some of the substances covered by the present restriction proposal. However, the scientific basis and assumptions underlying the values are not available to the Dossier Submitter. Hence, they were not takeninto consideration.

B.10.1.6. Sensitivity analysis

A change of one or several parameters in the above formula will affect the proposed concentration limit in textile. See Table 15 and calculated examples below.

Table 15 : Effects of changes in the parameters in the formula on the concentration limit in textile.

	Effect on the concentration limit in textile	
Parameter	Increase	Decrease
ED10-value/Elicitation threshold dose	↑	↓
Migration factor	↓	↑
Frequency of exposure	↓	↑
Surface weight	↓	↑
Contact surface	↓	↑

Below are calculated examples on how a change in one parameter (bolded) will affect the concentration limit in textile. Calculations are performed based on the formula for generating a generic concentration limit: Limit in textile (µg/cm^2) = 0.8/(0.1 *1*3) = 2.66. Limit in textile (mg/kg) = 2.66 *10000/(1000*0.2) = 133 (see section B.10.1.3).

Elicitation threshold dose:
A low elicitation threshold dose (ED10-value): Limit in textile (µg/cm^2) = **0.0003**/(0.1*1*3) = 0.001. Limit in textile (mg/kg) = 0.001*10 000/(1 000*0.2) = **0.05 mg/kg**

A high elicitation threshold dose (ED10-value): Limit in textile (µg/cm^2) = **20.1**/(0.1*1*3) = 67. Limit in textile (mg/kg) = 67*10 000/(1 000*0.2) = **3350 mg/kg**

The range for the concentration limit using a low or a high ED10-value (0.0003 – 20.1 µg/cm^2) is 0.05 – 3 350 mg/kg. The elicitation threshold dose/ED10-value is the most important parameter affecting the concentration limit. For most substances the elicitation threshold dose/ED10-value is not known.

Migration factor:
A low migration factor: Limit in textile (µg/cm^2) = 0.8/(**0.001***1*3) = 267. Limit in textile (mg/kg) = 267*10 000/(1 000*0.2) = **13 350 mg/kg**

A high migration factor: Limit in textile (µg/cm^2) = 0.8/(**0.3***1*3) = 0.9. Limit in textile (mg/kg) = 0.9*10 000/(1 000*0.2) = **44 mg/kg**

The range for the concentration limit using a low or a high migration factor (0.1 – 30 %) is 44 – 13 350 mg/kg. The migration factor is the second most sensitive parameter. For most substances the migration factor is not known.

Surface weight:
A low surface weight: Limit in textile (µg/cm^2) = 0.8/(0.1*1*3) = 2.66. Limit in textile (mg/kg) = 2.66*10 000/(1 000***0.07**) = **380 mg/kg**

A high surface weight: Limit in textile (µg/cm^2) = 0.8/(0.1*1*3) = 2.66. Limit in textile (mg/kg) = 2.66*10 000/(1 000***0.4**) = **67 mg/kg**

The range for the concentration limit using a low or a high surface weight (0.07 -0.4 kg/m^2) is 67 – 380 mg/kg.

Frequency of exposure:
A low frequency of exposure: Limit in textile (µg/cm^2) = 0.8/(0.1*1*1) = 8. Limit in textile (mg/kg) = 8*10 000/(1 000*0.2) = **400 mg/kg**

A high frequency of exposure: Limit in textile (µg/cm^2) = 0.8/(0.1*1*3) = 2.7. Limit in textile (mg/kg) = 2.7*10 000/(1 000*0.2) = **133 mg/kg**

The range for the concentration limit using a low or a high frequency of exposure (1-4) is 133 – 400 mg/kg.

Contact surface:
A lower contact surface than used in this restriction proposal (i.e. <100%) will lead to a higher concentration limit.

The above examples are calculated for textiles, but the same conclusions can be drawn for leather.

B.10.2. Human health risk from exposure to skin sensitisers in leather, hide and fur

To reduce the risk for the general population from exposure to skin sensitising substances in leather, hide and fur the exposure to a chemical substance migrated from the materials should not exceed the elicitation threshold dose (ED10 or $MET_{10\%}$), considered as the safe dose on skin over 24 hours.

B.10.2.1. Equations to derive concentration limits in leather

The limit in leather per surface area was calculated using the following equation:

*Limit in leather (**µg/cm²**) = elicitation threshold dose/(migration factor * contact surface * frequency of exposure)*

To convert the limit in leather per surface area to mg/kg the following equation was used:

*Limit in leather (**mg/kg**) = Limit in leather (µg/cm^2)*10 000 (conversion factor cm^2 to m^2) /(1 000 (conversion factor µg to mg)* surface weight)*

Changes in any of the parameters in the above formula will affect the proposed concentration limit in leather, hide and fur. For more information see Table 17 in section B.10.1.6.

B.10.2.2. Concentration limits for substances/groups of substances with information on elicitation threshold doses and migration: Quantitative, substance specific approach

Allergenic disperse dyes
Disperse dyes may be used to colour leather (Dossier Submitter's communication, 2018). An elicitation threshold dose of 0.0003 µg/cm^2 (Ryberg et al., 2009) was used in combination with a substance specific migration factor of 5% and the exposure scenario for leather to derive a concentration limit for allergenic disperse dyes.

The limit of allergenic disperse dyes in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm^2) = 0.0003/(0.05*1*2) = 0.002*
Limit in leather (mg/kg)** = 0.002*10 000/(1 000*0.9) **= 0.03 mg/kg

The Dossier Submitter would like to point out, that the concentration limit is relevant for all disperse dyes included in the scope whether the substances have a harmonised classification as a skin sensitiser according to the CLP regulation or are included in the scope through the list of concern. Since the derived limits are below the current quantification limit for disperse dyes (30 - 50 mg/kg), the Dossier Submitter proposes a ban of allergenic disperse dyes in leather articles. By proposing a ban, the Dossier Submitter intends a limit not exceeding the limit of detection. The limit of detection should be below the concentration limit calculated here above.

Chromium VI compounds
Chromium VI is restricted to 3 mg/kg in leather articles (entry 47 of REACH Annex XVII) due to its allergenic properties. In the present proposal, an elicitation threshold dose of 0.02 µg/cm^2 and a migration factor of 30% (ECHA 2012b) was used in the calculations. This information was used in combination with the exposure scenario for leather to identify a concentration limit.

The limit of chromium in leather to ensure that the elicitation threshold dose on skin is not exceeded is:

*Limit in leather (µg/cm^2) = 0.02/(0.30*1*2) = 0.03*
Limit in leather (mg/kg)** = 0.03*10 000/(1 000*0.9) **= 0.37 mg/kg

The calculated concentration limit of 0.37 mg/kg is stricter than the concentration limit for chromium VI of 3 mg/kg in entry 47 of REACH Annex XVII. Allergic reactions to levels of chromium below 3 mg/kg was reported in a study performed by Anses (2018). One reason for setting a 3 mg/kg limit in the agreed chromium VI restriction was that it was the lowest possible detection limit with existing analytical testing methods. According to various stakeholders, the challenge of proposing a concentration limit at 1 mg/kg is related to the lack of reliability of the available analytical methods. Technological advances in test methods does however make it possible to detect even 1 mg/kg of chromium VI today. The present restriction proposal therefore argues for a lower concentration limit for chromium VI at 1 mg/kg and calls a revision of current entry 47 of Annex XVII of the REACH Regulation. The proposed concentration limit refer the total dry weight of the leather part.

B.10.2.3. Concentration limits for substances/groups of substances with information on elicitation threshold doses or migration: Quantitative, substance semi-specific approach

Formaldehyde

In November 2019, Commission Directive (EU) 2019/1929 amending Appendix C to Annex II to Directive 2009/48/EC (the Toy Safety Directive), adopting the specific limit values for formaldehyde of 30 mg/kg (content limit) in leather toy material, among other limit values. The specific limit values is for formaldehyde used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. According to a report from the Organisation for Economic Cooperation and Development (OECD) published in 2002, the lowest threshold concentration for allergic contact dermatitis from formaldehyde is 30 mg/kg. On that basis and in order to protect also the most sensitised individuals, the Commission's Working group on Chemicals in Toys (subgroup Chemicals) recommended a formaldehyde content limit of 30 mg/kg when the content of formaldehyde is determined in accordance with the water extraction method in standard EN ISO 14184-1:2011.

An ED10-value of 20.1 µg/cm^2 (Fischer *et al.*, 2011) was used to calculate the limit concentration in leather for formaldehyde. No information on migration/emission from leather have been found in the literature. Hence, the Dossier Submitter uses the default migration factor of 10% in combination with the exposure scenario for leather in the calculations.

The limit in leather, to ensure that the elicitation threshold dose is not exceeded would then be:

*Limit in leather (µg/cm^2) = 20.1/(0.1*1*2) = 100.5*
Limit in leather (mg/kg)** = 100.5*10 000/(1 000*0.9)* **= 1117 mg/kg

The Dossier Submitter's derived concentration limit of 1117 mg/kg is higher than the concentration limit of 30 mg/kg for formaldehyde in leather as toy material, as stated in Appendix C to Annex II to the Toy Safety Directive. Since the concentration limit in the Toy Safety Directive is based on risk for contact allergy, the Dossier Submitter proposes to align the concentration limit for formaldehyde in leather in the present proposal with that of the Toy Safety Directive. Thus, a concentration limits of 30 mg/kg for formaldehyde in leather for articles in the scope of the restriction is proposed.

Nickel compounds

Nickel is used in some dye chromophores (KemI, 2019). Nickel can also be present in metallic parts such as buttons and zippers but such are not intended to be covered by the restriction proposal. These articles are covered by entry 27 of Annex XVII of the REACH Regulation. An ED10 value of 0.74 µg/cm^2, the lowest of 5 ED10-values reported in Fischer et al. (2011) was used in combination with the default migration factor of 10% and the exposure scenario for leather to derive a concentration limit.

The limit in leather to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in leather (µg/cm^2) = 0.74/(0.1*1*2) = 3.7*
Limit in leather (mg/kg)** = 3.7*10 000/(1 000*0.9)* **= 41 mg/kg

For simplicity, the Dossier Submitter proposes a concentration limit of **40 mg/kg** for nickel in leather.

The concentration limit for nickel in leatheris proposed to cover both nickel and the nickel compounds which are in the scope. The concentration limits are expressed as Nickel metal that can be extracted from the material.

Cobalt compounds

Cobalt has been found in leather furniture upholstery, shoes and gloves (Hamann et al., 2018). An ED10-value of 0.44 µg/cm^2 (Fischer et al. 2011), the default migration factor of 10% and the exposure scenario for leather have been applied in the calculations.

The limit in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm^2) = 0.44/(0.1*1*2) = 2.2*
Limit in leather (mg/kg)** = 2.2*10 000/(1 000*0.9) **= 24 mg/kg

For simplicity, the Dossier Submitter proposes a concentration limit of **20 mg/kg** for cobalt in leather.

The concentration limit for cobalt in leather is proposed to cover both cobalt and the cobalt compounds which are in the scope. The concentration limit are expressed as cobalt metal that can be extracted from the material.

1,4 paraphenylene diamine

1,4 paraphenylene diamine is used as a dye or in azo dyes manufacturing. An ED10 value of 1.5 µg/cm^2 (Sosted et al., 2006) and the default migration factor of 10%, in combination with the exposure scenario for leather have been used in the calculations.

The limit in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm^2) = 1.5/(0.1*1*2) = 7.5*
Limit in leather (mg/kg)** = 7.5*10 000/(1 000*0.9) **= 83 mg/kg

For simplicity, the Dossier Submitter proposes a concentration limit of **80 mg/kg** for 1,4 paraphenylene diamine in leather.

B.10.2.4. Concentration limits for substances/groups of substances with no information on elicitation threshold doses or migration: Quantitative default approach

The default elicitation threshold dose of 0.8 µg/cm^2 of skin and the default migration factor of 10% was used in combination with the exposure scenario for leather, to derive a concentration limit.

The limit in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm^2) = 0.8/(0.1*1*2) = 4*
Limit in leather (mg/kg)** = 4*10 000/(1 000*0.9) = **44 mg/kg

For simplicity, the Dossier Submitter proposes a concentration limit of **40 mg/kg** for these substances in leather.

The calculated limits in leather are proposed for all substances in the scope which are not specifically mentioned in section B.10.2.2 and B.10.2.3 above.

B.10.2.5. Conclusion on human health risk

For most of the targeted skin sensitisers in the scope of this restriction proposal, the concentration limits suggested for leatherabove are far below the approximated levels in leather at point of sale (as indicated by Table 11, and in section 1.2.4 of the main report). Hence, lowering the concentrations of the skin sensitising substance in leather to the ones proposed by the Dossier Submitter is considered to significantly reduce the risk for skin sensitisation in consumers. The concentration limits proposed are thus considered to adequately protect consumers against skin sensitisation. The proposed concentration limits in leatherfor the substances in the scope are given below (Table 16).

Table 16: Summary table of proposed concentration limits in leather for substances in the restriction scope

Substance / group of substances	**Proposed concentration limit in leather[1] (mg / kg)**
Disperse dyes	Ban[2]
Chromium VI compounds	1
Nickel compounds	40
Cobalt compounds	20
Formaldehyde	30
1,4 paraphenylene diamine	80
Other substances in scope	40

[1] Any concentration limit proposed for leather also applies for hides and furs.

[2] The ban refers to the limit of detection (that should be below the calculated concentration limits of 0.1 mg/kg in textile and 0.03 mg/kg in leather).

Some voluntary labelling schemes and/or standards (such as Oeko Tex, BlueSign, etc) may have established more restrictive concentration limits for some of the substances covered by the present restriction proposal. However, the scientific basis and assumptions underlying the values are not available to the Dossier Submitter. Hence, they were not taken into consideration.

B.10.2.6. Sensitivity analysis

A change in one or several parameter values in the equations used to derive concentration limits in leather will affect the proposed concentration limit identically to what was suggested for textile. Please refer to section B.10.1.6. for information.

Annex C: Justification for action on a Union-wide basis

The main reasons for a Union-wide restriction are summarised below.

Severity and extent of health risks

The severity of the possible health risk as documented in section 1.3 and section B.5 of the main report, and the extent of the risk as children and adults are in daily contact with articles of textile and leather that may contain skin sensitising substances call for a Union-wide restriction. A Union-wide regulatory measure would ensure a harmonised high level of protection for human health across the Union.

Prevalence studies on contact allergies in the general population, as documented in detail in Annex E.5 of this restriction proposal, would range 4.4 - 18.4% **with a lifetime prevalence considered to be around 15 - 20%** and the prevalence of allergic contact dermatitis from textile and leather in EEA31 general population is estimated around 0.8 - 1% (such as calculated by the Dossier Submitter), which is comparable with the value of 1 - 2% in Europe estimated by Bfr (2006) (also reported in RIVM, 2008 and RIVM, 2014). Prevalence studies of positive patch tests from chemicals contained in textile and leather in adults range from 0.4% to 17% with an average around 5% (calculated by the Dossier Submitter). There seems to be no significant difference in prevalence of contact allergies due to textile and leather (based on disperse dyes testing in particular) between children and adults. The incidence of textile dermatitis is unknown due to lack of data of controlled epidemiological studies. Nevertheless, incidence data of contact allergy and allergic contact dermatitis (all causes) are reported in the literature to be between 0.17% and 0.7% (for further details, please see section 1.1.2 of the main report and Annex E.5).

The free movement of goods

A Union-wide action to address the risks associated with textile and leather articles containing skin sensitising substances is needed to ensure the free movement of goods within the EU. The fact that textile and leather articles, imported as well as manufactured in the EU, need to circulate freely once on the EU market, stresses the importance of an EU-wide action rather than action by individual Member States, as these actions could differ significantly from Member State to Member State. In addition, a Union-wide action would eliminate the distortion of competition on the European market between markets with and without national legislation on the chemical composition of textile and leather articles.

Additionally, this EU-wide action will have an effect on the goods produced outside EU. Indeed, these skin sensitising substances often bare other hazards, in particular for environment. As their concentration will be limited to enter the EU market, their use will be controlled and limited as well when produced.

Annex D: Baseline

The Table 17 : Baseline scenarios on the cumulative number of prevalent and new cases of textile and leather ACD from 2019. below presents the baseline scenarios developed to build projections on the number of prevalent and new cases of textile and leather ACDs from 2019 (the date of elaboration of this restriction proposal) in the EEA31 (see Figure 3 in section 1.4 in the main report for the graph representation of these scenarios). The baseline scenarios relevant for the HHIA start from 2023+80 years, taken as the average life expectancy in the EEA31[33] (2023 being the date of entry into force (EIF) of this restriction). The cumulative number of prevalent and new cases of textile and leather ACD are however computed from 2019 to take into account the cumulative number of prevalent and new cases of textile and leather ACD from 2019 and 2023.

The min, max and average values indicated in the table below are the interval values of prevalent and new cases of textile and leather ACDs such as assessed in section 2.4.2.1 of the main report and detailed in the Baseline section 1.4 of the main report (Tables 15 and 16) and in Annex E.5 .

The 5 baseline scenarios are built based on the data from Tables 15 and 16 of the main report as follows:

- Baseline scenario 1 corresponds to the combination of the min value of prevalent cases in 2019 (3.9 million in Table 15 of the main report, which is in fact 3 885 461 in table below that was rounded up in the text for simplicity reasons) and the min value of incident cases (45 000 in Table 16 of the main report which is in fact 44 035 that was rounded up in the text for simplicity reasons) of textile and leather ACD. For example, the first cell in grey in the table below reads as follows: to 3 885 461 (which are the prevalent cases of ACD in 2019) have been added 44 035 new cases, resulting in 3 929 496 total cases in 2020, etc.; 44 035 new cases being incrementally added each year until 2103 (as explained in the main report, it is assumed that textile and leather ACD will steadily increase over time under the baseline).
- Likewise, baseline scenario 2 corresponds to the combination of the max value of prevalent cases in 2019 (5 million in Table 15 of the main report, which is in fact 5 180 614 in table below that was rounded down in the text for simplicity reasons) and the max value of incident cases (180 000 in Table 16 of the main report which is in fact 181 321 that was rounded down in the text for simplicity reasons) of textile and leather ACD. The same incremental approach has been then done until 2103.
- Baseline scenario 3 corresponds to the combination of the min value of prevalent cases in 2019 (3.9 million in Table 15 of the main report, which is in fact 3 885 461 in table below that was rounded up in the text for simplicity reasons) and the max value of incident cases (180 000 in Table 16 of the main report which is in fact 181 321 that was rounded down in the text for simplicity reasons) of textile and leather ACD
- Baseline scenario 4 corresponds to the combination of the max value of prevalent cases in 2019 (5 million in Table 15 of the main report, which is in fact 5 180 614 in table below that was rounded down in the text for simplicity reasons) and the min value of incident cases (45 000 in Table 16 of the main report which is in fact 44 035 that was rounded up in the text for simplicity reasons) of textile and leather ACD

[33] According to Eurostats, the average life expectancy in the EEA31 was 78.3 years for men and 83.6 years for women in 2017.

- Finally, baseline scenario 5 corresponds to the combination of the average value of prevalent cases in 2019 (4.5 million in Table 15 of the main report, which is in fact 4 533 037 in table below that was rounded down in the text for simplicity reasons) and the average value of incident cases (113 000 in Table 16 of the main report which is in fact 112 678 that was rounded up in the text for simplicity reasons) of textile and leather ACD

Table 17 : Baseline scenarios on the cumulative number of prevalent and new cases of textile and leather ACD from 2019.

	Baseline Scenario 1 Min/Min	**Baseline Scenario 2** Max/max	**Baseline Scenario 3** Min/Max	**Baseline Scenario 4** Max/Min	**Baseline Scenario 5** Mean/Mean
2019	3 885 461	5 180 614	3 885 461	5 180 614	4 533 037
2020	3 929 496	5 361 936	4 066 782	5 224 649	4 645 716
2021	3 973 531	5 543 257	4 248 104	5 268 685	4 758 394
2022	4 017 566	5 724 579	4 429 425	5 312 720	4 871 072
2023 (EIF)	4 061 601	5 905 900	4 610 747	5 356 755	4 983 751
2024	4 105 637	6 087 222	4 792 068	5 400 790	5 096 429
2025	4 149 672	6 268 543	4 973 390	5 444 825	5 209 107
2026	4 193 707	6 449 865	5 154 711	5 488 861	5 321 786
2027	4 237 742	6 631 186	5 336 033	5 532 896	5 434 464
2028	4 281 778	6 812 508	5 517 354	5 576 931	5 547 143
2029	4 325 813	6 993 829	5 698 675	5 620 966	5 659 821
2030	4 369 848	7 175 151	5 879 997	5 665 001	5 772 499
2031	4 413 883	7 356 472	6 061 318	5 709 037	5 885 178
2032	4 457 918	7 537 793	6 242 640	5 753 072	5 997 856
2033	4 501 954	7 719 115	6 423 961	5 797 107	6 110 534
2034	4 545 989	7 900 436	6 605 283	5 841 142	6 223 213
2035	4 590 024	8 081 758	6 786 604	5 885 178	6 335 891
2036	4 634 059	8 263 079	6 967 926	5 929 213	6 448 569
2037	4 678 095	8 444 401	7 149 247	5 973 248	6 561 248
2038	4 722 130	8 625 722	7 330 569	6 017 283	6 673 926
2039	4 766 165	8 807 044	7 511 890	6 061 318	6 786 604
2040	4 810 200	8 988 365	7 693 212	6 105 354	6 899 283
2041	4 854 235	9 169 687	7 874 533	6 149 389	7 011 961
2042	4 898 271	9 351 008	8 055 855	6 193 424	7 124 640
2043	4 942 306	9 532 330	8 237 176	6 237 459	7 237 318
2044	4 986 341	9 713 651	8 418 498	6 281 495	7 349 996
2045	5 030 376	9 894 973	8 599 819	6 325 530	7 462 675
2046	5 074 411	10 076 294	8 781 141	6 369 565	7 575 353
2047	5 118 447	10 257 616	8 962 462	6 413 600	7 688 031
2048	5 162 482	10 438 937	9 143 784	6 457 635	7 800 710
2049	5 206 517	10 620 259	9 325 105	6 501 671	7 913 388
2050	5 250 552	10 801 580	9 506 427	6 545 706	8 026 066
2051	5 294 588	10 982 902	9 687 748	6 589 741	8 138 745
2052	5 338 623	11 164 223	9 869 070	6 633 776	8 251 423

2053	5 382 658	11 345 545	10 050 391	6 677 812	8 364 101
2054	5 426 693	11 526 866	10 231 713	6 721 847	8 476 780
2055	5 470 728	11 708 188	10 413 034	6 765 882	8 589 458
2056	5 514 764	11 889 509	10 594 356	6 809 917	8 702 137
2057	5 558 799	12 070 831	10 775 677	6 853 952	8 814 815
2058	5 602 834	12 252 152	10 956 999	6 897 988	8 927 493
2059	5 646 869	12 433 474	11 138 320	6 942 023	9 040 172
2060	5 690 905	12 614 795	11 319 642	6 986 058	9 152 850
2061	5 734 940	12 796 117	11 500 963	7 030 093	9 265 528
2062	5 778 975	12 977 438	11 682 285	7 074 129	9 378 207
2063	5 823 010	13 158 760	11 863 606	7 118 164	9 490 885
2064	5 867 045	13 340 081	12 044 928	7 162 199	9 603 563
2065	5 911 081	13 521 403	12 226 249	7 206 234	9 716 242
2066	5 955 116	13 702 724	12 407 571	7 250 269	9 828 920
2067	5 999 151	13 884 046	12 588 892	7 294 305	9 941 598
2068	6 043 186	14 065 367	12 770 214	7 338 340	10 054 277
2069	6 087 222	14 246 689	12 951 535	7 382 375	10 166 955
2070	6 131 257	14 428 010	13 132 857	7 426 410	10 279 633
2071	6 175 292	14 609 332	13 314 178	7 470 446	10 392 312
2072	6 219 327	14 790 653	13 495 500	7 514 481	10 504 990
2073	6 263 362	14 971 975	13 676 821	7 558 516	10 617 669
2074	6 307 398	15 153 296	13 858 143	7 602 551	10 730 347
2075	6 351 433	15 334 618	14 039 464	7 646 586	10 843 025
2076	6 395 468	15 515 939	14 220 786	7 690 622	10 955 704
2077	6 439 503	15 697 261	14 402 107	7 734 657	11 068 382
2078	6 483 539	15 878 582	14 583 429	7 778 692	11 181 060
2079	6 527 574	16 059 904	14 764 750	7 822 727	11 293 739
2080	6 571 609	16 241 225	14 946 072	7 866 762	11 406 417
2081	6 615 644	16 422 547	15 127 393	7 910 798	11 519 095
2082	6 659 679	16 603 868	15 308 715	7 954 833	11 631 774
2083	6 703 715	16 785 190	15 490 036	7 998 868	11 744 452
2084	6 747 750	16 966 511	15 671 358	8 042 903	11 857 130
2085	6 791 785	17 147 833	15 852 679	8 086 939	11 969 809
2086	6 835 820	17 329 154	16 034 001	8 130 974	12 082 487
2087	6 879 855	17 510 476	16 215 322	8 175 009	12 195 166
2088	6 923 891	17 691 797	16 396 644	8 219 044	12 307 844
2089	6 967 926	17 873 119	16 577 965	8 263 079	12 420 522
2090	7 011 961	18 054 440	16 759 287	8 307 115	12 533 201
2091	7 055 996	18 235 762	16 940 608	8 351 150	12 645 879
2092	7 100 032	18 417 083	17 121 930	8 395 185	12 758 557
2093	7 144 067	18 598 405	17 303 251	8 439 220	12 871 236
2094	7 188 102	18 779 726	17 484 573	8 483 256	12 983 914
2095	7 232 137	18 961 048	17 665 894	8 527 291	13 096 592
2096	7 276 172	19 142 369	17 847 216	8 571 326	13 209 271
2097	7 320 208	19 323 691	18 028 537	8 615 361	13 321 949

2098	7 364 243	19 505 012	18 209 858	8 659 396	13 434 627
2099	7 408 278	19 686 334	18 391 180	8 703 432	13 547 306
2100	7 452 313	19 867 655	18 572 501	8 747 467	13 659 984
2101	7 496 349	20 048 976	18 753 823	8 791 502	13 772 663
2102	7 540 384	20 230 298	18 935 144	8 835 537	13 885 341
2103	7 584 419	20 411 619	19 116 466	8 879 573	13 998 019

Annex E: Impact Assessment

E.1. Risk Management Options

Herein existing regulations on textile and leather as well as actions in voluntary schemes are presented. For the presentation of other RMOs, please see section 2.2. of the main report.

E.1.1. Existing regulations on textile and leather

Footwear

French Decree No. 96-477 of 30 May 1996 on the labelling of materials used in the main components of footwear offered for sale to consumers, explains the requirements relating to this labelling.

This Decree also gives a definition for the concept of footwear, which served as the basis for this formal request. Footwear means any product with a sole intended to protect or cover the foot, including parts of shoes marketed separately (examples: sandals, boots, sports shoes, ski boots, ballet shoes, slippers, baby booties, etc.).

This Decree excludes safety shoes, second-hand shoes and shoes considered to be toys.

Textile clothing articles

Regulation (EU) No 1007/2011 of the European Parliament and of the Council of 27 September 2011 concerns textile fibre names and related labelling and marking of the fibre composition of textile products. This Regulation repeals Directives 73/44/EC, 96/73/EC and 2008/121/EC.

This Regulation aims to ensure the provision of accurate information to European consumers and improve the functioning of the clothing and textile markets in the EU.

To this end, it lays down rules concerning the use of textile fibre names and related labelling and marking of fibre composition of textile products. This Regulation also establishes rules concerning the labelling or marking of textile products containing non-textile parts of animal origin and rules concerning the determination of the fibre composition of textile products by quantitative analysis of binary and ternary textile fibre mixtures, with a view to improving the functioning of the internal market and providing accurate information to consumers.

It also establishes the analytical methods for verifying the information shown on the labels or markings.

Products with at least 80% of their weight in fibres are considered as having to comply with the Regulation.

This Regulation lists all the fibres concerned.

Leather clothing and goods

French Decree No. 2010-29 of 08/01/2010 repealed the Decree of 18/02/1986 concerning application of the Act of 1 August 1905 to trade in leather and imitation leather goods. A new regulatory architecture has also been adopted, since the Decree gives the main definitions and refers to the Ministerial Order of 8 February 2010 regarding the definitions of the raw materials and types of finish.

According to the Decree:

Leather is considered to be the product obtained from the animal skin through tanning or impregnation, retaining the natural structure of the skin's fibre and all or part of its grain;

Split leather is considered to be the internal part of the leather, obtained by dividing the leather across its thickness into layers, or any other operation resulting in the complete removal of the external layer, and on which all the attachment points of the hairs, feathers or scales are destroyed. In the case of pig split leather, the attachment of the hair follicles may remain visible.

New rules have thus been introduced, mainly in terms of labelling to improve the information provided to the consumer and the fairness of commercial practices.

Biocides Regulation (EU) No 528/2012

The "Biocides" Regulation requires an authorisation, including a risk assessment indicating safe use and control of potential risks for the consumer. According to the Biocides Regulation, a treated article is any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

Persistent Organic Pollutants Regulation (EC) No 850/2004

The term Persistent Organic Pollutant (POP) covers a group of organic substances with four properties. They are:

- persistent: the substance degrades "slowly",
- bioaccumulative: the substance "accumulates" within living beings,
- toxic: exposure to the substance is likely to cause harmful effects,
- mobile over long distances: high concentrations can be measured far from the discharge points (in the Arctic, for example).

The aim of the POP Regulation is to protect human health and the environment by prohibiting or restricting the production or introduction on the market of these substances. Certain substances regulated by the POP Regulation may be found as contaminants in the production of textiles (insecticides, hexachlorobenzene, PCBs, dioxins, dichlorodiphenyltrichloroethane (DDT), hexabromocyclododecane, polycyclic aromatic hydrocarbons (PAHs), polybrominated diphenyl ethers, perfluorooctanesulfonic acid (PFOS) and derivatives).

E.1.2. Existing EU and national restrictions

At EU level, Annex XVII of REACH Regulation imposes certain restrictions on hazardous substances in articles sold to the public and particularly textile products and/or leather. The associated existing restrictions under REACH are presented in the table below.

Table 18 : Restrictions on hazardous substances (Annex XVII of Regulation (EC) No 1907/2006)

Entry	Substance	Concentration limits / restriction on use	Comment
Entry 4	Phosphate de tri (2,3 dibromopropyle)	Shall not be used	Shall not be used in textile articles, such as garments, under garments and linen, intended to come into contact with the skin.
Entry 7	Tris(aziridinyl)phosphinoxide	Shall not be used	Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.
Entry 8	Polybromobiphenyls (PBB)	Shall not be used	Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.
Entry 20	Organostannic compounds (tributyl et triphenyltin) Dibutyltin Dioctyltin	0.1%$_w$ of tin 0.1%$_w$ of tin 0.1%$_w$ of tin	In all articles or mixtures
Entry 23	Cadmium and its compounds	0.01%$_w$ of the plastic material	Shall not be used in mixtures and articles produced from synthetic organic polymers
Entry 24	Monomethyl tetrachlorodiphenyl methane	Shall not be used	In all articles or mixtures
Entry 25	Monomethyl-dichloro -diphenyl methane	Shall not be used	In all articles or mixtures
Entry 26	Monomethyl-dibromo-diphenyl methane bromobenzylbromotoluene, mixture of isomers	Shall not be used	In all articles or mixtures
Entry 27	Nickel and its compounds	Release of nickel less 0.5 µg/cm²/week	Articles intended to come into direct and prolonged contact with the skin such as rivet buttons, tighteners, rivets,

Entry	Substance	Concentration limits / restriction on use	Comment
			zippers and metal marks, when these are used in garments,
Entry 43	Azocolourants and Azodyes	0.003 $\%_w$ of the aromatic amines	Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0.003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as: — clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags, — footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck, — textile or leather toys and toys which include textile or leather garments, — yarn and fabrics intended for use by the final consumer. 2. Furthermore, the textile and leather articles referred to in paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph. 3. Azodyes, which are contained in Appendix 9, 'List of azodyes' shall not be placed on the market, or used, as substances, or in mixtures in concentrations greater than 0,1 % by weight, where the substance or the mixture is intended for colouring textile and leather articles.

Entry	Substance	Concentration limits / restriction on use	Comment
Entry 45	Diphenylether, octabromo derivative	0.1%$_w$	1. Shall not be placed on the market, or used: — as a substance, — as a constituent of other substances, or in mixtures, in concentrations greater than 0,1 % by weight. 2. Articles shall not be placed on the market if they, or flame - retardant parts thereof, contain this substance in concentrations greater than 0,1 % by weight. 3. By way of derogation, paragraph 2 shall not apply: — to articles that were in use in the Community before 15 August 2004, — to electrical and electronic equipment within the scope of Directive 2002/95/EC
Entry 46	Nonylphenol and nonylphenol ethoxylates	0.1%$_w$	textiles and leather processing except: — processing with no release into waste water, — systems with special treatment where the process water is pre -treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);
Entry 47	Chromium VI compounds	0.0003%$_w$ (3mg/kg)	Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0.0003 % by weight) of the total dry weight of the leather.
Entry 50	Polycyclic - aromatic hydrocarbons	0.0001% $_w$ (1mg/kg)	Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short -term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0.0001 % by weight of this component) of any of the listed PAHs

Entry	Substance	Concentration limits / restriction on use	Comment
Entry 61	Dimethylfumarate	0.1 mg/kg	All types of articles
Entry 63	Lead and its compounds	Lead accessible 0.05%$_w$ and if it can be placed in the mouth by children	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. (…) 7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm² per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size.

Entry	Substance	Concentration limits / restriction on use	Comment
Entry 72	CMRs in textile	Specific to each CMR within the scope of this restriction[34]	33 CMRs are in the scope of entry 72

At national level, Disperse Blue 35, Disperse Blue 106, Disperse Blue 124, Disperse Orange 3, Disperse Orange 37, Disperse Orange 59, Disperse Orange 76 and Disperse Red 1 are banned since 2005 in Germany under German Food, Feed and Commodities Law §30 (LFGB §30).

E.1.3. Labelling schemes, ecolabels and standards

Labelling schemes

There are several voluntary initiatives in the form of different labelling schemes. These textile labels are guides for consumers and industry.

In the textile field, there are several ecolabels, which involve certification of industrial companies that meet these labels' criteria: Global Organic Textile Standard (GOTS), Nordic Eco-Label, EU Ecolabel, Oeko-Tex and Blue Sign.

European ecolabel for textiles and footwear

Decisions No 2009/567/EC and No 2009/563/EC specify the criteria for the award of the European ecolabel for textile products and footwear.

The aims of the criteria for textile products:

- to promote the reduction of water pollution related to the key processes throughout the textile manufacturing chain, including fibre production, spinning, weaving, knitting, bleaching, dyeing and finishing.

The aims of the criteria for footwear:

- to limit the levels of toxic residues[35],

[34] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2018:256:FULL&from=EN

[35] Arsenic, chromium VI, lead, cadmium, formaldehyde, pentachlorophenol (PCP) and tetrachlorophenol (TCP). No azo dyes shall be used that may cleave to any of the following aromatic amines: 4-aminodiphenyl (92-67-1); benzidine (92-87-5); 4-chloro-o-toluidine (95-69-2); 2-naphthylamine (91-59-8); o-amino-azotoluene (97-56-3); 2-amino-4-nitrotoluene (99-55-8); p-chloroaniline (106-47-8); 2,4-diaminoanisol (615-05-4); 4,4'-diaminodiphenylmethane (101-77-9); 3,3'-dichlorobenzidine (91-94-1). The following N-nitrosamines shall not be detected in rubber: N-nitrosodimethylamine, N-nitrosodiethylamine, N-nitrosodipropylamine, N-nitrosodibutylamine, N-nitrosopiperidine, N-nitrosopyrrolidine, N-nitrosomorpholine, N-nitroso-N-methyl-N-phenylamine, N-nitroso-N-ethyl-N-phenylamine, chloralkanes, alkylphenols, perfluorooctane sulfonates, dyes meeting the criteria for classification as sensitising to skin, phthalates, biocides.

- to limit the emissions of volatile organic compounds[36],
- to promote a more durable product.

Oeko-Tex

Oeko-Tex is an international association for research and testing in the field of textile and leather ecology. According to the Oeko-Tex website, *the Standard 100 by OEKO-TEX® is a worldwide consistent, independent testing and certification system for raw, semi-finished, and finished textile products at all processing levels, as well as accessory materials used. This label is widely used in Europe and Japan.*

The central focus of the Standard 100 by OEKO-TEX® has been the development of test criteria, limit values and test methods on a scientific basis.

Bluesign

Bluesign is an international label for textiles founded in Switzerland in 2000. It indicates that no harmful substance has been used in the production process and includes binding criteria for energy and water consumption.

It has lists of chemical substances that must not be used during the process or in the finished articles[37]. The environment, health and safety are taken into account in this label.

Joint Roadmap (ZDHC)

Several leaders of the global textile market joined forces in 2011, in order to compile a list of substances (Zero Discharge of Hazardous Chemicals) that may not be released from their production lines after 2020. These lists mainly include substances with CMR, PBT, vPvB or endocrine-disrupting properties.

Nordic Ecolabel

The Nordic Ecolabel was created in 1989[38] and is promoted by all the Nordic countries (Denmark, Finland, Sweden, Norway and Iceland). It is a voluntary tool for consumers, designed to guide them in the choice of products that are more environmentally friendly. The substances that should not be used are described in the document "Nordic Ecolabelling of Textiles, hides/skins and leather"[39].

[36] VOCs are any organic compound having at 293.15 K a vapour pressure of 0.01 kPa or more, or having a corresponding volatility under the particular conditions of use. The total use of VOCs during final footwear production shall not exceed, on average, 20 gram VOC/pair.

[37] https://www.bluesign.com/industry/infocenter/downloads
[38] This ecolabel was established in 1989 by the Nordic Council of Ministers.
[39] http://www.nordic-ecolabel.org/criteria/product-groups/?p=3

Global Organic Textile Standard

The Global Organic Textile Standard is a standard for textiles made from organic fibres. GOTS is a private international working group comprising organisations such as OTA (USA), IVN (Germany), the Soil Association (UK) and JOCA (Japan). This label's website *defines high-level environmental criteria along the entire organic textiles supply chain and requires compliance with social criteria as well. Only textile products that contain a minimum of 70% organic fibres can become GOTS certified.*

Standards

The ISO/TR 16178:2012 standard establishes a list of critical chemical substances potentially present in footwear and footwear components. This standard describes the critical chemical substances, their potential risks, the materials in which they can be found, and the test methods that can be used to quantify them.

The FD CEN/TR 16741 standard establishes environmental and health recommendations applicable to textile products in direct contact with the skin and found in the vicinity of the human body. This standard describes the chemical substances designed for use in textile products intended for clothing, interior textiles and upholstery, their potential risks, the materials in which they can be found, and the test methods that can be used to quantify them.

E.2. Alternatives

This section is based on the IN-list such as determined by KemI (2019) and such as refined by the Dossier Submitter (Master List). For further details about the method to determine this list, please see Annex A.1.2 and A.2.2. As explained, the Dossier Submitter's Master List includes 95 substances of the scope of this restriction proposal that are considered to be potentially present in textile and leather articles at point of sale in 2018. The original Master list from the restriction dossier has been complemented with additional information received in the public consultation. For all substances in the list, it captures chemical name and CAS number, use/function, where in the supply chain the chemical is used (deliberately or generated unintentionally), volumes, alternatives, costs, where applicable and when available.

The Master List is provided in the table below. As indicated in A.2, this list is indicative and cannot be claimed as exhaustive. It cannot be excluded that other substances are also used today but have not been identified.

The estimated concentration levels are categorized in accordance with Table 21.

Table 19 : Indicative Master List of chemicals relevant for the scope of the current restriction proposal and identified by the Dossier Submitter to be found today in the textile and leather articles manufacturing processes.

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	106-91-2/ 203-441-9	2-Propenoic acid, 2-methyl-, 2-oxiranylmethyl ester	(Meth)acrylates	**LOW - 10's mg/kg**	**VERY LOW - <10 mg/kg**	€6 100 - €8 700 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	2867-47-2/ 220-688-8	2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester	(Meth)acrylates	**LOW - 10's mg/kg**	**VERY LOW - <10 mg/kg**	€2 700 - €3 500 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	97-88-1/ 202-615-1	2-Propenoic acid, 2-methyl-, butyl ester [butyl methacrylate]	(Meth)acrylates	**LOW - 10's mg/kg**	**VERY LOW - <10 mg/kg**	€900 - €35 000 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	50-00-0/ 200-001-8	Formaldehyde	Aldehydes	**MED 100's mg/kg**	**LOW - 10's mg/kg**	€400 - €600 per metric ton at 37% purity	Restricted in textile (75 mg/kg). Restricted in Toys Safety Directive (30 mg/kg).	Y - harmonised classified as Skin Sens 1/1A/1B	DIN EN ISO 17226-2 and DIN EN ISO 14184-1 (16 mg/kg) (10 mg/kg)*, EN ISO 17226-1 (for leather)

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	100-97-0/ 202-905-8	1,3,5,7-Tetraazatricyclo[3.3.1.13,7]decane	Amines, Aliphatic	n.a	**LOW - 10's mg/kg**	€900 per ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	101-72-4/202-969-7	1,4-Benzenediamine, N1-(1-methylethyl)-N4-phenyl-	Amines, Polyaromatic, antioxidant	n.a		No cost data	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	111337-53-2/ 411-690-1	1,2-Benzisothiazol-3(2H)-one, lithium salt	Antimicrobial (in-can?)	**LOW - 10's mg/kg**		No cost data	-	N - biocide, derogated	n.a
1	4719-04-4/225-208-0	2,2,2-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	Antimicrobial (in-can?)	**LOW - 10's mg/kg**		€900 to €8 700 per metric ton	-	N - biocide, derogated	n.a
1	55965-84-9/ 911-418-6	3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-isothiazolone	Antimicrobial (in-can)	**LOW - 10's mg/kg**		No cost data	-	N - biocide, derogated	n.a
1	79-07-2/ 201-174-2	Acetamide, 2-chloro-	Antimicrobial (in-can)	**LOW - 10's mg/kg**		No cost data	-	N - biocide, derogated	n.a

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	59-50-7/ 200-431-6	Phenol, 4-chloro-3-methyl-	Antimicrobial (in-can)	**LOW - 10's mg/kg**		€900 per metric ton	-	N - biocide, derogated	EN ISO/DIS 13365-2(for leather)
1	26530-20-1/247-761-7	3(2H)-Isothiazolone, 2-octyl-	Antimicrobial (in-can)	**MED - 100's mg/kg**	**LOW - 10's mg/kg**	€900-€8 700 per metric ton	-	N - biocide, derogated	EN ISO/DIS 13365-2(for leather)
1	2634-33-5/220-120-9	1,2-Benzisothiazol-3(2H)-one	Antimicrobial (in-can)	**LOW - 10's mg/kg**		€1 700 to €4 400 per metric ton.	-	N - biocide, derogated	n.a
1	55406-53-6/259-62-5	3-IODO-2-PROPYNYL-N-BUTYL CARBAMATE	Antimicrobial (in-can)	**LOW - 10's mg/kg**		No cost data	-	N - biocide, derogated	n.a
1	21564-17-0/244-445-0	Thiocyanic acid, (2-benzothiazolylthio)methyl ester	Antimicrobial (leather processing)	**MED - 100's mg/kg**		unknown	-	N - biocide, derogated	EN ISO/DIS 13365-2(for leather)
1	75113-37-0/401-040-5	1,3,2,4-Dioxastannaboretane, 2,2-dibutyl-4-hydroxy-	Antimicrobial / catalyst	**LOW - 10's mg/kg**		No cost data	Restriction (0.1%w/w)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	97-77-8/202-607-8	Thioperoxydicarbonic diamide ([(H2N)C(S)]2S2), N,N,N',N'-tetraethyl-	Plasticiser	**HIGH - 1000's mg/kg - NEOPRENE** **LOW - 10's mg/kg - Rubber**		No cost data	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	7789-09-5/232-143-1	Chromic acid (H2Cr2O7), ammonium salt (1:2) AMMONIUM DICHROMATE	Chromium Compound	**MED 100's mg/kg**	**VERY LOW - <10 mg/kg**	€7 600 per metric ton	Restricted in leather (3 mg/kg) and textile (1 mg/kg)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	7789-00-6/ 232-140-5	Chromic acid (H2CrO4), potassium salt (1:2)	Chromium Compound	**MED 100's mg/kg**	**VERY LOW - <10 mg/kg**	€1 to €900 per gram. medicine grade.	Restricted in leather (3 mg/kg) and textile (1 mg/kg)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	7775-11-3/ 231-889-5	Chromic acid (H2CrO4), sodium salt (1:2) SODIUM CHROMATE	Chromium compounds	**MED 100's mg/kg**	**VERY LOW - <10 mg/kg**	€900-€8 700 per metric ton	Restricted in leather (3 mg/kg) and textile (1 mg/kg)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (KemI, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	1333-82-0/ 215-607-8	Chromium oxide (CrO3)	Chromium compounds	**MED 100's mg/kg**	**VERY LOW - <10 mg/kg**	€2 600-€2 900 per metric ton	Restricted in leather (3 mg/kg) and textile (1 mg/kg)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	14977-61-8/ 239-056-8	Chromium, dichloro dioxo-, (T-4)-	Chromium compounds	**MED 100's mg/kg**	**VERY LOW - <10 mg/kg**	No cost data	Restricted in leather (3 mg/kg) and textile (1 mg/kg)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	24613-89-6/ 246-356-2	Chromic acid (H2CrO4), chromium(3+) salt (3:2)	Chromium compounds	**MED 100's mg/kg**	**VERY LOW - <10 mg/kg**	No cost data	Restricted in leather (3 mg/kg) and textile (1 mg/kg)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	7778-50-9/ 231-906-6	Chromic acid (H2Cr2O7), potassium salt (1:2) [potassium dichromate]	Chromium compounds	**MED 100's mg/kg**	**VERY LOW - <10 mg/kg**	€1 700-€2 200 per metric ton	Restricted in leather (3 mg/kg) and textile (1 mg/kg)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	101-68-8/ 202-966-0	Benzene, 1,1'-methylenebis[4-isocyanato- MDI	Diisocyanate	**MED, can be >1000 mg/kg**	**VERY LOW - <10 mg/kg**	€0.87-€87 per metric ton	Restricted in articles (0.1%w/w)	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 14896:2009, ISO 14896, EN 13130-8, GC method and DIN EN 13130-8 (1 mg/kg), (5mg/kg)*
1	26471-62-5/ 247-722-4	m-tolylidene diisocyanate [TDI]	Diisocyanate	**MED, can be >1000 mg/kg**	**VERY LOW - <10 mg/kg**	€1 300 -€2 200 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 14896:2009, ISO 10 283, ISO 14896, EN 13130-8, GC method and DIN EN 13130-8 (I mg/kg), (5mg/kg)*
1	4098-71-9/223-861-6	Cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl- [IPDI}	Diisocyanate	**MED can be >1000 mg/kg**	**VERY LOW - <10 mg/kg**	€8 500 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 14896:2009, ISO 10283ISO 14896, EN 13130-8, GC method and DIN EN 13130-8 (I mg/kg), (5mg/kg)*
1	584-84-9/229-54-5	Benzene, 2,4-diisocyanato-1-methyl- TDI	Diisocyanate	**MED can be >1 000 mg/kg**	**VERY LOW - <10 mg/kg**	€1 700-€2 600 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 14896:2009, ISO 10283ISO 14896, EN 13130-8, GC method and DIN EN 13130-8 (1 mg/kg), (5mg/kg)*

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	5873-54-1/227-534-9	o-(p-isocyanatobenzyl)phenyl isocyanates	Diisocyanate	**MED can be >1 000 mg/kg**	**VERY LOW - <10 mg/kg**	€3 100 per metric ton	Restricted in articles (0.1% of MDI)	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 14896:2009, ISO 14896, EN 13130-8, GC method and DIN EN 13130-8 (1 mg/kg), (5mg/kg)*
1	822-06-0/212-485-8	Hexane, 1,6-diisocyanato- [HDI]	Diisocyanate	**MED can be >1 000 mg/kg**	**VERY LOW - <10 mg/kg**	€2 600-€6 100 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 14896:2009,ISO 10283 ISO 14896, EN 13130-8, GC method and DIN EN 13130-8 (1 mg/kg)
1	91-08-7/ 202-039-0	Benzene, 1,3-diisocyanato-2-methyl-	Diisocyanate	**MED can be >1 000 mg/kg**	**VERY LOW - <10 mg/kg**	No cost data	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 14896:2009, ISO 14896, EN 13130-8, GC method and DIN EN 13130-8 (1 mg/kg), (5mg/kg)*
1	141880-36-6/ 410-070-8	1,3-Naphthalenedisulfonic acid, 7-[[[3-[2-[4-[2-(2-hydroxy-1-naphthalenyl)diazenyl]phenyl]diazenyl]phenyl]sulfonyl]amino]-, potassium sodium salt (1:?:?) [ACID red 447]	Dye – Acid	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	No cost data	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 16373-1:2015 (50 mg/kg)

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	147703-65-9/410-150-2	Benzenesulfonic acid, 3-[2-[2-(acetylamino)-4-[2-[4-(2-hydroxybutoxy)phenyl]diazenyl]phenyl]diazenyl]-, sodium salt (1:1). Acid Dye " Yellow E-JD 3442"	Dye – Acid	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 16373-2:2014 (50 mg/kg)
1	124605-82-9/ 408-210-8	Direct Blue 301	Dye - Direct	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 16373-2:2014 (50 mg/kg)
1	81898-60-4/ 617-266-4	1,5-Naphthalenedisulfonic acid, 3,3'-[1,4-piperazinediylbis[(6-chloro-1,3,5-triazine-4,2-diyl)i mino [2-(acetylamion)-4,1-phenylene]bis-, tetrasodium salt. direct yellow 162	Dye - Direct	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 16373-2:2014 (50 mg/kg)
1	106359-94-8/430-010-7	Propanamide, N-[2-[(2-cyano-4,6-dinitrophenyl)azo]-5-(dipropylamino)phenyl]-	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 16373-2:2014 (50 mg/kg)

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	124605-82-9/408-210-8	2-Naphthalenol, 1-(2-phenyldiazenyl)-	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 16373-2:2014 (50 mg/kg)
1	155522-12-6/416-240-8	L-Alanine,N-[4-[(2-chloro-4-nitrophenyl)azo]-3-[(1-oxopropyl)amino]phenyl]-, methyl ester	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 16373-2:2014 (50 mg/kg)
1	188070-47-5/ 424-290-7	Glycine, N-[3-(acetylamino)phenyl]-N-(carboxymethyl)-, mixed ethyl and methyl diesters, reaction products with diazotized -2-chloro-4-nitrobenzenamine. SCARLET CLA 881. Terasil red WRS	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 16373-2:2014 (50 mg/kg)
1	2475-45-8/219-603-7	9,10-Anthracenedione, 1,4,5,8-tetraamino- (CI disperse blue 1)	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	(10 mg/kg)

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	2832-40-8/220-600-8	Acetamide, N-[4-[2-(2-hydroxy-5-methylphenyl)diazenyl]phenyl]- DISPERSE YELLOW 3.	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name (Most probable per kg, but not given).	-	Y - harmonised classified as Skin Sens 1/1A/1B	(10 mg/kg)
1	75511-91-0/407-970-8	3-Pyridinecarbonitrile, 1-butyl-5-[(2-chloro-4-nitrophenyl)azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	No cost data	-	Y - harmonised classified as Skin Sens 1/1A/1B	(10 mg/kg)
1B	126-90-9/204-810-7	1,6-Octadien-3-ol, 3,7-dimethyl-, (3S)- [linalool]	Fragrance	**LOW 10's mg/kg**		€900 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1B	126-91-0/204-811-2	1,6-Octadien-3-ol, 3,7-dimethyl-, (3R)- [linallol]	Fragrance	**LOW 10's mg/kg**		€900 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1B	78-70-6/ 2016134-4	1,6-Octadien-3-ol, 3,7-dimethyl- [linalool]	Fragrance	**LOW 10's mg/kg**		€ 900 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	85-44-9/ 201-607-5	1,3-Isobenzofurandione [phthalic anhydride]	Intermediate	**MED 100's mg/kg**	**VERY LOW - <10 mg/kg**	€900 to €1 300 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	106-89-8/ 203-439-8	Oxirane, 2-(chloromethyl)- [Epichlorohydrin]	Intermediate	**LOW 10's mg/kg**	**VERY LOW - <10 mg/kg**	€1 700 to €2 600 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	111-41-1/ 203-867-5	Ethanol, 2-[(2-aminoethyl)amino]-	Intermediate	**LOW 10's mg/kg**	**LOW 10's mg/kg**	€1 700 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	80-05-7/201-245-8	Phenol, 4,4'-(1-methylethylidene)bis- BISPHENOL A	Intermediate	**LOW 10's mg/kg**	**VERY LOW - <10 mg/kg**	€900 to €1 700 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	127-68-4/ 204-857-3	Benzenesulfonic acid, 3-nitro-, sodium salt (1:1)	Intermediate - Dye synthesis	**n.a**	**VERY LOW - <10 mg/kg**	€1 000 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	62-53-3/200-539-3	Benzenamine ANILINE	Intermediate Dye synthesis	**LOW 10's mg/kg**		€1 200 to €1 400 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO 17234 for leather1
1	106-50-3/203-404-7	1,4 paraphenylene diamine (PPD)	Intermediate Dye synthesis	**LOW 10's mg/kg** 16-40 mg/kg in textiles, Anses (2018).		No cost data	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO SO 14362-1 (5 mg/kg)

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	7440-48-4/ 231-158-0	Cobalt	Metals, Inorganic Compounds	**MED 100's mg/kg**		Not sure what to look for given that it isn't used in textiles as a metal	-	Y - harmonised classified as Skin Sens 1/1A/1B	Total Digestion, ICP (1mg/kg) EN ISO 17072-2 (for leather)
1	52645-53-1/ 258-067-9	Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, (3-phenoxyphenyl)methyl ester, PERMETHRIN	Mosquito repellent / Pesticide	**HIGH 10 000's mg/kg**		€8 700 to €1 7400 per metric ton	-	N - biocide, derogated	n.a
1	7440-02-0/ 231-111-4	Nickel	Nickel Compounds, Inorganic and catalyst	**LOW** 2.3 and 23.5 mg/kg, in the non-metal parts of the textile articles (Anses, 2018)		Can't get accurate cost - possibly looking at nickel phthalocyanine dyes rather than nickel	restricted in articles to come into direct contact with the skin (0.5 µg/cm2/week)	Y - harmonised classified as Skin Sens 1/1A/1B	EN ISO 17072-2 (for leather)
1	84-61-7/ 201-545-9	1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester DCHP}	Phthalates	**HIGH [30%]**		€3500 to €5 200 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	ISO/TS 16181:2011 and ISO 14389:2014 (50 mg/kg)

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	50-32-8/ 200-028-5	Benzo[a]pyrene	Polycyclic Aromatic Hydrocarbons	**LOW 10's mg/kg**		No cost data	Restricted in textile (1 mg/kg)	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	8052-10-6/232-484-6	Tall-oil rosin	Rosin	**HIGH 1 000's mg/kg**		€1 300 to €3 000 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	8050-09-7/232-475-7	Rosin	Rosin	**HIGH 1 000's mg/kg**		€1 300 to €1 700 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	136-23-2/205-232-8	Zinc, bis(dibutylcarbamodithioato-.kappa.S,.kappa.S')-, (T-4)-	Rubber related substance	**HIGH 1 000's mg/kg**		€2 600 to €6 100 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	149-30-4/205-736-8	2(3H)-Benzothiazolethione [Mercaptobenzothiazole]	Rubber related substance	n.a.		€1 900 to €2 600 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	GC/MS
1	137-26-8/205-286-2	Thioperoxydicarbonic diamide ([(H2N)C(S)]2S2), N,N,N',N'-tetramethyl-	Rubber related substance	**MED 100's mg/kg**		€1 300 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	137-30-4/205-288-3	Zinc, bis(N,N-dimethylcarbamodithioato-.kappa.S,.kappa.S')-, (T-4)-	Rubber related substance	**MED 100's mg/kg**		€2 200 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	137-42-8/205-293-0	Carbamic acid, N-methyldithio-, sodium salt	Rubber related substance	n.a.		€900 to €1 600 per metric ton.	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	14324-55-1/238-270-9	zinc bis(diethyldithiocarbamate)	Rubber related substance	n.a.		€900 to €8 700 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
1	5989-54-8/227-815-6	Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4S)-, LIMONENE	Solvent	**HIGH 1 000's mg/kg**		€1 700 to €10 400 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	HS GC/MS (5 mg/kg)*

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
1	5989-27-5/ 227-813-5	Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4R)-[r-limonene]	Solvent	**HIGH 1 000's mg/kg**	**VERY LOW - <10 mg/kg**	€900 to €8 700 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	No information, (5mg/kg)*
1	8006-64-2/ 232-350-7	Turpentine, oil	Solvent and intermediate	**HIGH 1 000's mg/kg**		€8 800 to €23 400 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	No information/experience, (5mg/kg)*
1	111-40-0/ 203-865-4	1,2-Ethanediamine, N1-(2-aminoethyl)-[diethylene triamine]	Solvent, Intermediate, Cross Linker	**MED - 100's mg/kg**	**LOW 10's mg/kg**	€8 700 to €43 500 PER METRIC TON. 99% PURITY	-	Y - harmonised classified as Skin Sens 1/1A/1B	No information/experience, (5mg/kg)*
1A	111-30-8/ 203-856-5	Pentanedial - [glutaraldehyde]	Tanning Agent and chemical intermediate	n.a.	**LOW or VERY LOW (** <20 mg/kg in leather).	€1 600 per metric ton	-	Y - harmonised classified as Skin Sens 1/1A/1B	n.a
-	13301-61-6/236-325-1	CI Disperse Orange 37/59/76	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€5 -10. need the CI name	-	Y - included in list of concern	ISO 16373-2:2014 (50 mg/kg)

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
						(Most probable per kg, but not given).			
-	6250-23-3/ 228-370-0	CI Disperse Yellow 23	Dye - Disperse	**HIGH 10 000's mg/kg**	**HIGH 10 000's mg/kg**	€8 700 per metric ton	-	Y - included in list of concern	(10 mg/kg)
-	2475-46-9/ 219-604-2	C.I. Disperse Blue 3	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	3179-90-6/ 221-666-0	C.I. Disperse Blue 7	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	3860-63-7/223-373-3	C.I. Disperse Blue 26	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	12222-75-2/ 602-260-6	C.I. Disperse Blue 35	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	12222-97-8/ 602-282-6	C.I. Disperse Blue 102	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
-	271-183-4/8516-81-4	C.I. Disperse Blue 106	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	15141-18-1/239-206-6	C.I. Disperse Blue 124	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	56548-64-2/260-255-0	C.I. Disperse Blue 291	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	23355-64-8/ 245-604-7	C.I. Disperse Brown 1	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	2581-69-3/ 219-954-6	C.I. Disperse Orange 1	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	730-40-5/ 211-984-8	C.I. Disperse Orange 3	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	85136-74-9/ 400-340-3	C.I. Disperse Orange 149	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
-	2872-52-8/ 220-704-3	C.I. Disperse Red 1	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	2872-48-2/ 220-703-8	C.I. Disperse Red 11	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	3179-89-3/ 221-665-5	C.I. Disperse Red 17	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	119-15-3/ 204-300-4	C.I. Disperse Yellow 1	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	6373-73-5/ 228-919-4	C.I. Disperse Yellow 9	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	12236-29-2/ 235-473-4	C.I. Disperse Yellow 39	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	54824-37-2/611-202-9	C.I. Disperse Yellow 49	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*

Skin sense category	CAS/ EC Number	Name	Category, Class and Function	Estimated amount on article (Keml, 2019)*	Estimated amount on article (public consultation)	Cost	Existing regulation in textile or leather	In scope of current restriction proposal?	Test method available (Detection limits LOQ [mg/kg])
-	10319-14-9/ 233-701-7	C.I. Disperse Yellow 64	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	128-95-0/ 204-922-6	C.I. Disperse Violet 1	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*
-	268221-71-2	C.I. Disperse Violet 93	Dye - Disperse	n.a	**HIGH 10 000's mg/kg**	n.a	-	Y - included in list of concern	(10 mg/kg)*

* Maximum amount potentially present in a worst case scenario

USD has been converted to EUR, using an exchange rate of 1 USD=0.8701 EUR, (2019-01-31). n.a = not available

Note: low=”below 100 mg/kg”, medium=”approximately 100 mg/kg”, and high=”above 100 mg/kg”.

E.2.1. Description of the use and function of the restricted substances

As indicated in the Dossier Submitter's Master list provided in A.1.2. above for the purposes of the identification and the analysis of alternatives the substances were grouped when feasible and when relevant. Whenever possible, a concentration of each substance potentially found in the article at point of sale is provided (also indicated in A.1.2.).

Based on the Master List provided in A.1.2, further refining has been done:

- The indication about the concentration potentially to be found in the finished articles from KemI (2019) and the public consultation allowed the Dossier Submitter to break down the substances that would comply with the concentration limits proposed in this restriction proposal, and the substances that would not. Given the concentration limits proposed in this restriction proposal for the different substances of the scope (see Annex B), the Master List has then been further narrowed to the substances that would not comply with these limits (and should be substituted) and are listed in Table 20 below.
- A second refinement has then been done on this list by excluding the substances or groups of substances that are already regulated (further details below).

This final (narrower) Master List of substances such as refined served as a basis for the analysis of alternatives and is provided below.

Table 20: Narrow Master List of substances that should be substituted

CAS Number / EC Number	Substance Name	Substance group	Estimated amount in article, mg/kg (Table 19)
141880-36-6/ 410-070-8	A mixture of: sodium/potassium 7-[[[3-[[4-((2-hydroxy-naphthyl)azo)phenyl]azo]phenyl]sulfonyl]amino]-naphthalene-1,3-disulfonate [ACID red 447]	Dye - Acid	60 000
147703-65-9/ 410-150-2	Benzenesulfonic acid, 3-[2-[2-(acetylamino)-4-[2-[4-(2-hydroxybutoxy)phenyl]diazenyl]phenyl]diazenyl]-, sodium salt (1:1). Acid Dye " Yellow E-JD 3442"	Dye - Acid	60 000
124605-82-9/408-210-8	Direct Blue 301	Dye - Direct	40 000
81898-60-4 /400-010-9	1,5-Naphthalenedisulfonic acid, 3,3'-[1,4-piperazinediylbis[(6-chloro-1,3,5-triazine-4,2-diyl)i mino [2-(acetylamion)-4,1-phenylene]bis-, tetrasodium salt. direct yellow 162	Dye - Direct	40 000
106359-94-8 / 403-010-7	Propanamide, N-[2-[(2-cyano-4,6-dinitrophenyl)azo]-5-(dipropylamino)phenyl]-	Dye - Disperse	40 000
124605-82-9 /	2-Naphthalenol, 1-(2-phenyldiazenyl)-	Dye - Disperse	40 000

408-210-8			
13301-61-6, 12223-33-5, 51811-42-8/236-325-1, 602-312-8	CI Disperse Orange 37/59/76	Dye - Disperse	40 000
155522-12-6 /416-240-8	L-Alanine,N-[4-[(2-chloro-4-nitrophenyl)azo]-3-[(1-oxopropyl)amino]phenyl]-, methyl ester	Dye - Disperse	40 000
188070-47-5 / 424-290-7	Glycine, N-[3-(acetylamino)phenyl]-N-(carboxymethyl)-, mixed ethyl and methyl diesters, reaction products with diazotized -2-chloro-4-nitrobenzenamine. SCARLET CLA 881. Terasil red WRS	Dye - Disperse	40 000
2475-45-8 / 219-603-7	9,10-Anthracenedione, 1,4,5,8-tetraamino- (CI disperse blue 1)	Dye - Disperse	40 000
2832-40-8 / 220-600-8	Acetamide, N-[4-[2-(2-hydroxy-5-methylphenyl)diazenyl]phenyl]- DISPERSE YELLOW 3.	Dye - Disperse	40 000
75511-91-0 / 407-970-8	3-Pyridinecarbonitrile, 1-butyl-5-[(2-chloro-4-nitrophenyl)azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-	Dye - Disperse	40 000
6250-23-3/ 228-370-0	C.I Disperse Yellow 23	Dye - Disperse	10 000
2475-46-9 / 219-604-2	CI Disperse Blue 3	Dye - Disperse	10 000
3179-90-6 / 221-666-0	CI Disperse Blue 7	Dye - Disperse	10 000
3860-63-7 / 223-373-3	CI Disperse Blue 26	Dye - Disperse	10 000
12222-75-2 /	CI Disperse Blue 35	Dye - Disperse	10 000

602-260-6			
12222-97-8 / 602-282-6	CI Disperse Blue 102	Dye - Disperse	10 000
68516-81-4 / 271-183-4	CI Disperse Blue 106	Dye - Disperse	10 000
15141-18-1 / 239-206-6	CI Disperse Blue 124	Dye - Disperse	10 000
56548-64-2 / 260-255-0	CI Disperse Blue 291	Dye - Disperse	10 000
23355-64-8 / 245-604-7	CI Disperse Brown 1	Dye - Disperse	10 000
2581-69-3 / 219-954-6	CI Disperse Orange 1	Dye - Disperse	10 000
730-40-5 / 211-984-8	CI Disperse Orange 3	Dye - Disperse	10 000
2872-52-8 / 220-704-3	CI Disperse Red 1	Dye - Disperse	10 000
2872-48-2 / 220-703-8	CI Disperse Red 11	Dye - Disperse	10 000
3179-89-3 / 221-665-5	CI Disperse Red 17	Dye - Disperse	10 000
119-15-3 / 204-300-4	CI Disperse Yellow 1	Dye - Disperse	10 000
6373-73-5 / 228-919-4	CI Disperse Yellow 9	Dye - Disperse	10 000

12236-29-2 / 602-641-7	CI Disperse Yellow 39	Dye - Disperse	10 000
54824-37-2 / 611-202-9	CI Disperse Yellow 49	Dye - Disperse	10 000
10319-14-9 / 233-701-7	CI Disperse Yellow 64	Dye - Disperse	10 000
85136-74-9 / 400-340-3	CI Disperse Orange 149	Dye - Disperse	10 000
128-95-0 / 204-922-6	CI Disperse Violet 1	Dye - Disperse	10 000
268221-71-2 / -	CI Disperse Violet 93	Dye - Disperse	10 000
136-23-2 /205-232-8	Zinc, bis(dibutylcarbamodithioato-.kappa.S,.kappa.S')-, (T-4)-	Rubber Accelerator	100
149-30-4 / 205-736-8	2(3H)-Benzothiazolethione+E106:F110 [Mercaptobenzothiazole]	Rubber Additives	100
137-26-8 / 205-286-2	Thioperoxydicarbonic diamide ([(H2N)C(S)]2S2), N,N,N',N'-tetramethyl-	Rubber Vulcanisation	100
137-30-4 / 205-288-3	Zinc, bis(N,N-dimethylcarbamodithioato-.kappa.S,.kappa.S')-, (T-4)-	Rubber Vulcanisation	100
137-42-8 / 205-293-0	Carbamic acid, N-methyldithio-, sodium salt	Rubber Vulcanisation	100
14324-55-1 / 238-270-9	zinc bis(diethyldithiocarbamate)	Rubber Vulcantisation and stabilizer	100
97-77-8 /202-607-8	Thioperoxydicarbonic diamide ([(H2N)C(S)]2S2), N,N,N',N'-tetraethyl-	Plasticiser	1 000
8006-64-2 / 232-350-7	Turpentine, oil	Solvent and intermediate	Estimated as “high” (but not quantified)

5989-54-8 / 227-815-6	Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4S)-, LIMONENE	Solvent	1 000
5989-27-5 /227-813-5	Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4R)- [r-limonene]	Solvent	1 000
111-40-0 / 203-865-4	1,2-Ethanediamine, N1-(2-aminoethyl)- [diethylene triamine]	Solvent, Intermediate, Cross Linker	100
8052-10-6/ 232-484-6	Tall-oil rosin	Rosin	1 000
8050-09-7/ 232-476-7	Rosin	Rosin	1 000
84-61-7 / 201-545-9	1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester DCHP}	Phthalate	Estimated as “high” (but not quantified)
85-44-9 / 201-607-5	1,3-Isobenzofurandione [phthalic anhydride]	Intermediate	100
7440-48-4 /231-158-0	Cobalt	Metals, Inorganic Compounds	100
50-00-0 / 200-001-8	Formaldehyde	Aldehydes	100

E.2.2. Identification of potential alternative substances and techniques by group of substances

Substitution of substances in textile and leather articles is depending on many aspects and influences, e.g. product stability, compatibility with other chemical components in the chemical products themselves as well as with other process chemicals used in the same textile finishing process step and/or a previous/subsequent process step, impacts on emissions (air, waste water, waste), textile substrate, unwanted negative consequences on energy, water and time consumption. Therefore when it comes to textile and leather, the issue of identifying alternatives and more generally speaking of substituting is complex. The section E.2.2 and E.2.3., below is mainly based on the report from KemI (2019), itself based on information from industry. This is the best information made available to the Dossier Submitter even though the Dossier Submitter recognizes that the industry might have better information. Therefore the Dossier Submitter hopes that the industry will participate in the public consultation process to provide better information.

The identification of the groups and substances, which are included below (for identification of potential alternative substances and techniques) have been done in accordance with the methodology described in Annex A.2.2.

The Dossier Submitter first presents the groups of substances in alphabetic order and then present the single substances in a separate section in alphabetic order.

This section is also meant to be read together with section E.2.3, where the Dossier Submitter assesses the availability of alternatives together with economic and technical feasibility of the alternatives.

Cost data in this section has been converted from USD to EUR using an exchange rate of 1 USD=0.8735 €(2019-01-29).

In many parts of sections E.2.2. and E.2.3. the concentration level (mg/kg) is discussed both in qualitative and quantitative way. The definitions used are based on the KemI (2019) report. For the convenience of the reader the definitions used about concentration ranges from KemI (2019) are included in Table 21 below.

Table 21 : Chemical concentration ranges for formulations and finished articles

Range	Concentration	Rationale (examples from KemI (2019))
Textile or leather chemical formulations		
Very low	< 100 mg/kg	By-products, contaminants, preservatives, wetting agents, anti-oxidisers etc.
Low	Between 100 and 1 000 mg/kg	By-products, contaminants, preservatives, wetting agents, anti-oxidisers etc.
Med	Between 1 000 and 10 000 mg/kg	Active ingredients, solvents
High	> 10 000 mg/kg	This usually represents the active ingredient in a textile formulation such as a dye or a softener. The percentage will usually be between 10 and 70% with most of the remaining being the solvent
Leather or textile articles		
Very low	< 10 mg/kg	Residuals, contaminants & substances used upstream
Low	Between 10 and 100 mg/kg	Some residuals may be present in this concentration or chemicals that are unintentionally used by the wet processor
Med	Between 100 and 1 000 mg/kg	Some residuals may be present in this concentration or chemicals that are unintentionally used by the wet processor
High	> 1 000 mg/kg	This concentration is for chemicals that are added intentionally especially at the dyeing and finishing stages of the supply chain

E.2.2.1. Diisocyanates

As indicated in Table 19 above, seven Diisocyanates may be present in finished articles in textile and leather articles above the concentration limit considered as safe by the Dossier Submitter (diisocyanates are estimated to be present above 1 000 mg/kg in articles at point of sale).

According to comments received during the public consultation on this restriction proposal, the concentration level of diisocyanates in consumer articles estimated in KemI (2019) is based on results from the use of inappropriate analytical techniques. The actual concentration levels in articles within the scope of the proposed restriction are claimed to be considerably lower than 1000 ppm, and should not be found in concentrations above 10 ppm. The Dossier submitter does not have information to further challenge these comments.

The following diisocyanates, which are all classified as skin sensitisers in category 1 according to Annex VI of CLP Regulation, are included in the restriction proposal:

Table 22 : Diisocyanates in the finished articles above concentration limits considered safe

EC Number	CAS Number	Chemical name
202-966-0	101-68-8	Benzene, 1,1'-methylenebis[4-isocyanato- MDI
247-722-4	26471-62-5	m-tolylidene diisocyanate [TDI]
223-861-6	4098-71-9	Cyclohexane,5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl- [IPDI}
209-544-5	584-84-9	Benzene, 2,4-diisocyanato-1-methyl- TDI
227-534-9	5873-54-1	o-(p-isocyanatobenzyl)phenyl isocyanates
212-485-8	822-06-0	Hexane, 1,6-diisocyanato- [HDI]
202-039-0	91-08-7	Benzene, 1,3-diisocyanato-2-methyl-

Diisocyanates are used in the manufacturing of polyurethanes (PU). They may be present in coating and printing finishing formulations, and in applications such as PU foams and elastomers, thermoplastic resins and spandex fibers, millable gums and adhesives. Unblocked diisocyanates are considered a bigger concern than blocked. According to KemI (2019), the levels of diisocyanates present in *in situ* polymerisation formulations are very high. For articles 1 000 mg/kg are estimated.

Polyurethane is sometimes sold in pre-polymerised form with diisocyanates present as low-level contamination, and sometimes sold un-polymerised for in-situ polymerisation.

No substitutes exists. However if best practice is used, with correct amount of ingredients, catalysts, high enough curing temperatures and potential washing afterwards, the chemicals should not be present in articles at point of sale (for further definition of “best practice”, see further below in section E.2.2.9.5.). Although no alternatives seem to exist, the Dossier Submitter suggests a restriction nonetheless since best practice can solve the matter. Since best practice is assumed to be needed if a very low limit is set on both blocked and unblocked diisocyanates it is assumed that some costs will be incurred on the part of the industry not following best practice at the moment. As discussed below in E.2.2.9, it is assumed that most companies follow subnormal, normal or good practice and only a smaller share follow best practice. It has not been possible to get data on substitution cost (in this case the cost of moving towards best practice) for diisocyanates despite both a questionnaire contact and consultant enquiries carried out by the Dossier Submitter (see Annex G for a detailed description). Getting feedback from the industry on cost estimates for moving towards best practice is therefore something that needs to be addressed in the public consultation process.

Since asymmetric information does not allow consumers to pay a premium for the best practice textiles (if the textile companies are not able to signal best practice in another way), not requiring best practice from all textile producers (i.e. restricting diisocyanates in the textiles at point of sale) would imply a market failure as far as asymmetric information is

concerned. Without a restriction, risk adverse consumers would thus not be able to choose best practice textiles, for a price premium even if they want to (since the asymmetric information makes choosing impossible).

With regard to volumes, diisocyanates are used in 18 000 000 tons for all applications. Of these, 540 000 tons are estimated to be used in textiles and 105 600 tons are estimated to be used in leather application according to KemI (2019). For further details on volumes, see Table 18 of the main report below as well as Annex G2. It is further estimated that the volume trend for these substances is increasing.

E.2.2.2. Dyes

Dyes may cause a problem for consumers by causing allergic contact dermatitis. Various type of dyes exist (anthraquinonic ones, azoic ones, disperse etc).

It is however uncertain that all dyes will be a problem of equally high concern. The likelihood that dyes will be a problem increases with the amount of unfixed dyes that is present in the finished textile and leather articles. The degree to which dyes are fixed to the textile is dependent on both the type of dyes and the type of textile, that the dyes are used on, as well as other parameters in the dying process, which the industry consider to be best (good and normal) practice (for further definition of “best practice”, see further below). Good practice for dyes (as described in section E.2.2.9.5. below) is for example using the correct amount of dyes, pre-washing the textile when necessary and using right type of dye for the right type of textile, thereby creating the best possible fastness to the textile without compromising the colour of the textile. Apart from these factors, the chemical properties of the dyes themselves also contribute to allergic contact dermatitis to a different degree. Some dyes are known to have skin sensitising properties and these need to be restricted whenever possible. Substituting away from skin sensitising dyes to safe alternatives are to be considered good or even normal practice (see E.2.2.9.5 below for definition and discussion about good and best practice). As long as substitutes exist (and the cost of the substitutes are the same), no additional cost is thus expected for substituting away from skin-sensitising dyes.

Acid dyes

Two acid dyes (Acid Red 447 and Yellow E JD 3442), described in the table below, used mostly for wool and nylon and classified as skin sensitisers in category 1, have been identified in connection to the review conducted for this restriction proposal. These dyes are estimated to be found in high concentration level (0- 60 000 mg/kg) in the textile, but the amount of loose unfixed dyes is estimated to be much lower (maybe 20 mg/kg) (KemI, 2019). It is estimated that these dyes are used in a low percentage of all textile articles. Moreover, it is estimated that adequate substitutes exist and that using them can be done at no additional cost. The two acid dyes are registered at ECHA for EU production at more than 20 tons. However since most textile articles are mostly imported it is estimated that 333 tons are used in textiles and 465 tons are used in leather. For additional and more differentiated volume, estimates please see Appendix G2. The volume trend is consistent to the baseline and is not expected to increase or decrease.

Table 23 : Acid dyes in the finished articles above concentration limits considered safe

EC Number	CAS Number	Chemical Name
410-070-8	141880-36-6	A mixture of: sodium/potassium 7-[[[3-[[4-((2-hydroxy-naphthyl)azo)phenyl]azo]phenyl]sulfonyl]amino]-naphthalene-1,3-disulfonate
410-150-2	147703-65-9	Benzenesulfonic acid, 3-[2-[2-(acetylamino)-4-[2-[4-(2-hydroxybutoxy)phenyl]diazenyl]phenyl]diazenyl]-, sodium salt (1:1). Acid Dye " Yellow E-JD 3442"

Direct dyes

Two direct dyes (Direct Blue 301 and Direct Yellow 162) described here below, (classified as skin sensitisers in category 1) used mostly for example in cotton, linen, viscose and lyocell, have also been found (KemI, 2019). It is estimated that they are used in textiles in a “medium” high (see definitions in Table 21 above) percentage of all textiles and that they are found in high concentration level in textiles (0- 40 000 mg/kg). For these dyes, fastness has not been estimated. It is estimated that adequate substitutes are readily available, and that they can be used at no additional cost. For one of these dyes, information on registered volumes at ECHA was confidential and for the other + 1 tons/year was registered. It is however estimated that volumes on textile and leather sold in the EU are much larger due to imports. Therefore, it is estimated that 1 378 tons/year are used on textiles in the EU. No use in leather is estimated. The volume trend is consistent to the baseline (volume used today), and neither increases nor decreases are expected in used volumes. (KemI, 2019)

Table 24 : Direct dyes in the finished articles above concentration limits considered safe

EC Number	CAS Number	Chemical Name
408-210-8	124605-82-9	Direct Blue 301
617-266-4	81898-60-4	1,5-Naphthalenedisulfonic acid, 3,3'-[1,4-piperazinediylbis[(6-chloro-1,3,5-triazine-4,2-diyl)imino [2-(acetylamion)-4,1-phenylene]bis-, tetrasodium salt. direct yellow 162

Disperse dyes

Nine disperse dyes (8 with a harmonised classification as skin sensitisers in category 1 according to Annex VI of CLP Regulation and another one (CI Disperse Yellow 23) with no harmonised classification, see Table 25) were identified as textile relevant in KemI (2019). They can be present at concentrations up to 40 000 mg/kg in finished textile articles. This is several magnitudes above the concentration levels considered as safe by the Dossier Submitter (see B.10.1).

Table 25 : Disperse dyes in the finished articles in concentration above levels considered safe

EC Number	CAS Number	Chemical Name
403-010-7	106359-94-8	Propanamide, N-[2-[(2-cyano-4,6-dinitrophenyl)azo]-5-(dipropylamino)phenyl]-
408-210-8	124605-82-9	2-Naphthalenol, 1-(2-phenyldiazenyl)
236-325-1	13301-61-6	CI Disperse Orange 37/76
416-240-8	155522-12-6	L-Alanine,N-[4-[(2-chloro-4-nitrophenyl)azo]-3-[(1-oxopropyl)amino]phenyl]-, methyl ester
424-290-7	188070-47-5	Glycine, N-[3-(acetylamino)phenyl]-N-(carboxymethyl)-, mixed ethyl and methyl diesters, reaction products with diazotized -2-chloro-4-nitrobenzenamine. SCARLET CLA 881. Terasil red WRS
219-603-7	2475-45-8	9) ,10-Anthracenedione, 1,4,5,8-tetraamino- (CI disperse blue 1)
20-600-8	2832-40-8	Acetamide, N-[4-[2-(2-hydroxy-5-methylphenyl)diazenyl]phenyl]- DISPERSE YELLOW 3.
407-970-8	75511-91-0	3-Pyridinecarbonitrile, 1-butyl-5-[(2-chloro-4-nitrophenyl)azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-
228-370-0	6250-23-3	CI Disperse Yellow 23

For disperse dyes, and as explained in the scope section, an additional number of dyes with no harmonised classification have also been identified as problematic from a skin sensitising perspective by industry and labelling initiatives. These dyes are also included in this restriction proposal since there is a consensus that they are of concern. This list of substances of concern can be seen in Table 2 of the main report, as well as in Table 26 below. For the disperse dyes from the list of concern, the Dossier Submitter does not have as good information regarding concentration level and substitution as for the ones above, which are investigated in KemI (2019), except for Disperse Yellow 23. Information by stakeholders in the public consultation indicate that, if used as nuancing dyes, dyes in general are present on textile in an amount of 0.1%, otherwise the amount is 1 - 2% depending on the required shade.

Table 26: Additional disperse Dyes of the list of concern without available concentration and substitution information

	CAS Number	**EC Number**
CI Disperse Blue 3	2475-46-9	219-604-2
CI Disperse Blue 7	3179-90-6	221-666-0
CI Disperse Blue 26	3860-63-7	223-373-3
CI Disperse Blue 35	12222-75-2 56524-77-7	602-260-6 260-243-5
CI Disperse Blue 102	12222-97-8	602-282-6
Ci Disperse Blue 106	271-183-4	68516-81-4
CI Disperse Blue 124	15141-18-1	239-206-6
CI Disperse Blue 291	56548-64-2	260-255-0
CI Disperse Brown 1	23355-64-8	245-604-7
CI Disperse Orange 1	2581-69-3	219-954-6
CI Disperse Orange 3	730-40-5	211-984-8
CI Disperse Orange 37 (=/59=/76)	13301-61-6 12223-33-5 51811-42-8	236-325-1 602-312-8
CI Disperse Orange 149	85136-74-9	400-340-3
CI Disperse Red 1	2872-52-8	220-704-3
CI Disperse Red 11	2872-48-2	220-703-8
CI Disperse Red 17	3179-89-3	221-665-5
CI Disperse Yellow 1	119-15-3	204-300-4
CI Disperse Yellow 9	6373-73-5	228-919-4
CI Disperse Yellow 23	6250-23-3	228-370-0
CI Disperse Yellow 39	12236-29-2	602-641-7
CI Disperse Yellow 49	54824-37-2	611-202-9
CI Disperse Yellow 64	10319-14-9	233-701-7
CI Disperse Violet 1	128-95-0	204-922-6
CI Disperse Violet 93	268221-71-2	-

KemI (2019) estimates that loose unfixed dye is low if post-dye reductive washing is conducted. However, depending on the fastness, other dye may come to the surface during use. Amount of exposure will depend on colour, shade, depth and fastness. These dyes are used on a large percentage of all textiles. The type of textiles on which they are used are polyester textile and acetate (and to a smaller degree nylon).

Stakeholder consultation indicate that disperse dyes are not and can not be used to dye leather.

According to KemI (2019) adequate substitutes exist. Confirmation that the same colour could be provided by the substitute of the restricted disperse dye is all that is needed. Using substitutes should not impose any additional cost to the textile producer. The existence of substitutes for skin sensitising disperse dyes is also confirmed by the AFIRM group (which is one of the expert groups that the consultants have confirmed their assumptions and analysis with). They indicate to their members that safer alternatives exist and various substitutes are available with full colour ranges for synthetic textiles.

Comments received in the public consultation does however indicate that there are no apparent available substitutes for the following disperse dyes:

- Disperse Blue 291,
- Disperse Violet 93,

- Disperse Violet 1, and
- Disperse Yellow 64.

The Dossier Submitter has not been able to confirm or challenge this information. The Dossier Submitter acknowledges that there is a need for further consultation with technical expertise to clarify this issue.

For the disperse dyes, no volumes are given at ECHA except for one of them (2-Naphthalenol, 1-(2-phenyldiazenyl), with CAS 124605-82-9/EC 408-210-8), where 1 + tons/year are registered. According to KemI 2019, it is however estimated that 8 233 tons/year are used for the nine disperse dyes in Table 25 in textiles. No uses in leather are estimated.

E.2.2.3. Intermediates

The intermediate 1,3-Isobenzofurandione [phthalic anhydride] (CAS 85-44-9 / EC 201-607-5; and with harmonised classification as skin sensitiser in category 1 according to CLP regulation) has been identified in several finishing/ coating / ink formulations, as well as intermediate for various chemical resins, dyes, and pigments; curing agent for epoxy resins. The intermediates estimated to be present in concentrations of up to 100 mg/kg or more in articles at point of sale and is estimated to be present in these levels for a high share of both textile and leather products. Volumes of 100 000 – 1 000 000 tons/year are registered under REACH regulation. It is further estimated that, 540 tons/year of these are used for textiles and 53 tons/year are used for leather, the volume trend is decreasing due to legalisation. According to KemI (2019) it is not possible to substitute this substance due to its many uses. Cost of substitution has therefore not been estimated. The cost per metric ton of the intermediate has however been estimated to be € 900-1300 (KemI, 2019).

Comments received during the public consultation state that this substance is an intermediate in chemical processes, that residuals are converted in aqueous / humid environment in phthalic acid and that there is no use in textile and leather manufacturing. The commenting stakeholders consider that very low concentration levels in textile and leather articles should be expected. The dossier submitter does not have information to confirm or challenge this comment.

It has to be noted that under REACH, on-site isolated intermediate uses of substances cannot be restricted (according to art. 68 of REACH) and non-isolated intermediate are out of the scope of REACH (according to article 2). The only legal possibility to restrict intermediates uses is related to transported intermediates (defined as an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites). This is not the case of the intermediate identified herein. However, strictly speaking, within this restriction proposal, the Dossier Submitter does not aim at restricting the uses of intermediates in the textile and leather manufacturing processes but only their content in the articles at point of sale. This is allowed by REACH and is the purpose of including this group in the list for the analysis of the alternatives.

Another intermediate / dye synthesiser, found in the review connected to this restriction proposal is Benzenesulfonic acid, 3-nitro-, sodium salt (1:1), (with CAS 127-68-4/ EC 204-857-3 and classified as skin sens. 1. according to CLP regulation). The substance is used as

intermediate in dye synthesis. It is most probable that this substance will not be present at point of sale, but this has not been possible to confirm in KemI (2019). Therefore it is included in order to get feedback from the industry in the public consultation process. The cost per metric tons of this intermediate has been estimated to be € 1100 in KemI, (2019).

According to comments received during the public consultation, this chemical is used during the dyeing of cotton with reactive dyes. No relevant amount is expected to remain of the dyed fabric at the end of the textile dyeing and finishing process because this chemical is consumed during the process.

If this dye intermediate is present in articles at point of sale, despite the Dossier Submitter believes that it is not, then substituting the dye intermediate would need very detailed dialogue with the dye industry and eliminating a single intermediate could affect multiple dyes. Changing any intermediate would change the final dye (KemI, 2019).

For further information on technical feasibility and economic feasibility, see section E.2.3.

E.2.2.4. Plasticisers

One phthalate (1,2-benzenedicarboxylic acid, 1,2-dicyclohexyl ester, DCHP, with CAS 84-61-7/ EC 201-545-9, and classified as a skin sensitiser in category 1 according Annex VI of CLP regulation) has been found with textile connection. This substance can be used in coated and pigment printed textile articles and will then be present in high concentrations. It has not been possible to estimate the concentrations levels more precisely for this substance. The substance has a registration for 1 000 – 10 000 tons/year on ECHA's website. For textile, it is estimated that 4 050 tons/year is used in textiles and 792 tons/year for leather articles, the volume trend is consistent to the baseline use of today and is not expected to neither increase or decrease. Alternatives to phtalates exist and a lot of work has been done in that field. It is however uncertain which substitutes will be most suitable as an alternative in textile articles. The possible alternatives include adipates, benzoates, citrates, cyclohexane dicarboxylic acids, epoxidized vegetable oils, glycerol acetylated esters, phosphate esters, sebacates, terephthalates and trimellitates. The industry needs to be involved further in order to analyse which one of these (or another) is best for textile applications. (KemI, 2019)

Looking into the restriction on phthalates (ECHA, 2017) it is clear that a number of substitutes with textile application exists (see section E.2.3.4, for more details on the economic and technical feasibility of substitutes), which are feasible from both an economically and a technical perspective. DCHP in particular is not described in the ECHA (2017) restriction. However several phthalates-free substitutes exist, which implies that a technical and economic feasible substitute for textile applications without any phthalates at all exists (ECHA, 2017). These substitutes are described in more detail in section E.2.3.7, where the Dossier Submitter also assesses technical and economic feasibility. Therefore substitution of this phthalate substance should be possible for the industry without substantial substitution costs.

Another substance (thioperoxydicarbonic diamide ([(H2N)C(S)]2S2), N,N,N',N'-tetraethyl-, CAS 97-77-8/ EC 202-607-8) with a harmonised classification as skin sens 1 and with an application as a plasticiser has been found. This substance is estimated to be present in for example neoprene materials at high concentrations (1 000 mg/kg) in KemI (2019). This substance is registered at 100-1000 tons/year at ECHA for all usages and it is estimated that (for textiles) 54 tons/year is used for rubber vulcanisation (see Annex E.2.2.6 below)

and 180 tons/year are used as plasticizer for neoprene. For leather applications, it is estimated that 5.3 tons/year is used for rubber vulcanisation (see Annex E.2.2.6 below). The volume trend is unknown (KemI, 2019).

One comment received in the public consultation claims that the identification of this substance as a plasticiser appears erroneous, since neoprene (chloroprene) does not require plasticisation in uses relevant in this proposal. The dossier submitter does not have information to further confirm or challenge this comment.

For neoprene applications, dioctyl sebacate, dioctyl adipate, dioctyl phthalate and diisononyl phthalate may be substitutes, but industry indicated that they may be regrettable substitutes according to KemI (2019), (see section E.2.3.5. for a further assessment on hazard profiles etc. for these substances). The chemical industry needs to be involved further in order to get a better grip on substitution issues related to these substances.

For details on volumes and chemical names, see Table 18 in the main report.

For further information on technical feasibility and economic feasibility, see section E.2.3.

E.2.2.5. Rubber accelerators

Seven different rubber accelerators with a harmonised classification as skin sensitisers in category 1 (see Table 26), have been found in the review, which was made in connection to this restriction proposal. The articles of concern are rubber coated textiles. The rubber accelerators with CAS 136-23-2 and EC 149-30-4 are registrated at ECHA for 1000-10 000 metric tons per year (but there is no available information on the other five). For all seven of them it is estimated that the 378 metric tons / year are used in textile applications and 37 metric tons / year in leather. The volume trend is unknown. (KemI, 2019)

Table 27 : Rubber accelerators in finished articles above concentration limits considered safe

EC Number	CAS Number	Chemical Name
205-232-8	136-23-2	Zinc,bis(dibutylcarbamodithioato-.kappa.S,.kappa.S')-, (T-4)-
205-736-8	149-30-4	2(3H)-Benzothiazolethione [Mercaptobenzothiazole]
205-286-2	137-26-8	Thioperoxydicarbonic diamide ([(H2N)C(S)]2S2), N,N,N',N'-tetramethyl-
205-288-3	137-30-4	Zinc,bis(N,N-dimethylcarbamodithioato-.kappa.S,.kappa.S')-, (T-4)-
205-293-0	137-42-8	Carbamic acid, N-methyldithio-, sodium salt
238-270-9	14324-55-1	zinc bis(diethyldithiocarbamate)

KemI (2019) and the review conducted in connection to this restriction proposal did provide some information on these substances, but KemI (2019) advised to contact a rubber expert for further knowledge on these substances. A rubber expert connected to the consultant firm “Lysmask Innovation AB” has therefore been involved in the review of these substances. The rubber expert has concluded that all substances are accelerators and that the relevant application for these substances are for vulcanized rubber. One type of products where these substances can be used are for example high end premium rubber boats and dish washing gloves. In general, since the information on rubber accelerators is based on one expert’s judgement (even though experienced and reliable) the Dossier Submitter hopes for additional information in the public consultation to improve further in this information.

It is further explained by the rubber expert that under a perfect recipe, mixture and chemical process, then the concentrations will be below 100 mg/kg. This would lead to the exclusion of these substances based on the risk analysis in the annex B. A perfect recipe, mixture and chemical process is however, according to the rubber expert, so unlikely that it is almost certain that flair ups with concentrations higher than 100 mg/kg will be common for these vulcanized rubbers.

According to the rubber expert, substitution should be no problem, but it will be hard to say in beforehand which the substitutes will be and if they will be less problematic from a skin sensitising perspective. This follow from the fact that a reformulation process will be needed for substitution. Several of the identified substances are also connected to work related hazards and he therefore suspects that some kind of substitution discussion might be ongoing. Work related hazards are not covered in this restriction proposal, but reducing such problems is of course a bonus, all else equal.

According to the rubber expert the cost of the substitutes in €/kg of substitute will not be a big issue since they will be a very small share of the total cost of production. The rubber expert, estimates that they may be less than one percent of the material costs. The material cost is in itself estimated to be a small cost of the total production cost according to the rubber expert.

The larger cost will instead be the reformulation costs. Reformulation can be both quite easy and also relatively hard. For the easy cases, the rubber expert estimates a couple of days in the lab (with for example a chemical engineer) and then some simple tests in the factory. For the very difficult reformulation cases one year work cost and then substantial changes in processes in the factory can be expected followed by certification and other quality related costs. It is however expected that the reformulations connected to textile applications are of the easier kind according to the rubber expert (since for example certification costs do not exist).

In order to calculate the reformulation cost, the estimated cost per reformulation is needed. The number of reformulations needed due to this restriction proposal are also needed. In addition to this business as usual reformulations are also needed in order to estimate how big the additional burden of reformulation will be due to this restriction as compared to the reformulations that the industry plan to conduct regardless of this restriction proposal.

It is here assumed that the reformulation will be of the easier type, that is to say a couple of days, or more (the Dossier Submitter here assumes four weeks) for reformulation in laboratories.

€50/hour is assumed as labour cost, which is about twice the average labour cost in EEA31, according to Eurostat's, and is approximately what a Chemical engineer earns in Sweden. This is motivated since the personal working on reformulation will be experienced and with an above average salary. For the laboratory cost estimates, the Dossier Submitter is assuming that 60% of the total reformulation cost is labour cost and that the remaining 40% is the cost of using the laboratory itself. This is based on the (COLA, 2015) where labour cost is estimated to be 50-70% of the total clinical laboratory cost. This gives the following "on the back of an envelope"-calculations based on an additional assumption of one month full time work for one person;

- 40 hours per week, for four weeks gives 160 hours work in total. Labour cost is €8 000 per month (based on €50 /hour for 160 hours). Laboratory costs are estimated to be

40% of total reformulation costs (and 60% labour cost). This gives that total reformulation cost is €13 300/reformulation, with laboratory costs of €5 300/reformulation and labour cost of € 8 000 /reformulation.

This is however only an estimate based a number of assumption and best available data and the Dossier Submitter has not been able to get this information at first hand from the industry. Improvements with better data during the public consultation process may therefore improve the quantitative assessment.

The number of products which will be in need of reformulation due to this restriction proposal has not been possible to estimate at this stage, but the Dossier Submitter hopes to improve on this information gap as well in the public consultation. In Annex E.4.1.6 a simple sensitivity analysis is conducted to problematise and discuss the potential total cost of reformulation connected to rubber accelerators. That analysis is however based on assumed numbers of reformulations and better information from industry is highly needed in order to improve the assessment.

It is further assumed that the industry under a business as usual scenario would reformulate products even without a restriction proposal with some frequency. Discussing the reformulation frequency with the rubber expert it is however clear that reformulation frequency can differ a lot depending on company strategy and products. For some mature products, a new reformulation is not done during the products life range. For other companies (and other product types) both regulatory driven and cost driven reformulations are business as usual practice. Regarding the product type in question for reformulation due to this restriction, “accelerators for vulcanized rubber”, the rubber expert states that reformulation will not be done without external demands in a business as usual case. Therefore the Dossier Submitter has to assume that the companies are bearing the full cost of reformulation due to this restriction and that reformulation would not have been done in a long time span without this restriction proposal.

It is however not possible to know in beforehand if the reformulated substitutes would be better for consumers with regard to skin sensitising or other human health endpoints, according to the consulted rubber expert. Reformulation costs can therefore turn out to be sunk costs with some unknown probability.

For further information on technical feasibility and economic feasibility, see section E.2.3.

E.2.2.6. Rosins

Two different rosins, one tall-oil rosin and one “other” rosin have been identified in connection to point of sale articles. These substances may be used in the synthesis of adhesives, coated, pigment printed textiles, and if they are used, they may be present at high concentration (1 000 mg/kg) (see Table 21 for definitions on very low to high concentration).

For the tall-oil rosin, (CAS 8052-10-6/ EC 232-484-6 with a harmonised classification as skin sensitiser in category 1) no volumes have been confirmed and even the estimated volumes (based on concentration levels in articles and the share of the total volume of textiles they are used in) are estimated to be zero (KemI, 2019). Therefore probably very marginal impact on both cost and benefit side with a restriction for this tall oil rosin, unless there is a hidden

usage. However, while investigating this further at least some confirmed production of tall rosin with textile application have been found. Production of tall-rosin is ongoing in Europe by one identified company and is a by-product from forest production. It is also confirmed that some products are used in textiles (among other applications). It is however unclear if the tall-rosin are left on articles at point of sale. These products appear to have advantages in some areas and are marketed as environmental friendly since it is made from a renewable natural resource. Further information about the eventual use of tall oil rosins in articles within the scope of this restriction of this restriction proposal was requested in the public consultation. Two stakeholders mentioned this substance during the public consultation but none of them provided information on occurrence of tall-oil rosin in articles on the scope of the proposed restriction.

For the "other" rosin (CAS 8050-09-7/ EC 232-475-7, with a harmonised classification as skin sensitiser in category 1) there is an estimated usage of 10 800 metric tons /year for textiles and also a registered usage at ECHA of 100 000 – 1 000 000 tons/year, but this ECHA volume includes all type of usage and not just textile applications. The volume trend is unknown. With regard to substitution, other binders such as acrylics and polyurethanes may be alternatives. There is however a big concern from industry consulted about regrettable substitution for these alternatives, which would need further investigation (KemI, 2019) (see Annex E.2.3.10).

For further information on technical feasibility and economic feasibility, see Annex E.2.3.

E.2.2.7. Solvents

Four different solvents have been identified with a strong textile application and a harmonised classification as skin sensitisers in category 1 (see Table below).

Table 28 : Solvent in finished articles above concentration limits considered safe

EC Number	CAS number	Chemical Name
227-815-6	5989-54-8	Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4S)-, LIMONENE
227-813-5	5989-27-5	Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4R)- [r-limonene]
232-350-7	8006-64-2	Turpentine, oil
203-865-4	111-40-0	1,2-Ethanediamine, N1-(2-aminoethyl)- [diethylene triamine]

These are used in similar but a bit differentiated applications (see KemI, 2019 for details). Three of them are estimated to be found in high concentrations (>1 000 mg/kg) and one in low concentrations (10-100 mg/kg) (see Table 21 for definitions). Two of them (CAS 5989-54-8 and CAS 5989-27-5) are in general present in textile and leather applications and one (CAS 8006-64-2) is primarily found in pigment printed and coated textiles. One of the solvents can be present in all textile and leather applications if used in finishing formulations, however it can also be used for coated and pigment printed textiles and are then only present in those type of textiles (CAS 111-40-0).

- For the solvent with CAS 5989-54-8, 100-1 000 per metric ton per year is registered at ECHA. For textiles 7.2 tons/year is estimated to be used in articles and 0.704 tons/year in leather.

- For the solvent with CAS 5989-27-5, 1 000-10 000 tons/year is registered at ECHA. For use in textiles, 3 600 tons/year is estimated and for leather 141 tons per year is estimated.
- For the solvent with CAS 8006-64-2, 10 000 – 100 000 ton per year is registered at ECHA. For use in textile applications 3 600 tons/year is estimated and for leather 141 ton/year is estimated.
- For the solvent with CAS 111-40-0, 10 000 tons/year is registered at ECHA. For use in textile applications 54 tons/year is estimated and for leather 53 tons/year is estimated.

The volume trend is unknown for all solvents (KemI, 2019).

Some further information has been submitted during the public consultation:

- Some stakeholders stated that Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4S)-, LIMONENE and Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4R)- [r-limonene are used as fragrances only in cosmetics and not as solvents. Concerning the latter, stakeholders stated that limonene could be used as solvent in washing agents but estimated amount on article due to physical properties should be very LOW.
- Concerning 1,2-Ethanediamine, N1-(2-aminoethyl)- [diethylene triamine], stakeholders stated that it is an intermediate in chemical synthesis, e.g. synthesis of sequesterant agents or fatty acid condensates. In rare cases it is used to neutralize solutions for ph-adjustment. The chemical is volatile and residuals in aricles are predicted LOW.
- However the dossier submitter does not have information to further challenge or check these comments.

The KemI report (2019) states that specific knowledge of which formulation the solvent (and /or intermediate) is present in, is necessary in order to make any practical suggestions on alternatives. Solvents are used to dissolve materials (or sometimes act as a carrier for insoluble materials) and they adjust the rheology. It is also necessary to have information on where in the production chain the solvent is used. Some of the solvents are deliberately used by formulators (it is in general easier to substitute these deliberate usages) and others carry -over from upstream synthesis (KemI, 2019). More information is therefore needed in order to assess alternatives and the Dossier Submitter follows the suggestions of KemI (2019) to initiate a dialogue (in the public consultation) with the chemical industry to discuss the presence and use of solvents in formulations.

Since the exact usage have not been identified, alternatives have not been identified either.

The cost of substitution is therefore not clear for these substances. The cost of the substances themselves have however been identified. Depending on which type of solvent (intermediate) the price per ton ranges from €900/ metric ton to €44 500 / metric ton (KemI, 2019). Nevertheless, based on other information collected during the elaboration of this restriction proposal, best practice may also solve the issue of non-compliance of solvents (but that needs to be confirmed by industry). For further definition of “best practice”, see further below in E2.2.2.9.5.

For further information on technical feasibility and economic feasibility, see section E.2.3.

E.2.2.8. Other substances

E.2.2.8.1. Benzenamine (aniline)

Based on the questionnaire sent out in connection to this restriction proposal, one intermediate dye synthesis, Benzenamine, or aniline, with CAS 62-53-3/ EC 200-539-3, has been identified by EURATEX to have higher concentrations at point of sale than what was identified in KemI (2019).

According to KemI (2019), the substance is used in dye manufacture synthetic indigo which can result in aniline residues in unwashed denim, leather dyes, synthesis of dyes, rubber additives, drugs, isocyanates, and pesticides.

According to some comments received during the public consultation, aniline is not used intentionally in textile industry and might be present as an impurity in dyes (esp. in indigo) and some leather dyes. However, other comments stated that aniline can also be used in the manufacture of many dyes and pigments. Then it can be present as impurities from many dyes if process standards are not respected. Some MRSL (Manufacturing Restricted Substance List) limits are not scientifically derived - they are intended to make originators look responsible. Aniline can be present in very dark, unwashed denim at up to 60 mg/kg but is rare.

EURATEX does however identify that this substance can be present at 100 mg/kg in articles at point of sale, and it is therefore included in the restriction proposal.

Benzenamine is registered at ECHA for 1 000 000 – 10 000 000 metric tons per year, but this is for all applications. For use in textile 180 tons per year and 18 tons/year for leather is estimated. The price per metric ton for Benzenamine is estimated to be € 1 300 – 1 400. (KemI, 2019)

Powder indigo contains usually more than 5 000 ppm of aniline according to comments received.

Regarding substitution for indigo, there are a couple of replacements but these are not feasible given the size of the denim industry. Natural indigo grown in the US, China and India. Fermented Indigo made from bacteria and a sugar source. The issue is low yield, water use and competing for arable land (Corn is the typical feedstock and it is needed in large quantities). Some sulfur dyes can mimic indigo but these have not gained any momentum in the industry since their introduction a few year ago. They are claimed to be all significantly more expensive than indigo. Indigo can be made without using aniline but aniline is a building block chemical for many other dyes. If it is restricted, these colours/dyes simply will not be available (KemI, 2019).

E.2.2.8.2 Metals and inorganic compounds

Cobalt (CAS 7440-48-4/ EC 231-158-0) could possibly be used in textile pigments (nylon and wool are most probable). The substance could then be present in 100 mg/kg. A couple of dyes may be affected. No volumes are registered at ECHA but it is estimated that 11 tons/year are used in textile applications and that the volume trend is decreasing (KemI, 2019).

Other acid dyes may be substitutes, but confirmation is needed by industry in order to clarify if cobalt based dyes have some special properties.

For further information on technical feasibility and economic feasibility, see section E.2.3.

Nickel compounds (inorganic and catalyst) are other metal compounds for which concern regarding skin sensitising properties is high. Metallic nickel is not used in textiles but nickel salts may be used in dye making. It is estimated that nickel is used at a low or even zero level in textiles according to KemI (2019). The concentration levels have not been estimated for nickel due to lack of data. The substance may be used in dye making as a catalyst. Nickel is used in some dye chromophores but is 'tied in' and not extracted in sweat. There are very few other options in this colour area. Regarding substitutes, greens made from yellow and blue are far inferior in terms of resistance to light. Costs of the nickel substances, substitutes and cost of substitution have not been estimated due to lack of data.

Nickel has also been found in the ANSES 2018 study and is therefore included despite of lack of concentration data (ANSES, 2018).

E.2.2.8.3. Formaldehyde

Formaldehyde is harmonised classified as skin sensitiser in category 1 (CAS 50-00-0 EC 200-001-8) and is used in a various applications in textiles and leather articles. Formaldehyde is not used on its own but most of the time in a resin, adhesives, building block for some finishes and in printed/silkscreened textiles.

Volume registered at ECHA for all uses is 1 000 000 tons/year. KemI (2019) estimates that the use in textiles is 288 tons/year and that the use in leather is 28 tons/year.

In KemI (2019), formaldehyde is in general estimated to be potentially present at several hundred mg/kg in articles at point of sale. In the ANSES 2018 study, formaldehyde has been quantified in articles (textiles and leather) at concentrations between approximatively 6 mg/kg and 160 mg/kg (ANSES, 2018). The proposed concentration limit is 30 mg/kg. This indicates that substitution will be required to some extent. Prewashing will remove formaldehyde and can thus hopefully be used to comply with a restriction but this needs to be confirmed by industry.

For use in textile, low and zero formaldehyde resins exist for cross linking cotton and anti-pill resins for viscose. These tend to be more expensive and seem to not work as well as their low formaldehyde counterparts. Polycarboxylic Acid is identified as a substitute for textile application (Chemsec 2019 Guide[40]) and may be a good substitute as well for leather, but no information on this has been provided in stakeholder consultations. Information on substitutes for formaldehyde in leather is thus somewhat lacking compared to substitutes for use in textiles.

For further discussion on the technical and economic feasibility of this potential alternative to formaldehyde, see Annex E.2.3.9.3.

[40] http://textileguide.chemsec.org/find/textiles-come-with-a-toxic-footprint

E.2.2.8.4. Tanning agents, Glutaraldehyde and Chromium compounds

A large majority of global leather manufacture uses chromium III salts for tanning. During the public consultation one stakeholder claims that the share is 85%, others indicate levels of around 80-90%. As noted by several stakeholders, presence of chromium VI in leather products is incidental, due to a degree of oxidation of the high concentration of chromium III compounds that are used in leather manufacture. KemI (2019) estimates that 70,400 tons of chromium compounds are used in leather for the EU market every year.

Chromium VI in leather is covered by entry 47 of Annex XVII of the REACH regulation, with a binding concentration limit at 3 mg/kg. From the background document (2012) for that restriction it can be seen that substitution to chromium free substitutes is not really needed to comply with entry 47 since using good production methods can keep the chromium VI concentration below 3 mg/kg in leather articles at point of sale. The risk assessment in B.10.2.2 does however indicate a risk at concentration levels well below the limit in the present restriction. ANSES (2018) also indicates that consumers can be affected in a way that cause allergic reactions at concentrations below 3 mg/kg. One reason for setting a 3 mg/kg limit in the agreed chromium VI restriction entry 47 was that it was the lowest possible detection limit with existing testing methods. Technological progress in test methods does however make it possible to detect even 1 mg/kg of chromium VI today. This restriction proposal therefore argues for a lower concentration limit for chromium VI at 1 mg/kg and calls a revision of current entry 47 of Annex XVII of the REACH regulation. Discussion with a leather expert indicates that industry may have no problem at all with a 1 mg/kg limit, and that only lack of good testing methods has kept the limit from being lowered before. If that would be true, then no additional cost would arise due to a lower concentration limit. If this assumption is incorrect then substantial consequences may arise in moving from a 3 mg/kg limit to a 1 mg/kg limit and some extra costs may be borne by leather industry. Several stakeholders do point out that since the current standard test method does not provide reliable results at concentrations as low as 1 mg/kg it is difficult to say with any degree of certainty whether that concentration level is achievable on a consistent basis.

Regarding substitution, stakeholders indicate that other tanning agents than chromium III result in leathers with markedly different chemical and physical properties and may not be suitable to fulfil the specifications required for many applications.

Aldehydes such as glutaraldehyde (Pentanedial CAS 111-30-8/ EC 203-856-5) are the most common substitutes at day for chromium tanning, but glutaraldehyde is itself included in the restriction proposal since it has harmonised classification as skin sens. 1A under the CLP Regulation. Using glutaraldehyde results in leather called "Wet white" because it is an off-white shade. It can be produced using aldehydes, aluminium, zirconium, titanium, or iron salts, or a combination thereof (KemI, 2019). Glutaraldehyde is primarily used for leather in automobiles, but can also be used in for examples shoes. A registration of 1 000 ton/year exist at ECHA and it is estimated that 7.04 tons/year is used in leather articles (KemI, 2019).

Four stakeholders have submitted information about concentration levels of glutaraldehyde in leather articles. All of them indicate concentration levels below 20 ppm, and three of them indicate levels well below 10 ppm. These concentration levels are below the concentration limit in this restriction proposal (100 ppm).

Glutaraldehyde is approved as an active substance for use in biocidal products for product-types 2, 3, 4, 6, 11 and 12. Uses of the substance for biocidal purposes in line with the

approval are exempted from the restriction. However, when used as a tanning agent, the substance is not used for its biocidal properties and is thereby covered by the restriction.

Vegetable tanning agents also exists, but several stakeholders indicate that they are not viable alternatives to chromium based tanning. The stakeholders highlight that vegetable tannages are only retained in uses of heavy leather (strapping and sole leather), because in most other applications chromium tanned leather is considered superior in terms of (e.g.) physical properties, production speed and production costs, environmental impact, performance and versatility. In addition, the supply of vegetable tannages cannot meet the quantities demanded by the market, at least not in the short to medium term.

If the lower concentration limit proposed for chromium VI leads to the fact that chromium cannot be used at all in leather tanning, then tanning based on glutaraldehyde and (to a lesser extent) vegetable tanning methods appear as the primary substitutes. Stakeholders do however indicate that these substitutes result in leathers with markedly different chemical and physical properties and may not be suitable to fulfil the specifications required for many applications. If this scenario plays out substantial consequences for the industry may be realised. The dossier submitter does not however have information to assess these consequences.

E.2.2.9. Normal, good and best practice

A concept often used in KemI (2019) and in connection to this restriction proposal is *normal, good and best practice*. There are no clear cut definitions agreed to by industry and academia as to what is exactly meant by normal, good and best practice. The definitions in KemI (2019) have here been expanded further based on mail correspondence between the Dossier Submitter and the authors of KemI (2019).

In this restriction proposal based on KemI (2019) and based on mail correspondence (with the authors of KemI, 2019), done in connection to this restriction proposal **normal practice** is what the majority does. **Good practice** will in this context indicate that the company in some way go beyond what is normal and initiate steps that further improve human health and environmental quality. **Best practice** would further imply that best available technology is used and that specific process checks are used when needed.

For dyes the following example can be given:

“For example, it is 'normal' to use reactive dyes for dyeing cotton T-shirts and it is considered that most dyers follow 'good' practice in terms achieving good colour fastness.

However most do not follow 'good' practice with respect to efficient use of water and energy.

In this example, 'Good' practice would be to measure water consumption and to establish the minimum amount of water and minimum process temperatures that can be used to achieve good wash fastness on their machinery using standard bleaching and dyeing processes.

Finally, "best" practice would be using the best available technology and possibly specific process checks. This would require investment in low liquor dyeing machines, the use of low temperature enzymatic bleaching, high fixation dyes in a factory that is served by new,

efficient boilers, generators (and possibly renewable energy) with water, heat and even chemical recycling."

Based on mail correspondence with the authors of KemI, (2019) it is argued that the majority of the industry will be sub-normal, normal or good with only a small amount displaying best practice. This indicates that some costs will be incurred by the industry as a whole compared to business as usual if complying with this restriction requires normal, good or best practice.

It is further argued that in principle all industry is capable of good practice, if the standards are stringent enough and the company want to stay in business. The level of control and effort needed from the industry will however depend on the situation and sometimes best practice is required.

The following two examples for dyes and diisocyanates can be given:

Dyes; "For example it only requires "good" practice to avoid the use of a restricted dye. It could even be argued that avoidance of banned dyes is "normal" in the industry and those using them are "sub-normal"."

Diisocyanates; "However if there is a very tight restriction on both 'free' and 'blocked' diisocyanates (I.e. unreacted starting materials) it may require "best" practice to ensure formulations are absolutely correct and curing conditions are perfect in all instances."

***Definitions* of "*best available techniques*" (BAT), as defined in article 3(10) of the IED Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (former IPPC Directive):**

The definition of "*best available techniques*" (BAT), as defined in article 3(10)[41] of the IED Directive, is: "*the most effective and advanced stage in the development of activities and their methods of operation which indicate the practical suitability of particular techniques for providing in principle the basis for emission limit values and other permit conditions designed to prevent and, where that is not practicable, to reduce emission and the impact on the environment as a whole*." *Best* is to be understood as most effective in achieving a high general level of protection of the environment as a whole.

As the best available techniques change over time, the BAT reference document (BREF) is also to be reviewed and updated when appropriate. Such an update is now ongoing for the BREF for the textile industry that has not been reviewed since 2003. But as the BREF are related to the IED 2010/75/EU it only concerns the environmental impacts, perspective and parameters of best practice.

E.2.3. Technical and economic feasibility, and availability of alternatives

In this section the Dossier Submitter presents the assessment of alternatives, with a focus on economic and technical feasibility. The presentation is based on alphabetic order of groups and with a separate section for single substances also in alphabetic order. Most of the information is based on the industry consulted, as reported in KemI (2019) and since Dossier Submitter did not have access to contradicting information, this information was considered

[41] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010L0075&from=EN

as the best available data.Table 18 in the main report also provides an overview and summary on substances information and their substitutability.

E.2.3.1. Assessment of alternatives to diisocyanates

According to the comments received during the public consultation, the concentration level of diisocyanates in consumer articles estimated in KemI (2019) is based on results from the use of inappropriate analytical techniques (please see section E.2.2.1). The actual concentration levels in articles within the scope of the proposed restriction should be considerably lower than the 1000 ppm. The dossier submitter does not have information to further challenge these comments. But if the high levels of diisocyanates in finished products are only due to inappropriate analytical methods used, there is no need for assessing alternatives to diisocyanates.

E.2.3.2. Assessment of alternatives to dyes

Availability

According to the information collected by the Dossier Submitter, available substitutes exist (KemI, 2019).

Information received in the public consultation does however indicate that there are no apparent available substitutes for the following disperse dyes:

- Disperse Blue 291,
- Disperse Violet 93,
- Disperse Violet 1, and
- Disperse Yellow 64.

The Dossier Submitter has not been able to confirm this information. The Dossier Submitter acknowledges that there is a need for further consultation with technical expertise to clarify this issue.

Technical feasibility

Confirmation of the same colour for the substitute is all that is needed according to KemI (2019).

Economic feasibility

No additional cost is estimated for substitutes. This has been confirmed by KemI (2019) study as well as the experts consulted (see Annex G2 for more information). The dyes used as substitutes should on average have the same cost, therefore no costs are estimated to substitute away from skin sensitising dyes.

E.2.3.3. Assessment of alternatives to intermediates

Availability

For 1,3-Isobenzofurandione [phthalic anhydride] with CAS 85-44-9 / EC 201-607-5 or for Benzenesulfonic acid, 3-nitro-, sodium salt (1:1) (with CAS 127-68-4/ EC 204-857-3), no substitutes has been identified.

Technical feasibility

It is assumed that it is not technically feasible to substitute (1,3-Isobenzofurandione [phthalic anhydride], with CAS 85-44-9/ EC 201-607-5) due to its many uses.

Substituting the dye intermediates (Benzenesulfonic acid, 3-nitro-, sodium salt (1:1), with CAS 127-68-4) would need very detailed dialogue with the dye industry and eliminating a single intermediate could affect multiple dyes. Changing any intermediate would change the final dye (KemI, 2019).

Economic feasibility

Given that there are no technically feasible substitutes available, it is not possible to substitute 1,3-Isobenzofurandione [phthalic anhydride] with CAS 85-44-9/ EC 201-607-5, due to its many uses. Cost of substitution has therefore not been investigated further. The cost per metric ton of the intermediate has however been estimated to be €900-1 300 per ton (KemI, 2019).

As explained above, it is most probable that this substance will not be present at point of sale but due to uncertainty, it has still been included in the analysis of alternatives in this restriction proposal. Due to a general lack of information, economic feasibility has not been investigated further for Benzenesulfonic acid, 3-nitro-, sodium salt (1:1), (with CAS 127-68-4/ EC 204-857-3). The cost per metric ton of this intermediate has however been estimated to be €1100 per metric ton. (KemI, 2019)

E.2.3.4. Assessment of alternatives to plasticisers

E.2.3.4.1 Assessment of alternatives to DCHP

Availability

From the ECHA (2017) restriction on phthalates the following is said on substitutes for textiles:

"DINP is used as substitutes for DEHP in table cloths, dinner mats and shower curtains. Other plasticisers than phthalates in use for tablecloth/cover are ATBC, DINCH and DOA in combination with ESBO. Phthalates-free table cloth/covers of PVC film and PVC-coated textile are available on the European market. Plasticisers used include, among others, TBC (tributyl citrate but probably ATBC, often used for PVC for food contact), DINCH, DOA and ESBO. Various alternatives to PVC shower curtains are available at low cost. Many synthetic, woven textiles, for example of polyester, but also plastic film of EVA/PEVA, are marketed. European

retailers are also marketing PVC-free plastic coated table cloths (oil cloth style), for example coated with acrylics (ECHA 2012a).”

Technical feasibility

According to ECHA (2017) substitution is feasible from a technical standpoint.

Looking into the issue of regrettable substitution for the potential substitute acetyl tri-butyl citrate (ATBC) with CAS 77-90-7/EC 201-067-0, 7 out of 1 304 notifications have self-classified the substances as Mutagen. 1B and Carcinogenic. 1B.

In 2016, France concluded in their RMOA on ATBC[42] that there is no need to initiate further regulatory risk management action at this time. ATBC is an alternative to phthalates in various applications, especially in sensitive ones like medical devices or toys. ATBC is not considered as toxic for reproduction and no alert was found on potential endocrine disruption properties, in particular on estrogenic and androgenic activity. However, there is a concern for activation of the PXR pathway but it is currently unclear which adverse effects this may lead to. So, it is not possible to conclude on the endocrine disruptor character of ATBC because there is no solid information on the other ED effects (thyroid). Danish EPA, Swedish chemical agency (KemI) and Ireland agree with France’s conclusions based on the current available data (following ED Expert Group discussions the 2-3 September 2015). In particular, Ireland considers that PXR/ SXR interaction is not endocrine disruption.

Regarding environment, ATBC is not considered as PBT nor vPvB. No alert for endocrine disruptor endpoint has been identified. However, ATBC could be classified as Aquatic Chronic 3 according to CLP if its persistent behaviour would be demonstrated. Contradictory results on aquatic biodegradation suggest an alert regarding P criteria of ATBC and further information would be necessary for clarifications[43].

In the compliance check during dossier evaluation, the registrant has been requested to submit information on pre-natal developmental toxicity studies and *in vitro* mutagenicity studies.

In conclusion, ATBC can therefore work as a better substitute, but the gathered information also point towards some concern.

Economic feasibility

It has not been concluded which substitutes are most suitable for which application. The cost of the phthalates are €3 600-€5 400 per metric ton (KemI, 2019). With regard to the cost of the possible substitutes, only the cost of ATBC (Acetyl Tributyl Citrate with CAS 77-90-7/ EC 201-067-0 (also called Tributyl 2-acetylcitrate)) has been identified at Alibaba website. This substance is used as plastic auxiliary agents, rubber auxiliary agents and is also classified as a chemical auxiliary agent. The cost per metric ton is €1 700 - €2 600.

[42] https://echa.europa.eu/fr/rmoa/-/dislist/details/0b0236e180785866
[43] https://echa.europa.eu/sv/substance-information/-/substanceinfo/100.000.971 (accessed 28 November 2018)

This information, indicates that there are alternatives with lower costs than DCHP. It has however not been possible to assess if quality differences or other apects, such as eventual reformulation costs, will induce substantial costs on the industry.

One comment received in the public consultation refers to a commercial report from IHS that claims that using alternatives to phthalates is more likely to result in higher prices. No quantitative cost estimate was provided. The Dossier Submitter has not been able to confirm or challenge this information.

E.2.3.4.2. Assessment of alternatives to plasticiser for neoprene applications

During the pubic consultation, one stakeholder stated that the identification of EC 202-607-8 (TETD) as a plasticiser is not correct, because neoprene (chloroprene) does not require plasticisation in uses relevant in this proposal. For this reason, the stakeholder concluded that identification of potential substitutes is irrelevant. However the Dossier submitter does not have information to further challenge and check these statements.

Availability

For neoprene applications, the substances dioctyl sebacate, dioctyl adipate, dioctyl phthalate, diisononyl phthalate, may be substitutes.

Technical feasibility

These substitutes are not confirmed substitutes. The industry consulted warns that all of these may be regrettable substitutes due to their hazards (KemI, 2019). The chemical industry needs to be involved even further in order to get a better grip on these substitution issues.

- Dioctyl sebacate: the Dossier Submitter has found that the registrant of dioctyl sebacate (CAS 117-84-0/ EC 204-214-7) has concluded that the substance is not predicted to cause irritation, sensitisation or genetic toxicity. Regarding PBT assessment, the Registrant concluded that the substance fulfils the B criterion but does not fulfil the P and T criterion and has therefore not been classified as a PBT compound within Annex XIII of the REACH Regulation.[44]

  According to Annex III Inventory of the REACH Regulation, the substance is suspected to be hazardous to the aquatic environment.

- Investigation has shown that the substance dioctyl phtalate (CAS 117-84-0, EC 204-214-7) is self-classified as skin sensitiser in category 1 and as reproductive toxicity in category 2. It is further restricted within REACH in concentrations above 0,1% for toys and children articles. It is further according to an Annex III inventory suspected carcinogenic, reprotox, skin allergic and environmentally hazardous[45].

- Dioctyl adipate (CAS 123-79-5/ EC 204-652-9) is self classified as a skin irritant (category 2) and eye irritant (category 2). According to REACH Annex III inventory it

[44] https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/20294 (accessed 28 November 2018)
[45] https://echa.europa.eu/sv/substance-information/-/substanceinfo/100.003.832 (accessed 28 November 2018)

is suspected to be carcinogenic, reproduction toxic, skin sensitising and environmental dangerous[46].

- Diisononyl phthalate (CAS 28553-12-0/ EC 249-079-5) is registered under REACH in the tonnage band of 100 000 – 1 000 000 tons per year. In addition, there is a European Union Risk Assessment Report carried out in accordance with Council Regulation (EEC) 793/931 on the evaluation and control of the risks of "existing" substances. Self-classified in C&L Inventory as 'Not classified' (by 510 out of 513 notifiers), as Acute Tox. 4 (by 2 out of 513 notifiers) and as Aquatic Acute 1 (by 1 out of 513 notifiers). In 2017, Denmark proposed a harmonised classification as a presumed human reproductive toxicant (Repr. 1B). In March 2018, RAC concluded that no classification for DINP for either effects on sexual function and fertility, or for developmental toxicity is warranted. DINP is restricted in Annex XVII to REACH, entry 52, in concentrations greater than 0.1 % by weight of the plasticised material, in toys and childcare articles[47].

Based on this, there is indication from Industry that these substitutes may be regrettable substitutes in one way or another.

Economic feasibility

The cost of the restricted substance Thioperoxydicarbonic diamide, has been found on the trading website Alibaba. The cost is indicated to be € 86 000/metric ton.

The cost of the following substitutes (as an alternative in neoprene production) have also been found on Alibaba website:

- Dioctyl sebacate (DOS) CAS 122-62-3/ EC 204-558-8): the cost of this alternative differs a lot depending on the supplier. The cost interval is €900-€89 200/metric ton.
- Dioctyl Adipate DOA for PVC plasticizer (used as plastic auxiliary agents, rubber auxiliary agents), the cost of this alternative is €2 100-€2 500/ metric tons (purity 99.5%)

These substitutes are not confirmed but only indicated by the industry consulted and as stated above, they are claimed to be regrettable substitutes based on other risk factors and health end points. As far as economic feasibility, the costs are lower for the substitutes as can be seen above, but quality differences is not known.

E.2.3.5. Assessment of alternatives to rubber accelerators

Availability

No alternatives are available, but reformulation is possible according to consulted rubber expert (see Annex G for further details).

[46] https://echa.europa.eu/sv/substance-information/-/substanceinfo/100.004.231 (accessed 28 November 2018)
[47] https://echa.europa.eu/sv/substance-information/-/substanceinfo/100.044.602 (accessed 28 November 2018)

Technical feasibility

Reformulation is required to reduce the concentration of the restricted rubber accelerators in the finished articles. It is however technically possible to reformulate and substitute according to the rubber expert consulted. Reformulation can be relatively easy (a few days work in lab) or very hard with for example a year of work in lab by team of experts, process optimization and other changes in factory and demanding certification process. However an easier reformulation process may be more probable for textile application as compared to other application for industrial use.

Economic feasibility

According to the rubber expert, the cost of the substitutes will not be a big issue since they will be a very small share of the total cost of production. The rubber expert estimates that they may be less than one percent of the material costs, with the material cost itself being a very small share of the total production cost. The cost of the rubber accelerators are however in a wide range. The cost interval for the whole group of rubber accelerators is in the range of €900-€89 200 / metric ton (KemI, 2019).

The larger cost will instead be the reformulation costs. Reformulation can according to the rubber expert be both quite easy and also relatively hard:

- For the easy cases the rubber expert estimates a couple of days in the lab (with for example a chemical engineer) and then some simple tests in the factory.
- For the very difficult reformulation cases one year work cost and then substantial changes in processes in the factory can be expected followed by certification and other quality related costs.
- It is however expected that the reformulations connected to textile applications are of the easier kind (since for example certification costs do not exist).

Based on the calculations in Annex E.2.2., it is estimated that the total cost per reformulation is reformulation cost is €13 300 /reformulation. It has however not been possible to estimate the number of articles that need reformulations due to this restriction proposal, at this stage (better information might arrive through the public consultation).

It is however not possible to know in beforehand if the reformulated substitutes are better for consumers with regard to skin sensitising. Reformulation costs can therefore turn out to be sunk costs with some unknown probability.

E.2.3.6. Assessment of alternatives to rosins

Note that the public consultation has not brought any information on occurrence of tall oil rosins in articles within the scope of this restriction proposal.

Availability

Substitution with other binders such as acrylics and polyurethanes may be alternatives. Referring to acrylics, according to one comment received from the public consultation there are countless commercial grades of acrylic resins with adhesive properties.

Technical feasibility

There is however a concern from the industry consulted about regrettable substitution for these alternatives, which would need further investigation according to KemI (2019).

Looking into the issue it may be suspected that the acrylic monomers may be regrettable substitute, according to the industry consulted (According to the comments received during the public consultation, acrylics monomers are generally corrosive or sensitising, and technically can not be used as glue).

KemI (2019) does not specify which acrylics might be the most suitable substitute. One acrylic with problematic properties is ethyl 2-cyanoacrylate (CAS 7085-85-0/EC 230-391-5). This substance is both Skin Irrit. 2, Eye Irrit. 2 and STOT SE 3[48].

Another of the possible acrylic substitutes with CAS 79-10-7/ EC, 201-177-9 is classified as strongly corrosive (Skin Corr. 1A).[49]

Based on industry consulted, this indicates that the acrylics may be regrettable substitute.

Economic feasibility

The cost of the restricted substance and the substitutes are quite similar (somewhat lower) for one substitute (adhesion styrene acrylic emulsion binder) and somewhat higher for the other substitute (PUR/hot melt pu adhesive/polyurethane) as can be seen below.

The cost of the rosins themselves is in the range of €1 300 - €3 100 per metric ton for the tall oil rosin and €1 300-€1 800/metric ton for the “other” rosin.(KemI, 2019)

As an example, substitution cost for PUR/hot melt pu adh/polyurethane reactive is in the range of €3 100 - €4 400/metric ton[50].

Substitution cost for adhesion styrene acrylic emulsion binder for fabric coating is in the range €900-€1 300/metric ton[51].

During the public consultation, one stakeholder confirmed that polyurethane binders may also be suitable but are known to be more expensive than acrylic ones. If both substitutes are suitable, the dossier submitter would expect that the industry would rather replace rosins by acrylics binders than with PUR (all else equal).

E.2.3.7. Assessment of alternatives to solvents

Availability

No substitutes have been identified in KemI (2019), but information indicates that best practice might reduce the concentration limit in articles at point of sale below the restriction

[48] https://echa.europa.eu/sv/information-on-chemicals/cl-inventory-database/-/discli/details/107550 (accessed 28 November 2018)
[49] https://echa.europa.eu/sv/information-on-chemicals/cl-inventory-database/-/discli/details/110237 (accessed 28 November 2018)
[50] www.alibaba.com
[51] www.alibaba.com

limit. This is however not confirmed. Confirmation and better information for this is therefore asked for in the public consultation process.

Technical feasibility

KemI (2019) states that specific knowledge of which formulation the solvent (and / or intermediate) is present in, is necessary in order to make any practical suggestions on alternatives. Solvents are used to dissolve materials (or sometimes act as a carrier for insoluble materials) and they adjust the rheology. It is also necessary to have information on where in the production chain the solvent is used. Some of the solvents are deliberately used by formulators (it is in general easier to substitute these deliberate usages) and others carry over from upstream synthesis. (KemI, 2019). More information is therefore needed in order to assess alternatives. It is suggested in KemI (2019) that a dialogue with the chemical industry should be initiated to discuss the presence and use of solvents in formulations. It is by the dossier submitter suggested that such a discussion is organised in the public consultation process.

Economic feasibility

The cost of substitution is therefore not clear for these substances. The cost of the substances themselves have however been identified. Depending on which type of solvent (intermediate), the price per ton ranges from € 900 /ton to €44 500 /ton (see Table 18 of the main report for details or KemI, (2019)).

ECHA suggests that best practice can result in articles where solvents are not present in articles at point of sale, this should also be checked with the industry during the public consultation for better certainty, since it is only an indication at the moment. The cost for this has however not been estimated[52] .

As reflected in section E.2.2.8, information has been submitted during the public consultation on the solvents identified as found in the finished articles of the scope: Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4S)-, LIMONENE and Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4R)- [r-limonene are claimed to be used as fragrances only in cosmetics and not as solvents (limonene could be used as solvent in washing agents but estimated amount on article due to physical properties should be very LOW); 1,2-Ethanediamine, N1-(2-aminoethyl)- [diethylene triamine] is an intermediate in chemical synthesis, and in rare cases it is used to neutralize solutions for ph-adjustment (residuals in articles are predicted LOW); If this would be confirmed, the analysis of alternatives for solvents may be not relevant. However the dossier submitter does not have information to further challenge or check these comments.

E.2.3.8. Other substances

E.2.3.8.1. Assessment of alternatives to Benzenamine (aniline)

Availability

[52] 2019 Dossier Submitter's personal communication

As explained above, Benzenamine (aniline) is said to be used in the dye manufacturing of synthetic indigo. Regarding substitution for indigo, there are a couple of replacements but these are not feasible given the size of the denim industry.

Technical feasibility

Technical feasibility has not been assessed due to lack of data. Better data may arrive in the public consultation. The concern for this substance was raised very late after the end of the deadline for the questionnaire sent by the Dossier Submitter to industry (see Annex G for more details). Therefore, information may exist that has not been made available to the Dossier Submitter.

Economic feasibility

The price per metric ton for Benzenamine is estimated to be € 1 300 – € 1 400 (KemI, 2019). Economic feasibility with regard to alternatives has however not been further assessed due to lack of data**.**

E.2.3.8.2. Assessment of alternatives to metals (cobalt), inorganic compounds

Availability

Other acid dyes may be substitutes for cobalt dyes used in wool and nylon, but this is uncertain according to KemI (2019).

Regarding nickel, no information has been found by the Dossier Submitter on substitutes. This might be because nickel is used to a low degree, but this is regarded as an uncertainty and new information may arrive during the public consultation.

Technical feasibility

Technical feasibility is uncertain according to KemI (2019) and confirmation by industry is needed in order to assess if pre-metallised dyes with cobalt have some special properties, which will be lost in substitution.

Economic feasibility

No cost data has been found by the Dossier Submitter.

E.2.3.8.3. Assessment of alternatives to formaldehyde

Availability

Formaldehyde-free substitutes exists for a number of applications. The industry needs to confirm which are most suitable. For textiles some substitutes are identified (see above section E.2.2), but not for leather at this stage. The public consultation has not provided any input to cover the identified information gaps.

Since no specific information on substitutes to formaldehyde with application to leather exists, the Dossier Submitter assumes that polycarbolic acid, which has been identified as a

substitute for textile applications according to Chemsec 2019 Guide[53] can also be a potential substitutes for leather.

Technical feasibility

The quality of the substitutes may be of lower quality for textiles according to KemI (2019). However Polycarboxylic Acid is identified as a substitute for textile application (Chemsec 2019 Guide).

It is also clear that additional washing can remove formaldehyde from textile. Confirmation is needed to assess if this is also a viable method for leather, hides and fur in cases where substitutes are hard to find.

Economic feasibility

The cost difference between formaldehyde at € 400-€ 600 per metric ton (37% purity) (KemI, 2019) and the potential alternative Polycarboxylic Acid "Superplasticizer" (40% purity) available at € 700- € 1100 per metric ton[54] gives an indication about the cost of substitution, with regard to price difference for the chemical at € 400 / metric ton on average, all else equal. It should however be kept in mind that this substitute is used for textile applications only. Due to the lack of better information this is used as an approximation of the cost of alternatives for leather applications as well.

E.2.3.8.4. Assessment of alternatives to tanning agents (Glutaraldehyde and Chromium)

Availability

As presented above under section E.2.2.9.4, according to the chromium VI (2012) restriction proposal the following substitutes to chromium III exist: Glutaraldehyde, mineral tannages (aluminium, titanium, zirconium salts), oil tannage, synthetic tannage (resin –syntans) and vegetable tanning.

It would then follow that mineral tannages (aluminium, titanium, zirconium salts), oil tannage, synthetic tannage (resin –syntans) and vegetable tanning are substitutes for glutaraldehyde.

Technical feasibility

The substitutes do not, according to the chromium VI (2012) restriction background document, result in leather with the same quality properties as chromium tanned leather. They are therefore not technically equivalent. This conclusion is supported by comments provided by stakeholders in the public consultation.

Based on an overall comparison, the chromium VI (2012) restriction background document states that aldehyde (glutaraldehyde) is the main substitute to chromium III.

[53] http://textileguide.chemsec.org/find/textiles-come-with-a-toxic-footprint
[54] Alibaba.com

Wet white tanning, which is used in the automobile industry and where glutaraldehyde is often used, is preferred over chromium for these applications since the leather has less tendency to shrink.

According to comments received in the public consultation, the occurrence of elevated levels of chromium VI can be avoided by several process adjustments, such as:

- not using natural products such as fish oils that heavily influence chrome VI formation,
- employing vegetable tanning and retaining agents,
- properly adjusting pH values in neutralization,
- avoiding ammonia as a wetting agent before dyeing and instead, use agents with reducing abilities, and
  having a higher moisture level during storage.

Economic feasibility

It appears that glutaraldehyde (€1 600 per metric ton) is the main substitute to chromium III, when considering both economic and technical feasibility. Chromium III is however considered to be a more simple and cost-effective tannage.

Economic feasibility of glutaraldehyde has not been assessed in detail. The background document for the current chromium VI restriction in leather refers to a 2011 report from TEGEWA that claims that leather based on glutaraldehyde tannage is on average 2-6% more expensive than chrome tanned finished leather.

It would appear that vegetable tanning agents cannot with regard to volume substitute chromium. This may lead to large investment costs if supply is to be increased substantially, since new land may be needed to be cultivated with vegetable tanning trees. Other investment costs may also follow if supply is to be increased substantially. It is also assumed that vegetable tanning is more expensive even without a need to increase the supply substantially.

E.3. Restriction scenario(s)

The three restriction scenarios further assessed out of eight, and presented in section 2.2.1 of the main report, differ mainly in terms of substances included in the scope and the concentration limits proposed. Therefore, RO1a, RO2 and RO3 impacts will differ in terms of risk reduction capacity, substitution costs, enforceability and impacts on industry. The following sections focus on the impacts of RO1a (the restriction proposed).

E.4. Economic impacts

E.4.1. Substitution cost

Substitution costs include the cost related to complying with the limits set for the finished article at point of sale. It includes the replacement of skin sensitising chemicals with alternatives without skin sensitising properties (and ideally with general better hazards profile for human health and environment). It also includes changes/improvements in the production process, both for the recipe and the formulation of the chemicals as well as in the curing steps and inclusion of potential after washing before articles reaches point of sale. Another cost of substitution which has been identified in some cases is reformulation costs. These costs are in part discussed in the assessment of alternatives above for the different chemicals and

chemical groups. They are however for the convenience of the reader also summarised here based on the type of cost. Table 18 in the main report provides an overview and summary on substances information and their substitutability.

E.4.1.1. Cost of substituting to alternative chemical substances

The Dossier Submitter's analysis of the cost of substitution to alternative non-skin sensitising chemicals indicates that the cost of the new chemical themselves will in the cases where (possible) substitutes have been identified not be an insurmountable economic burden for the industry as a whole. This can be seen in Table 18 in the main report for the different substances, where it can be shown that the cost/weight unit for the alternatives is similar to the cost/ weight unit for the substances used today for most substances (and targeted to be restricted). The economic and technical feasibility of the different substances is also analysed and described per substance (group) in more detail in section E.2.3. above. A total cost calculation for the substances (where data exists on both the cost per metric ton of the chemical used and the cost of the alternative) is also included in section E.4.1.5. From the total cost analysis it can be seen that the total costs is dependent on both the cost difference between the chemical used and the proposed alternative, as well as on the total volume used in textile and leather production of the chemical in need of substitution.

E.4.1.2 Costs related to reformulation, research and development

At the moment, reformulation needs have been identified for a number of rubber accelerators. To assess these costs a rubber expert connected to the consultant firm "Lysmask Innovation AB" has therefore been involved in the review of these substances.

According to the rubber expert, substitution should be no problem, but it will be hard to say on beforehand which the substitutes will be and if they will be less problematic from a skin sensitising perspective. This follows from the fact that a reformulation process will be needed for substitution. Moreover, several of the identified substances are also connected to work-related hazards and it is therefore suspected that a substitution process is already ongoing, primarily to reduce occupational exposure. Work-related hazards are not covered in this restriction proposal, but reducing such problems is of course a bonus, all else equal.

The cost of the substitutes in €/kg may not be a major issue since they will be a very small share of the total production cost. The expert consulted estimates that they may be less than one percent of the material costs. The material cost is in itself estimated to be a small cost of the total production cost.

The larger cost will instead be the reformulation costs. As described in section E.2.2.6, each reformulation will cost approximately €13 000.This is however only an estimate based on a number of assumption and best available data, and the Dossier Submitter has not been able to get this information at first hand from the industry. Additional data provided during the public consultation process may therefore improve this approximation of cost per reformulation.

The number of products which will be in need of reformulation due to this restriction proposal has not been possible to estimate at this stage (and that is needed in order to calculate the total cost of reformulation). The Dossier Submitter hopes to improve on this information gap as well during the public consultation.

It is further assumed that the industry in a business as usual scenario would reformulate products even without a restriction proposal with some frequency. This has also been confirmed by the rubber expert among other actors consulted when drafting this restriction proposal. Discussing the reformulation frequency with the rubber expert, it is however clear that reformulation frequency can differ a lot depending on company strategy and products. For some mature products, a new reformulation is not done during the products life range. For other companies (and other product types) both regulatory driven and cost driven reformulations are business as usual practice. Regarding the product type in question for reformulation due to this restriction, “accelerators for vulcanized rubber”, the rubber expert states that reformulation will not be done without external demands in a business as usual case. Therefore the Dossier Submitter has to assume that the companies are bearing the full cost of reformulation due to this restriction proposal and that reformulation would not have been done in a long time span without this restriction proposal.

It is however not possible to know in beforehand if the reformulated substitutes would be better for general population with regard to skin sensitising or other human health endpoints, according to the consulted rubber expert. Reformulation costs can therefore turn out to be sunk costs with some unknown probability.

In Annex E.4.1.6. a simple sensitivity analysis is conducted, where the number of reformulations is included. This is done based on assumptions about the number of reformulations in order to problematise and discuss about the potential total cost of reformulation connected to rubber accelerators. Better information from industry about the number of reformulations is however needed in order to improve the assessment.

Reformulation might also be needed for other substances, but that has not been clarified or indicated to the Dossier Submitter.

E.4.1.3 Production process changes incurred when moving towards best practice (including possible investment costs for new machinery)

KemI (2019) indicates that diisocyanates may be present in consumer articles in concentrations up to 1000 ppm. According to comments received during the public consultation on this restriction proposal, this statement is based on results from the use of inappropriate analytical techniques. The actual concentration levels in articles within the scope of the proposed restriction are claimed to be considerably lower than 1000 ppm, and should not be found in concentrations above 10 ppm. The Dossier submitter does not have information to further challenge these comments. In case new information that challenges the comments received during the public consultation emerges, then a move to best practice would be needed to ensure compliance to the proposed restriction.

According to the information collected, no substitutes exist for diisocyanates. However if best practice is used, with correct amount of ingredients, catalysts, high enough curing temperatures and potential washing afterwards, the chemicals should not be present in articles at point of sale (KemI, 2019). As is discussed in section E.2.2.9. above it is assumed that most companies follow subnormal, normal or good practice and only a minority follows best practice. It has not been possible to get data on the cost of moving towards best practice for diisocyanates despite both a questionnaire contact and consultants’ enquiries (see Annex G for a detailed description on the efforts made).

Indications from ECHA suggest that similar best practice improvements might be a way forwards for solvents[55]. This has however not been confirmed by industry or any other available information.

E.4.1.4 Groups and substances where substitution has not been identified as technical feasible, or where substitution cost has not been identified

For a number of substances, there is a lack of information on alternatives or the identified substitutes are considered as regrettable by the industry consulted. For these substances, more information is needed during the public consultation process in order to take the analysis further. For a summary of these substances, see Table 18 in the main report.

For cobalt there is a lack of information on all parameters. For the intermediates and the solvents, substitution has been considered to be technically not possible due to their many uses, (but indications give that solvents can be solved by best practice, but that is not confirmed).

For chromium VI, as an oxidation product of chromium III tanning, it is indicated that a stricter limit could be a problem. Glutaraldehyde has been identified as a substitute, but several comments in the public consultation indicate that it is not a feasible alternative to chromium in all applications. According to the pubic consultation, the concentration of glutaraldehyde in leather articles at point of sale is below 20 ppm (see Table 19), thus it can be considered that the industry could comply with the proposed concentration limit for glutaraldehyde in leather (40 ppm).

For Benzenamine (aniline) the information is inadequate since it was recognized very late in the process by industry. But according to KemI (2019), Benzenamine (used for synthetic indigo) is hard to substitute and no possible alternative is identified that can be used for the large volumes needed.

For a summary of all analysed substances, including those where there is a lack of information, see Table 18 in the main report. For the cases where information on price and volumes used exist for substances used as well as alternatives, a total cost assessment is made below in Annex E.4.1.5.

E.4.1.5 Total substitution cost estimates for substances where cost data are available

For those substances where cost data was made available to the Dossier Submitter for both the substances used and for the proposed alternatives, total costs with regard to cost difference between chemical used and the alternative, can be calculated based on the estimated volumes used for textile and leather applications. This is per definition an incomplete picture of the total cost of substitution since the analysis assumes that all other factors are held constant (due to lack of information on those). In this all else equal analysis the Dossier Submitter therefore assumes that volume used of the chemical is unchanged between the chemical used and the alternative, the Dossier Submitter also leaves quality changes out due to lack of information. It is also possible that process optimisation in factories or even investments in new equipment can be needed, but at the moment the Dossier Submitter does not have such indications and therefore a total annual cost of substitution with regard to the price difference of the chemical used and the proposed alternative is

[55] 2019 DS personnal communication

presented. The degree of uncertainty in these assumptions and analysis made is not known, but it is assumed that costs may be underestimated somewhat.

Based on Table 19 in the main report, it can be seen that the total costs are largest for rosins, with a total cost of substitution (only with regard to the price difference between the chemical used and the alternative) at €23.7 million per year if the substitution of rosins is made with polyurethane binders. However, according to the public consultation, polyurethane binders may also be suitable but are known to be more expensive than acrylic ones. If both substitutes are suitable, the dossier submitter would expect that the industry would rather replace rosins by acrylics binders than with PUR (all else equal). In that case, if the substitution of rosins is made with acrylic binders, the cost of substitution of rosins (only with regard to the price difference between the chemical used and the alternative) would be around - €5 million per year.

For formaldehyde a total cost of substitution of €126 000 per year is estimated.

For dyes no additional costs are expected for substitution since price and function should be comparable on average.

The cost that stands out the most is the total cost for plasticiser for neoprene, which is a negative cost, since the alternative is approximately €40 950 cheaper per metric ton on average, than the substance used. From a revealed preferences point of view it seems unlikely that the market would not have chosen the cheapest substitute unless there is some hidden cost, not observed by the Dossier Submitter (which may be the reason why industry is using the seemingly more expensive chemical). This is however only speculation and the industry needs to give some feedback in this negative cost issue.

The same concern exist for phthalates, where the costs of substitution also is negative due the fact that the substitute is around €2 750 cheaper per metric tonne.

Including both of the negative costs gives a **negative total cost of substitution** for all of the chemicals in table 19 of the main report, where cost data exists for both the substances used and the proposed substitute at around - **€ 25 million per year (if rosins are substituted with acrylics) or 3 million € per year (if rosins are substituted with PUR).** The negative cost of € -25 million may be anticipated to be an underestimation of the cost of substitution connected to this restriction proposal. **Excluding the negative costs gives a total cost of around 0.1 million € per year (if rosins are substituted with acrylics) or 23 million € per year (if rosins are substituted with PUR).**

For the rubber accelerators where the cost difference between the substance used and the alternative is estimated to be similar but where reformulation is anticipated a sensitivity analysis is done in Annex E.4.1.6. below.

E.4.1.6. Total reformulation cost estimates for rubber accelerators

For rubber accelerators an estimation of the cost per average reformulation has been estimated in Annex E.4.1.2. to be €13 300/reformulation. From this analysis it is however clear that the number of reformulations needed is not known despite consulting rubber experts, experts on textile, as well as a general questionnaire and a call for evidence (see Annex G for details). In order to get a better understanding for the potential magnitude of these costs a simple sensitivity analysis is conducted where a high low and medium number of reformulations is assumed. The products most likely to be affected are rubber coated

textiles and the number of reformulations assumed is 100 reformulations for the low case, 1000 reformulations for the medium reformulation case and 10 000 reformulations for the high reformulation case. These numbers are however only a guess and the industry needs to contribute if this is to be improved.

Table 29: Total cost estimates of substitution between restricted rubber accelerators and alternatives (based on assumed number of reformulations)

	Total cost of reformulation, low assumption with 100 needed reformulations.	**Total cost of reformulation, medium assumption with 1 000 needed reformulations.**	**Total cost of reformulation, high assumption with 10 000 needed reformulations.**
Rubber accelerators, cost per reformulation estimated to be €13 300/reformulation.	€1 330 000	€13 300 000	€133 000 000

For the cost assessment performed in section 2.4.1 of the main report, it is assumed that the medium scenario is most likely, and the total cost of reformulation would amount to approx. €13.3 million (one time cost). The industry however needs to give feedback during the public consultation on the assumption regarding the number of reformulations in order to improve.

E.4.2. Testing and enforcement costs

In this section, the associated administrative costs for testing and enforcement that will be incurred by industry and enforcement authorities in order to ensure compliance with the restriction are assessed.

Initially it has to be noted that there are many uncertainties related to testing costs. The most important ones identified by the Dossier submitter are:

- the costs per test,
- the number of articles on the EEA market to be tested,
- the frequency of test required from companoes to establish compliance,
- which chemicals of the scope are already tested routinely by companies, either due to existing regulations or due to various voluntary schemes, and
- how many of the affected companies are already testing substances in the scope proposed restriction.

The Dossier submitter has assessed the costs per test (see section E.4.2.1) and made some assumptions on the number of additional tests that will be performed annually. As explained in the main report (section 2.4.1.2), these assumptions are however very uncertain.

The public consultation brought very limited quantitative information. Information on the costs per test provided in the public consultation are in line with the Dossier submitters assessment. The public consultation does however indicate that other assumptions made by the Dossier submitter leads to an underestimated of the total testing costs.

Overall, the very limited information at hand does not allow for a proper assessment of testing costs. More information would be needed.

E.4.2.1. Assessment of costs per test

These costs are indicative costs to individual enforcement authorities and to individual companies and do not represent the aggregated EU wide costs for all substances within the scope of this restriction proposal. The testing costs depend on how the tests are set up and if substances have to be extracted from materials. In many cases the leather material is more time demanding to test.

Four laboratory associations (see Section G) as well as the enforcement unit at the Swedish Chemicals Agency were consulted to get information on testing costs. In the testing costs below the costs for a written report is included. The costs for testing and enforcement vary depending on the number of tests to be conducted. A discount of 10% can for instance be given for tests of more than four materials/analysis and a 20% discount for seven or more materials/analysis. This indicates that there are considerable economies of scale in testing.

A quantitative analysis for all substances is not offered by any of the laboratories that the Dossier Submitter has consulted. A non-quantitative GC-MS screening of material is however offered. The substances that can be detected in such a screening, if present, are the substances that are leached from material with the chosen extraction method/solvent.

The consulted laboratories mainly conduct ISO, EN or DIN based tests. If required these laboratories can also develop new methods for testing, the costs for these tests will be higher than for standardised methods.

The detection limits vary from laboratory to laboratory depending on the analytical instrument used. The quantification or detection limits are specific for the laboratory where the tests are conducted as well as specific to the information used at that laboratory. The LoQ should in any case be under the required/set limit (For further information regarding the detection limits please see the Master List, Table 19 above).

Disperse dyes

Test methods used for disperse dyes in textiles are many. The method applied for most of the disperse dyes used in textile is OEKO-TEX method/LoQ 50 mg/kg. Another method used is ISO 16373-2:2014. This method specifies the analyses used to detect extractable dyestuffs in textile products, with the extraction performed for all kind of fibers and types of dyestuffs using pyridine/water (1:1). It lists the allergenic and carcinogenic dyestuffs which can be analysed using this method. The lists of dyestuffs are expandable. Another method used is DIN 54231.The laboratories consulted when preparing this restriction proposal did not have full capacity in order to test all of the listed dyes of the scope. Some of the dyes are unknown to these laboratories and for others it is not possible to test salts.

One laboratory that provided information regarding costs for testing parts of the group of disperse dyes in textiles indicate that the testing cost is around €260/material[56]. [57]. In this test all substances on the list are tested. If several materials/samples are to be tested at the

[56] Dossier Submitter's personal communication, 2018.
[57] Dossier Submitter's personal communication, 2018.

same time, as a discount is given. Another source consulted by the Dossier Submitter indicated a cost of €70/material[58].

Testing disperse dyes using the test method LC-MS would cost approximately €50[59]. The costs can vary depending on the service provider and the number of tests to be conducted.

Chromium

The testing cost for the extractable chromium analysis in textile articles within the scope of this restriction proposal is about €250/material. For total chromium the cost for testing is about €260/material. For chromium VI in leather the costs are about €240/material[60].

Usually, with respect to textiles, either total Chromium or Chromium (VI) tests are applied. The cost associated with total Chromium or Chromium (VI) vary depending on the specific test to be run. Total chromium is analysed using ICP-OES and costs are around €20 while Cr (VI) cost about €26/material[61]. Another source consulted by the Dossier Submitter indicated a cost of €70/material with method EN ISO 17075[62].

Phthalates

Two ISO standards that specifies methods to apply when determine the presence of phthalate compounds are ISO/TS 16181:2011 (applicable to all types of footwear materials) and ISO 14389:2014 (applied when determining phthalates in textiles with gas chromatography-mass spectrometry (GC-MS) with mass selective detector). It is applicable to textile products where there is a risk of the presence of some phthalates.

For phthalates in textiles the analytical methods OEKO-TEX, ISO 14389 method /LoQ 100 mg/kg (and method/LoQ10 mg/kg from 2019) are applied. The costs for testing are about €260/material[63].

Besides, based on Dossier Submitter's personal communication with experts, a cost for testing the presence of phthalate compounds was indicated to be about €134/material[64].

Cobalt

For Cobalt in textile and leather the method applied for extractable cobalt is OEKO-TEX method (ICP detection) with ISO 105-E04 extraction method, LoQ 0.3 mg/kg. The cost for testing is €250/material[65]. Another source consulted by the Dossier Submitter indicated a cost of €100/material for heavy metals (Co, Cd, total Cr and Pb) with EN ISO 17072-266.

[58] Dossier Submitter's personal communication, 2017.
[59] Dossier Submitter's personal communication,, 2018.
[60] Dossier Submitter's personal communication, 2018.
[61] Dossier Submitter's personal communication, 2018.
[62] Dossier Submitter's personal communication, 2017.
[63] Dossier Submitter's personal communication, 2018.
[64] Dossier Submitter's personal communication, 2019.
[65] Dossier Submitter's personal communication, 2018.
[66] Dossier Submitter's personal communication, 2017.

Formaldehyde

For formaldehyde in leather and textile the costs for testing with the method DIN EN ISO 14184-1 for textiles (EN ISO 17226-1 for leather articles)/LoQ 16 mg/kg is € 145 as a basic fee plus an additional cost of €165/material[67]. Another source consulted by the Dossier Submitter indicated a cost of €80/material for textile or leather[68].

E.4.2.2. Assessment of total testing and enforcement costs

It is foreseen that the enforcement costs per test for authorities could be higher than for the concerned companies. The total enforcement costs are estimated to be higher than average for a REACH restrictions since the number of substances required to be tested are much higher than for a regular restriction. However as can be seen in Table 30 below the kind of substance that needs to be tested may have a higher impact on the testing and enforcement costs than the actual number of substances that needs to be tested as the cost for testing/material vary.

As a result of the proposed restriction both industry and enforcement authorities will need to perform additional testing in order to ensure the compliance. The extent of these additional required testing that needs to be performed compared to the testing already undertaken is not known. For industry it is however assumed that these costs would not outweigh possible gains for alternative suppliers due to surplus from marketing alternative substances. To some extent the existing quality control testing performed by the concerned companies may already provide the necessary information. In general, the costs are not expected to outweigh the overall societal gains.

In general, companies would commission standard laboratories for testing the levels of the concerned substances. It is assumed that only a minority of companies would invest money in in-house laboratory devices. According to our information standard laboratories are already equipped with suitable devices for testing most of these substances and prices are not expected to change as a result of this restriction proposal. It is therefore assumed that the additional costs for testing are most probably affordable and of minor importance to the concerned actors compared to the overall costs of the restriction.

For enforcement authorities, testing costs might be of higher importance. A higher burden and cost for testing compliance could result in that less enforcement activities and control is in fact conducted.

Based on the price information from consulted laboratories on the substances within the scope of this restriction the cost of testing is estimated to be somewhat higher than for an average restriction since it includes far more substances than on average. But as already been mentioned above and as can be seen in Table 30 below the final actual cost for testing will in the end be more depending on the actual substances that needs to be tested as the costs for testing vary depending on the substance.

In the table below the testing costs are calculated based on the information provided by various laboratories. As the information about cost/test vary a low, high and best estimate have been estimated.

As indicated in the opening remarks of Annex E.4.2. there is considerable uncertainty regarding the number of additionsal tests that will be done due to the proposed restriction.

[67] Dossier Submitter's personal communication, 2018.
[68] Dossier Submitter's personal communication, 2017.

The number of tests in Table 30 are only indicative. More information would be needed for a more accurate assessment of testing costs.

Table 30: Total testing cost estimates for companies and authorities expected from the restriction

Substance group	**Cost for testing in €/material**	**Number of tests/year during the first couple of years**	**Cost for testing in €/test**	**Cost for testing in €/year during the first couple of years**
Phthalates	134-260	Low=50, High= 150, Best Estimates = 100	Low=134 *50, High= 260* 150, Best Estimates=158*100	Low=6 700, High=39 000, **Best=15 800**
Disperse dyes	50-260	Low=50 , High= 150, Best Estimates =100	Low =50*50, High = 260*150, Best Estimates=100 *260	Low=2 500, High=39 000, **Best=26 000**
Cobalt	100- 250	Low= 50 High=150, Best Estimates = 100	Low= 100*50, High=250*150, Best Estimates= 140*100	Low=5 000, High=37 500, **Best=14 000**
Formaldehyde	80 - 145 + 165	Low=50, High=150, Best Estimates= 100	Low=80*50, High=310*150, Best Estimates= 200*100	Low= 4000, High=19500, **Best=20000**
Chromium	20-250	Low=50, High=150, Best Estimates = 100	Low=20*50, High=250*150, Best Estimates=70*100	Low=1000, High=37500, **Best=7000**
Rubber accelerators	€62,00 ?	100	too uncertain data	
Rosins	€62,00 ?	100	too uncertain data	
Tall rosins	€62,00 ?	100	too uncertain data	
Plasticiser for neoprene	€62,00 ?	100	too uncertain data	
Total (best estimate)				**€82 800/year**

* source: Dossier Submitter's personal communication with the inspections unit at the Swedish Chemicals Agency, November 2018; the low, high and best estimates are based on cost provided by experts and available information.

The best estimates of the testing costs for the four groups of substances in the bottom of the table 31 above (for which no other information is available) could have been performed based on the testing costs per substance that the enforcement authorities can have for testing of each additional substance, i.e €62 (based on information from the Swedish Chemicals Agency's own experience). However, the Dossier Submitter considers that there is too much uncertainty to use it for calculating the testing costs.

With regard to information submitted by some consulted laboratories saying that a discount of 10% is given when testing >4 materials/test and a discount of 20% is given when testing >7 materials/test, the costs in the table 31 above are most certainly overestimated.

In the main report a comparison to the testing costs for the tattoo inks and permanent make-up in the restriction proposal from 2017 is made based on the following assumptions and data (see Main report, section 2.4.1.2) .

Table 31: Assumptions and data used for the estimates of testing costs (based on tattoo inks and permanent make-up restriction proposal)

Tattoo inks and permanent make-up (restriction proposal from 2017)	**Textile and leather articles (present restriction proposal)**
Number of substances:	Number of substances:
4130	~1000
Number of tests/year:	Number of tests/year:
100	100
Cost:	Cost:
€500/sample	€500/sample
EEA22:	EEA22:
Annual average incremental cost	Annual average incremental cost
€200 000	€48 000

In the restriction dossier for tattoo inks the testing costs for compliant tattoo inks per year were reported up to €80 000 (that were the costs for manufacturers testing of input materials in order to meet national regulations or to ensure compliant products) and 24%[69] of €80 000 would result in €19 200/year for this restriction proposal for textiles and leather articles. If extrapolated to EEA31 (and assumed that the costs per MS would be the same) the costs for testing for compliance per year would be €27 055.

Other costs

Some of the other costs that industry may face if this restriction is implemented could be the cost associated with transportation, packaging and dispatch from one country to another. These costs are however not expected to be changed as a result of this restriction proposal and are therefore not assessed in this restriction report.

[69] 1000 substances/4130 subtances = 24%.

E.4.3. Uncertainty aspects connected to the Analysis of Alternatives

Several uncertainty factors may affect the assessment of alternatives done in chapter E.2.2. and E.2.3.

On the one hand, there are uncertainties related to the methodological approach which is used to include or exclude substances for the SEA (and the rest of the restriction). Firstly substances may have been missed in the original search done by the Dossier Submitter. Secondly the estimation of the mg/kg limits done by KemI (2019) can be an over- or underestimation since it is based on assumptions and best available knowledge (which they themselves also discuss). This can in turn lead to the inclusion or exclusion of substances if/when the estimated mg/kg limits are reassessed once better information arrives during the public consultation process. It is hard to estimate the magnitude of this uncertainty but the Dossier Submitter does anticipate that a restructure of the estimated mg/kg limits can occur due to new and better information during the public consultation process. This will in turn lead to an inclusion and exclusion of the substances for which the restriction proposal will be binding or not.

On the other hand, there is an uncertainty as to how the dynamic connection with CLP will evolve (see section 1.1.4.3 in the main report). In cases where newly identified substances, which are found after the implementation of the restriction proposal, with a harmonised classification as skin sensitiser and with a concentration level for articles at point of sale, above the allowed, do not coincide with the groups and substances analysed in the SEA, additional analysis may very well be needed in order to assess the costs and benefits (and risk) of new substances. However, the consequences of this uncertainty are difficult to anticipate.

Uncertainties also follow due to the lack of adequate information that still persist in certain areas despite substantial efforts (call for evidence, questionnaire and KemI (2019)). For the cases where substitution cost have not been assessed due to information gaps, there is a substantial risk that there are some important substitution costs, which have not been assessed properly. For these cases the Dossier Submitter expects that further information can be presented in the public consultation process.

Looking at Table 18 in the main report it can be seen that the uncertainties differs in origin for the different substances (even though there are some general uncertainties as well).

For the intermediates and the solvents, it is estimated that substitution is not technical possible, but there is some uncertainty as to if changes in practice (for solvents) can reduce the substances at point of sale.

For the diisocyanates there is some uncertainty regarding whether best practice is required to comply with the proposed restriction, and there is substantial uncertainty about the cost of moving towards best practice (no cost data available).

For a number of substances there is indication that the identified substitutes may be considered as regrettable in one aspect or another, by the industry consulted. For rosins, Phthalates, plasticiser for neoprene, for instance, there is an uncertainty as to whether or not substitutes exist with a better health/risk profile.

For rubber accelerators a source of uncertainty is the fact that the number of articles in need of reformulation has not been estimated, which makes the total cost for this reformulation uncertain.

There is also an uncertainty connected to the lowered concentration limit from 3 mg/kg to 1 mg/kg for chromium VI, and the suggested restriction on glutaraldehyde. For chromium and moving from 3 mg/kg to a more stringent 1 mg/kg target, the uncertainty lies in whether or not this stricter limit implies that usage of chromium will be rendered impossible in the upstream tanning process. At the moment chromium tanning is possible in the upstream tanning process and the concentration in articles at point of sale can be kept below 3 mg/kg. Three mg/kg was the detection limit at point of restriction for chromium VI (2012). At present, point in time test methods are better (but some uncertainties about positive negatives has been lifted) and detecting 1 mg/kg can be possible for chromium VI. It is however not known if this will make usage of chromium in the upstream tanning impossible, which may imply large costs (not assessed). This is therefore considered a source of uncertainty even though some information has arrived late in the process that indicate that the industry can comply with a stricter 1 mg/kg limit.

For glutaraldehyde there is an uncertainty as to how a restriction would affect the industry. Information is lacking with regard to concentrations in articles at point of sale as well as substitution costs. According to the chromium VI (2012) restriction proposal, glutaraldehyde is the main substitute for chromium tanning in leather. It is mainly used in the car industry, but also for shoes and other articles. It is uncertain as to whether or not the supply of vegetable tanning and other substitutes to glutaraldehyde are available in large enough quantities. The combined aggregated uncertainty connected to both a stricter limit for chromium VI and glutaraldehyde might also be greater than the sum of the two uncertainties in separate. This follows since glutaraldehyde is a substitute for chromium tanning.

The (described) uncertainties can also affect the total cost calculations in Annex E.4.1.5. The total costs are calculated with regard to the cost difference between chemical used and the alternative. All other factors are assumed to be held constant (due to lack of data discussed above), for example volume used and quality aspects. This is a source of uncertainty but unless better data is provided, it is a hard issue to address.

For the rubber accelerators the total cost is estimated in a sensitivity analysis in Annex E.4.1.6. That analysis has large uncertainties since the number of reformulations needed due to this restriction is based on assumptions. For that reason better information on the number of needed reformulations is highly needed in order to improve the assessment.

E.5. Human health and environmental impacts

E.5.1. Human health impacts

Such as described in the main report, and as Figure 8 and Figure 9 below show, contact with textile and leather articles may result in contact dermatitis such as urticaria, irritation contact dermatitis (ICD) and allergic contact dermatitis (ACD).

As explained above, the human health impacts assessment performed in this restriction proposal focusses on allergic contact dermatitis since they are associated with contact with sensitising substances and are largely reported in the literature and because there is little information about urticarial cases due to chemicals that could have additionally fed the human health impact assessment. But in principle, restricting sensitising substances in textile and

leather articles should also prevent some part of ICD and urticaria cases. To this respect, the health benefits expected from the restriction have to be seen as underestimated.

E.5.1.1. What is an allergic contact dermatitis?

- ACD is a particular type of dermatitis that must be distinguished from psoriasis, atopic eczema or other contact dermatitis such as urticarial and irritation contact dermatitis (ICD). Irritation (or irritant) contact dermatitis is an eczematous reaction provoked by acute or prolonged and repeated contact with a substance or substances which are injurious to the skin (such as defined by the WHO ICD-11 international classification of diseases 11th revision[70] of December 2018)
- Psoriasis is a common, chronic, relapsing, inflammatory skin disorder characterized by abnormal epidermal keratinization and hyperproliferation. It has a strong genetic component (WHO ICD-11).
- Atopic dermatitis (or atopic eczema) is a chronic inflammatory genetically-determined eczematous dermatosis associated with an atopic diathesis (elevated circulating IgE levels, Type I allergy, asthma and allergic rhinitis). Filaggrin mutations resulting in impaired epidermal barrier function are important in its pathogenesis. Atopic eczema is manifested by intense pruritus, exudation, crusting, excoriation and lichenification. The face and non-flexural areas are often involved in infants; involvement of the limb flexures may be seen at any age (WHO ICD-11).
- Urticaria can be allergic or not. Urticaria results from skin or mucosal contact with a substance or substances capable of inducing wealing either by immunological or by non-immunological means. Allergic contact urticaria is a Type I IgE-mediated immediate immune reaction from cutaneous or mucosal contact to a substance or substances to which the individual has previously been exposed (WHO ICD-11).
- Allergic contact dermatitis is an eczematous response provoked by a Type IV delayed immune reaction in the skin to a substance or substances to which the individual has previously been sensitised (WHO ICD-11).

Allergic contact dermatitis is caused by external factors such as the contact with chemicals present in consumer products like textile and leather articles. It occurs after repeated exposure and sensitisation of the immune system. The allergy is prevented with the exposure avoidance, which is very difficult, even impossible, when it comes to clothing and shoes. Pictures below show examples of skin reactions due to ACDs.

[70] https://icd.who.int/

Figure 8. Examples of allergy contact dermatitis due to clothing articles

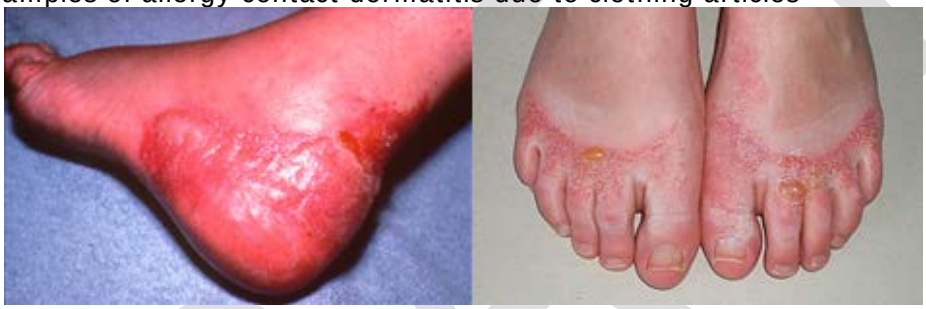

Figure 9. Examples of shoes allergy contact dermatitis

E.5.1.2. The disease course

As explained by COWI (2004), the contact allergy course can be divided into 3 states: diagnosis, daily treatment and acute care.

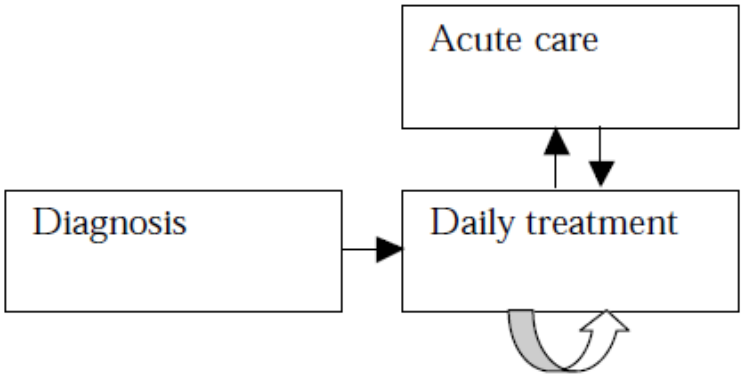

Figure 10. The disease course for ACD (Source: COWI, 2004)

E.5.1.2.1. Diagnosis

Diagnosis is the state where the patient is having allergic reactions and the diagnosis is in the process of being settled.

Diagnosis of ACD is quite complex. All individuals suffering from ACD don't systematically visit a GP (General Practitioner) or a dermatologist: i. because they don't know what they suffer from and they haven't identified a specific cause; ii. because their symptoms are not invalidating enough and they think that they will disappear quickly; iii. or because the waiting time to get an appointment at a specialist or in a hospital may be very long (exceeding 1 year in some EU countries). Therefore, when individuals decide to examine their symptoms further, they may want to visit their pharmacist to get some advice and attempt 'first intention treatments' before visiting a doctor. In case of ACD, unless the patient manages to identify the specific textile or footwear article that contains the allergen, these first intention treatments are usually not efficient in the long-run. At this stage of the disease course, some individuals may go to see their pharmacist again and get some additional advice but (in some cases again) seldom treatments, whereas others may go to consult a medical practitioner. Most of the time, the latter will go first to their GP. If the GP is well-informed about allergic and dermatologic diseases, he may advise the patient to go to visit a dermatologist to get a definite diagnosis (with probably some relieving treatments in the meantime). If not, the GP may give some relieving (possibly efficient in the short-run or not) treatments to the patient. However, in case the source of the allergy is not identified and avoided, symptoms may appear again.

When (and if) finally the patients consult a dermatologist, then the usual medical best practice within the EU countries is as follows:

- First consultation with dermatologist: the dermatologist asks questions to the patients about the beginning of the skin problems, what the patient wore during and before the lesions occur, traces back the story until the day of the consultation. From this, if an ACD is suspected, patch tests are performed. In most of EU countries, tests are performed during a second consultation but in some countries they are carried out during the first consultation already (especially in areas where the waiting times to get an appointment to the dermatologists exceed several months)
- Second consultation with dermatologist ('testing consultation'): tests are performed. They take the form of square plasters of 1cm² based on EU standard sets containing about 30 substances including the most sensitising substances like nickel, chromium, rubber additives, glues resins, and more recently the Textile Dye Mix (TDM) which counts the 8 most allergenic colorants known in textiles (see further details below). The patch tests are applied onto the patient's back skin. Applying these patch tests must be done with precaution and takes time. The patch tests must remain on the patient's back over 48 hours. Into those patch tests, some allergens are not included. The standard set is not always sufficient to determine the exact cause of the ACD.
    - Additionally to the standard test batteries, dermatologists may add other commercial allergens as well as pieces of suspected cloth or shoe at the same time: the dermatologist sticks a piece of suspected fabrics or shoes onto the skin to see if there is a skin reaction (48h x 3 consultations: test/result/follow-up) that may allow to deduce an association with a specific allergen.
    - Overall, if it turns out that it is an irritation only, all the tests will be negative

- Third consultation with dermatologist ('follow-up' consultation): In any case (allergies or irritation), the dermatologist usually proposes to see the patient again at least once for a follow-up consultation.
- In most of the cases, after these 2 or 3 consultations, the patient is provided with a solution (some treatments and the name of the substances / the cloth or shoe to be avoided). However, for some allergies (for example, chromium in leather shoes or disperse colorants in synthetic textiles), it is not easy because, it is often very difficult to find allergens-free cloths or shoes and these alternatives are very expensive.

Even in the situation where the patients go to visit a dermatologist, many factors make the diagnosis of textile contact dermatitis difficult: skin lesions show very polymorphous clinical pictures with unusual localizations or unusual clinical patterns; patch tests with textile batteries are not systematically performed; specific textile series (textile dyes series in particular) contain substances that are nowadays employed in a limited group of garments; new dyes and new substances with unknown chemical compositions (or those not available in formulations suitable for patch testing) are continuously introduced into textile industry; dyes are rarely given a Colour Index number and their chemical structure is often unknown; different dyes are often used for a single garment (Manzini, 1991; Seidenari, 2002). As reported by Thyssen (2007), ACD is far from always confirmed after patch testing, with positive test results relating to past episodes of ACD or having uncertain clinical relevance in these cases. Hence, the contact allergy frequencies derived from patch test databases should not be interpreted as contact allergy incidence rates. Rather, the annual number of patients eligible for patch testing can be regarded to represent prevalence according to Thyssen (2007) and the German CE-DUR[71] However, this number is not available in the literature. As a result, the frequency of positivity of patch tests is in our view the best proxy to be used to establish prevalence and incidence rates.

Figure 11 below provides an overview of the disease course of ACD and the associated medical protocol (when diagnosed).

[71] Combination of clinical epidemiological (CE) data and the World Health Organization-defined drug utilization research (DUR) method

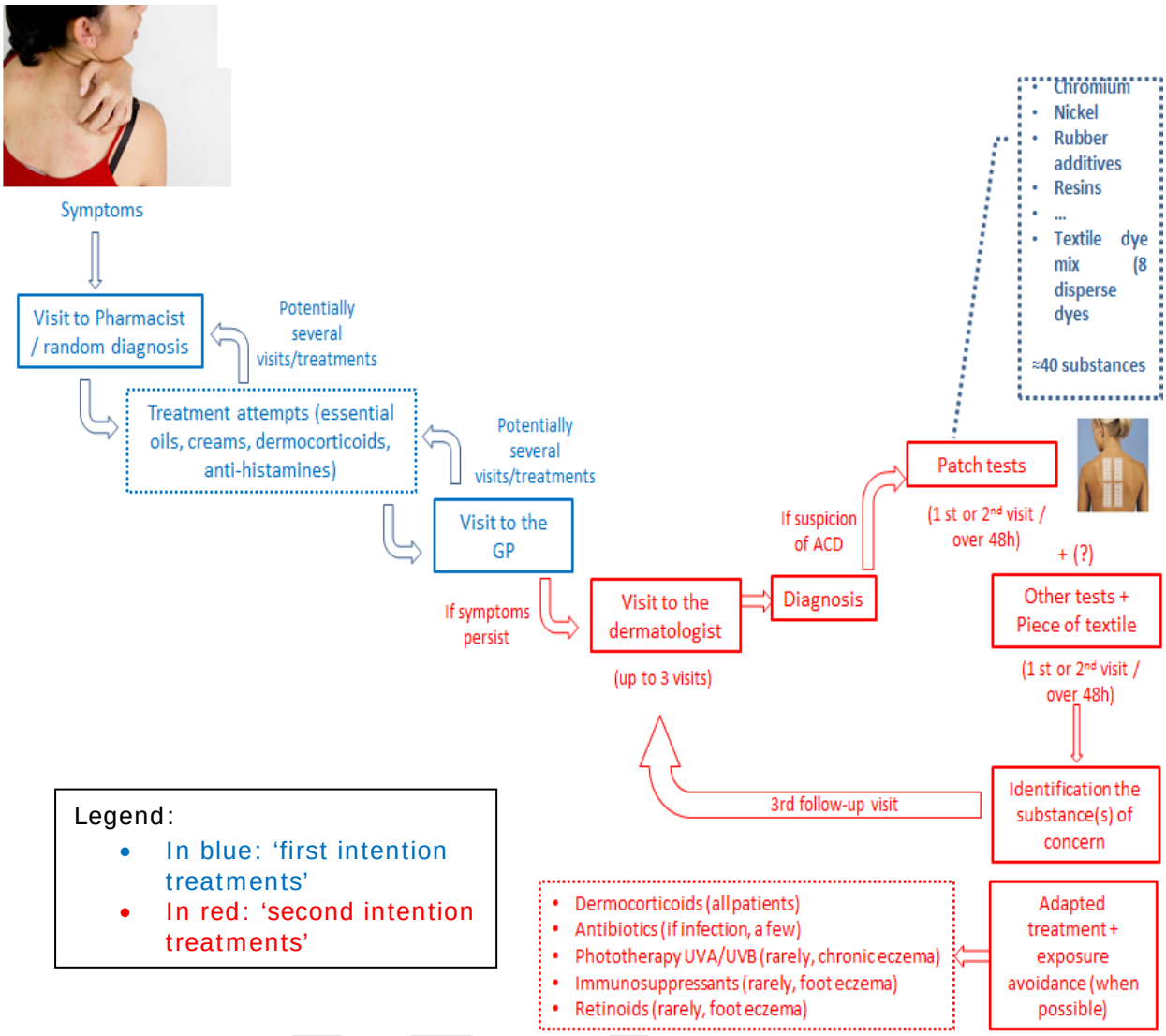

Figure 11. Typical ACD course and associated medical protocol (when diagnosed)

The patch tests

The standard European baseline series consists of haptens based on the experience from many years of studies of frequencies of contact allergy performed by the European Environmental and Contact Dermatitis Research Group (EECDRG). The series can be seen as a basic "standard" baseline series in case no country specific baseline series is offered.

Regarding textile and leather, the most commonly used series to test the patients are the following.

Table 32 :European Baseline Series S-1000

	Art.No	Chemical Name	Concentration
1.	P-014A	Potassium dichromate	0.5% pet
2.	P-006	p-PHENYLENEDIAMINE (PPD)	1.0% pet
3.	Mx-01	Thiuram mix	1.0% pet
4.	N-001	Neomycin sulphate	20.0% pet
5.	C-017A	Cobalt(II)chloride hexahydrate	1.0% pet
6.	B-004	Benzocaine	5.0% pet
7.	N-002A	Nickel(II)sulfate hexahydrate	5.0% pet
8.	C-015	Clioquinol	5.0% pet
9.	C-020	COLOPHONIUM	20.0% pet
10.	Mx-03C	Paraben mix	16.0% pet
11.	I-004	N-Isopropyl-N-phenyl-4-phenylenediamine (IPPD)	0.1% pet
12.	W-001	LANOLIN ALCOHOL	30.0% pet
13.	Mx-05A	Mercapto mix	2.0% pet
14.	E-002	Epoxy resin, Bisphenol A	1.0% pet
15.	B-001	Peru balsam	25.0% pet
16.	B-024	4-tert-Butylphenolformaldehyde resin (PTBP)	1.0% pet
17.	M-003A	2-Mercaptobenzothiazole (MBT)	2.0% pet
18.	F-002B	FORMALDEHYDE	2.0% aq
19.	Mx-07	Fragrance mix I	8.0% pet
20.	Mx-18	Sesquiterpene lactone mix	0.1% pet
21.	C-007A	QUATERNIUM-15	1.0% pet
22.	M-008	2-Methoxy-6-n-pentyl-4-benzoquinone	0.01% pet
23.	C-009B	METHYLISOTHIAZOLINONE+ METHYLCHLOROISOTHIAZOLINONE	0.02% aq
24.	B-033B	Budesonide	0.01% pet
25.	T-031B	Tixocortol-21-pivalate	0.1% pet
26.	D-049E	METHYLDIBROMO GLUTARONITRILE	0.5% pet
27.	Mx-25	Fragrance mix II	14.0% pet
28.	L-003	HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE	5.0% pet
29.	M-035B	METHYLISOTHIAZOLINONE	0.2% aq
30.	Mx-30	Textile dye mix	6.6% pet

Table 33 : Textile Colours & Finish Series TF-1000

	Art.No	Chemical Name	Concentration
1.	D-036	Disperse Yellow 3	1.0% pet

2.	D-032	DISPERSE ORANGE 3	1.0% pet
3.	D-034	Disperse Red 1	1.0% pet
4.	D-035	DISPERSE RED 17	1.0% pet
5.	D-029	Disperse Blue 153	1.0% pet
6.	D-026	DISPERSE BLUE 3	1.0% pet
7.	D-027	Disperse Blue 35	1.0% pet
8.	D-012	Dimethylol dihydroxy ethylene urea	4.5% aq
9.	D-052	Dimethyl dihydroxy ethylene urea	4.5% aq
10.	D-050	Dimethylol dihydroxy ethylene urea, modified	5.0% aq
11.	D-040	Disperse Blue 106	1.0% pet
12.	Mx-16	Ethyleneurea, melamine formaldehyde mix	5.0% pet
13.	U-001	Urea formaldehyde resin	10.0% pet
14.	M-001	Melamine formaldehyde	7.0% pet
15.	D-028	Disperse Blue 85	1.0% pet
16.	D-031	Disperse Orange 1	1.0% pet
17.	A-026	Acid Yellow 61	5.0% pet
18.	D-030	Disperse Brown 1	1.0% pet
19.	D-037	Disperse Yellow 9	1.0% pet
20.	D-041	Disperse Blue 124	1.0% pet
21.	B-026	Basic Red 46	1.0% pet
22.	R-004B	Reactive Black 5	1.0% pet
23.	R-005B	Reactive Blue 21	1.0% pet
24.	Deleted	Deleted	
25.	R-007B	Reactive Orange 107	1.0% pet
26.	R-008B	Reactive Red 123	1.0% pet
27.	Deleted 2	Deleted	
28.	R-010B	Reactive Red 228	1.0% pet
29.	R-011B	Reactive Violet 5	1.0% pet
30.	A-027	Acid Red 118	5.0% pet
31.	D-051	Direct Orange 34	5.0% pet
32.	A-028	Acid Red 359	5.0% pet
33.	Mx-26	Disperse Blue mix 106 / 124	1.0% pet
34.	Mx-30	Textile dye mix	6.6% pet

Source: https://www.chemotechnique.se/products/series/textile-colours-amp-finish/

Table 34 : Shoes Series SH-100:

	Art.No	Chemical Name	Concentration
1.	I-004	N-Isopropyl-N-phenyl-4-phenylenediamine (IPPD)	0.1% pet

2.	G-003A	GLUTARAL	0.2% pet
3.	D-032	DISPERSE ORANGE 3	1.0% pet
4.	A-019	Acid Yellow 36	1.0% pet
5.	H-019	Hydroquinone monobenzylether	1.0% pet
6.	Mx-01	Thiuram mix	1.0% pet
7.	P-014A	Potassium dichromate	0.5% pet
8.	B-024	4-tert-Butylphenolformaldehyde resin (PTBP)	1.0% pet
9.	P-006	p-PHENYLENEDIAMINE (PPD)	1.0% pet
10.	N-002A	Nickel(II)sulphate hexahydrate	5.0% pet
11.	C-020	COLOPHONIUM	20.0% pet
12.	F-002B	FORMALDEHYDE	2.0% aq
13.	D-025	N,N´-Diphenylthiourea (DPTU)	1.0% pet
14.	M-003A	2-Mercaptobenzothiazole (MBT)	2.0% pet
15.	D-039	N,N´-Diethylthiourea	1.0% pet
16.	D-022	1,3-Diphenylguanidine	1.0% pet
17.	D-038	N,N´-Dibutylthiourea	1.0% pet
18.	E-002	Epoxy resin, Bisphenol A	1.0% pet
19.	D-043	Dodecyl mercaptan	0.1% pet
20.	C-009B	METHYLISOTHIAZOLINONE+ METHYLCHLOROISOTHIAZOLINONE	0.02 aq
21.	A-005	4-Aminoazobenzene	0.25% pet
22.	O-004	2-n-Octyl-4-isothiazolin-3-one	0.1% pet
23.	D-054	4,4´-Dithiodimorpholine	1.0% pet

Source:https://www.chemotechnique.se/products/series/textile-colours-amp-finish/

Table 35 :Textile Dye mix (TDM) Mx30

	Art.No	Chemical Name	Concentration (%)
1.	D-027	Disperse Blue 35	1.0
2.	D-031	Disperse Orange 1	1.0
3.	D-032	DISPERSE ORANGE 3	1.0
4.	D-034	Disperse Red 1	1.0
5.	D-035	DISPERSE RED 17	1.0
6.	D-036	Disperse Yellow 3	1.0
7.	D-040	Disperse Blue 106	0.3
8.	D-041	Disperse Blue 124	0.3

Source : https://www.chemotechnique.se/products/series/european-baseline-series

E.5.1.2.2. Treatment

Daily treatment of a patient with contact allergy is the everyday coping with contact allergy. This may include daily treatment with topical agents, moistures and avoidance of certain chemicals. This treatment is opposed to acute care.

Acute care is when the patient is having an allergic reaction which requires specific treatment that is not included in the long term management of the disease; i.e. additional treatment due to an acute allergic reaction.

Most cases of allergic contact dermatitis can be treated once the substance is no longer in contact with the skin. However, since textile and leather are of concern in this case, exposure

avoidance might be impossible. To this respect, after diagnosis, treatments are sometimes the only relieving solution for patients. In the most severe cases, absence from work may be necessary for more or less long periods of time. Regarding treatments, dermatologists report different types of treatments taken during the disease course.

The 'first intention treatment' such as described above (purchased at the pharmacist or prescribed by GPs) are usually:

- Anti-itch treatments such as calamine lotion or hydrocortisone cream
- Dermocorticoids (work occasionally but as soon as the patients stop using them, dermatitis comes back) if there is no avoidance of the substance of concern
- Antihistamine drug such as diphenhydramine are (used occasionally) prescribed to cut down on itching and to reduce allergic response, but they are rarely efficient on ACDs

The 'second intention treatment' such as described above (prescribed by specialists in dermatology) are usually:

- anti-itch treatments such as calamine lotion or hydrocortisone cream
- All patients get corticoids: the most prescribed are diprosone, betneval, dermoval, clarelux, efficort, nérisone, tridesonit.
- Additionally, pharmacists and GPs often prescribe antihistamines but according to the dermatologist consulted, they don't work well for contact dermatitis.
- In addition if needed, the dermatologist may prescribe:
    - For a few patients, in case of secondary infection: antibiotics (Amoxicilline, often pyostacine, sometimes Fucine cream if lesions are limited to the feet)
    - For a few patients: UVA or UVB phototherapy for chronic eczema (in private dermatologists or in hospitals) – 10-15 sessions minimum
    - For a few patients: immunosuppressors especially for chronic feet eczema (pills or injections) for the worst cases (Methotrexate, Ciclosporine)
    - For chronic eczema, sometimes also prescription of retinoïds such as Alitretinoine

E.5.1.3 The number of ACD cases that can be prevented by the proposed restriction: prevalence and incidence data

A review of studies exploring contact dermatitis caused by textile clothing or footwear was carried out from 2000. No data-based and comprehensive study has assessed the prevalence of contact dermatitis induced by these articles in the general population. Only the positivity rate for tests in some populations investigated have been reported in the literature. Nevertheless, based on a thorough scrutiny of the studies reviewed, a link between the occurrence of dermatitis and a substance or group of substances found in the article in question could be established and the prevalence of textile contact dermatitis in the general population could be estimated. The state of the art of the literature in this matter as well as the studies reviewed are presented below.

Prevalence of contact dermatitis and contact allergies

International literature includes a few studies on the prevalence **of contact dermatitis and contact allergies**, either occupational, or non-occupational or both.

- At international level, the most recent US study from Lim et al. (2017) reports 4.17% being the (claims-based) prevalence of CD in the US general population in 2013. Other US studies are older: 1.4% reported by Johnson, 1977 and Johnson, 1995 and 2.8% reported by Behrens et al., 1994; those figures are also reported in Lushniak, 1997.
- As reported in the 1997 European White paper on allergy, routinely registered data are not informative because this disease is seldom a cause of hospitalization and patient populations from dermatology clinics represent only a small proportion of the true incidence (White paper, 1997). At the European level, some studies report however interesting prevalence data from surveys or clinical investigation.
    - As reported in the Bfr 2006 opinion, based on the Health Survey 2000 results, a lifetime prevalence of allergic contact eczema around 15% and an annual prevalence of approximately 7% were identified (Hermann-Kunz, 2000). By contrast, based on epicutaneous tests conducted between 1992 and 2000 in a total of 78 067 patients, IVDK identified, using the different extrapolation models, a 9-year prevalence of 7% (medium case scenario) and of 16.6% (worst case scenario) for the overall population in the Federal Republic of Germany (Schnuch et al., 2004).
    - Thyssen (2007) estimated contact allergy prevalence based on patch test reading data in combination with an estimate of the number of persons eligible for patch testing each year based on sales data of the 'standard series'. The prevalence of contact allergy among adult Danes older than 18 years is estimated between 7.3% (very liberal 'worst case') and 12.9% (conservative 'best case'), whereas the prevalence estimate for Danes of all ages ranged between 5.5% and 9.7%. The estimated 10-year prevalence of contact allergy ranged from 7.3% to 12.9%) for adult Danes older than 18 years.
    - Peiser et al. 2012 reports, from the literature, that in Europe 15 -2 0% of the general population suffers from contact allergy to at least one contact allergen. Most common are allergies to nickel, fragrances and preservatives. Allergic reactions to chromate and *p*-phenylenediamine (PPD) are generally less common but occur frequently in occupationally exposed subgroups of the population. Contact dermatitis occurs twice as frequently in women as in men and often starts at a young age, with a prevalence of 15% in 12–16 year olds (and 20% for older population), based on Mortz et al, 2002.
    - Saetterstorm et al. (2014) reports 25 000 new cases of CD being recognized by dermatologists each year in Denmark, including occupational and non-occupational CD; this corresponds to an incidence of 4.5 per 1 000 inhabitants.

Table 36 : Overview of prevalence data on contact allergies in the general population

Source	Prevalence	Population of reference / interpretation
Bfr, 2006 (based on Hermann-Kunz, 2000)	15% 7%	lifetime prevalence of allergic contact eczema- German population annual prevalence - German population
Alinaghi et al, 2018	>20.1%	Prevalence of contact allergy in general population in the Federal Republic of Germany (meta-analysis of 28 studies)
Schnuch et al., 2004	7 - 16.6%	9-year prevalence in the general population in the Federal Republic of Germany

RIVM (2008)	3.7 - 5.4%	Not specified (Dutch population)[72]
Thyssen, 2007	7.3 - 12.9% (medium case: 9.5%)	10-year prevalence of contact allergy in the general population in Denmark for people above 18 years old
	5.5 - 9.7% (medium case: 7.2%)	10-year prevalence of contact allergy for Danes all ages
	4.4 - 18.4% (medium case: 7.7%)	10-year prevalence of contact allergy in the general population for Germans all ages
Mortz et al, 2002	15.2%	prevalence for 12-16 years old (lifetime prevalence: 7.2%)

However none of these studies are specific to textile and leather ACD.

Prevalence is a measure of a health state of a population (general population for example), providing the number of cases of diseases at one given time (one year for example) or short period (5 years for example) and for one given place (one country for example). Depending on the purposes of the study and the data available, prevalence may be calculated over a short period of time (one year) or a medium period of time (10 years) or over lifetime. Lifetime prevalence data are usually considered as the most representative of the measure of the prevalence of a health state of the population. Lifetime prevalence is the measure of prevalence estimated over lifetime, i.e. over the entire life of individuals.

As reported above, literature provides only one single source for lifetime prevalence of contact allergies at all ages (Hermann-Kunz et al, 2000). The 'short' or 'medium-term' prevalence data are commonly considered as underestimated at least when they are calculated for the general population and not for a specific (potentially more sensitive) population. However, the table above shows that some shorter prevalence data are higher than the lifetime prevalence from Hermann-Kunz et al (2000): the 10 year prevalence of contact allergy at all ages (for Danes) from Thyssen (2007) is estimated up to 18.4% and the 9 year prevalence of contact allergy for German population from Schnuch et al 2004 is up to 16.6%. Moreover, a recent meta-analysis carried out by Alinaghi et al, in 2018 provides an updated estimate of the prevalence of contact allergy in the general population based on 28 studies published between 2007 and 2017. The meta-analysis confirmed that at least 20% of the general population are contact-allergic to common environmental allergens (20.1% specifically). Finally, it has to be noted that these "prevalence" studies are rather heterogeneous from a methodological standpoint since some of them may include individuals in the general population that are positively tested without the knowledge (or without specifying) whether these individuals have already shown clinical symptoms of allergy or not (in that case, they are sensitised without symptoms). Within these positively tested individuals, there however may have been actual "prevalent" allergic patients (with clinical symptoms). As a consequence, to reflect those uncertainties, the lifetime prevalence data of contact allergies used by the Dossier Submitter in their evaluation is thus 15-20% (more specifically for the

[72] Nationaal Kompas Volksgezondheid. Available at http://www.rivm.nl/vtv/object_document/o4237n16906.html (March 2008).

human health impact assessment, see Annex E.5). A sensitivity analysis has been performed on this parameter (please see further below).

Prevalence of allergic contact dermatitis related to textile and leather

As pointed out by Hatch et al (2000), while dermatologists have reported cases of skin reactions to be caused by textile dyes since 1869 (Wilson, 1869), they have reported textile-dye (and textile in general) prevalence results only during the last 1990s.

Gathering prevalence data on ACD related specifically to textile and leather articles is challenging. As mentioned above, no data-based and comprehensive study has assessed the prevalence of contact dermatitis induced by these articles in the general population. Only the positivity rate for tests in some populations investigated have been reported in the literature.

According to the literature, around 2/3 of all textile related cases of allergy seem to be attributed to disperse dyes according to the literature[73] (Bfr (2006); RIVM (2008) and RIVM (2014), based on Hatch and Maibach (1995; 2000) and Lazarov (2004)).

Moreover, there are many studies reporting prevalence data (frequency) of positive patch tests to chemicals contained in textile and leather. Based on a literature review, **the prevalence of positive patch tests to chemicals contained in textile and leather vary between 0.4% and 46.3%:**

➔ **Regarding prevalence of ACDs related to textile and leather in adults:**

- KemI 2016 RMOA reports that the prevalence of allergic textile dermatitis to disperse dyes among consecutive patients at dermatology clinics is around 3% (Isaksson et al., 2015a; Isaksson et al, 2015b; Ryberg et al., 2014; Ryberg et al., 2006, 2010, 2011, 2014) whereas the prevalence among patients with suspected allergic textile dermatitis tend to be higher (Lazarov, 2004; Lisi et al., 2011; Wentworth, 2012). KemI (2016) reports that total prevalence for textile dye mix allergy in 2015 was 3.12 % (Females 3.31%; Males 2.68 %) based on 2,531 tests performed at 15 dermatology departments in Sweden.
- KemI (2014) reports ten publications found from epidemiological studies of textile dermatitis among patients that seek care at dermatological clinics, published from 2004 until 2014. The number of patients enrolled in the studies ranged from 277 up to 3 325 and the prevalence data varied between 1.5% and 32.6% (Lisi et al, 2014; Ryberg et al, 2010, 2011, 2006; Lazarov, 2004; Wentworth, 2012; Slodownik et al, 2011; Isaksson et al, 2014 & 2015a; Ryberg et al, 2014).
- Ryberg et al, 2011 reports a prevalence of positive patch tests reactions to textile dyes of 2.6% based on a total of consecutive 2,049 patients from Sweden and 497 from Belgium tested.
- Ryberg et al (2014), a large European multicenter study, found that 3.7% of the 2,907 consecutively tested patients had a contact allergy to disperse dyes which was assessed as clinically relevant in one third of the cases (Ryberg et al, 2014). According to this study, contact allergy to TDM was found in 108 patients (3.7%). The frequency of contact allergy varied from 2.1% to 6.9% in different centres. Simultaneous reactivity to p-phenylenediamine was found in 57 of the TDM-positive patients (53%).

[73] The estimate of this proportion covers a certain degree of uncertainty which is discussed in the main report, in the Baseline section 1.4

The most frequent dye allergen among the TDM-positive patients was Disperse Orange 3. The contact allergy could have explained or contributed to the dermatitis in approximately one-third of the patients for whom clinical relevance of the TDM contact allergy was recorded.

- Reviews from Isaksson et al. (2015b) and Ryberg et al. (2011; 2014; 2015) assessed a mixture of eight disperse dyes known as the "Textile Dye Mix" (TDM), included in a standard European battery to detect allergies to disperse dyes during routine exploration in patients ranging from 8 to 94 years old. Many of the cross-reactions were observed between Disperse Orange 3 and 1,4-paraphenylenediamine. The clinical relevance was considered uncertain in more than 30% of the positive cases. The results showed a positivity rate for the TDM test of between 2.5% and 3.7%. This review was able to document this test limitations such as the red colouration of the skin after application, which makes reading of the test difficult, the risk of sensitisation from allergens contained in the TDM in patients tested and not previously sensitised, and the cross-reactions between the TDM and paraphenylenediamine due to the presence of Disperse Orange 3 (Isaksson *et al.,* 2015b).
- In Hatch et al 2000 review, in those studies in which patients appeared for routine patch testing and disperse dyes were included (Balato, 1990; Manzini et al, 1991; Seidenari et al, 1991; Seidenari et al, 1997; Lodi et al, 1998; Dooms-Goossens, 1992), prevalence values range from 1.4% to 5.8%. Prevalence for women appears to be higher than for men.
- Heratizadeh et al (2017) assessed clinical data and patch test results for dermatitis patients with suspected textile allergy based on data from the Information Network of Departments of Dermatology (IVDK) over 2007-2014 in Germany and reports that among the allergens of the textile dye series (1 628 were tested with the DKG textile and leather dyes series): the highest frequency of positive reactions was observed for p-aminoazobenzene (5.1%) and p-phenylenediamine (PPD) (4.5%), followed by Disperse Orange 3 (3.1%), Disperse Blue 124 (2.3%), Disperse Blue 106 (2.0%), Disperse Red 1.1%), and Disperse Yellow 3 (1.1%), partly with concomitant reactions. Patch testing with the patients' own textiles was performed in 315 patients, with positive reactions in 18 patients (7 women and 11 men).
- According to Malinauskiene et al (2012), the average prevalence in screening studies was >1% for Disperse Blue 106, Disperse Blue 124, and Disperse Orange 3. There is a lack of data on patch testing with Disperse Blue 26, Disperse Blue 102, Disperse Orange 37, Disperse Orange 149, Disperse Yellow 23 and Disperse Yellow 49, which are listed as allergens by the EU Commission. In those studies in which patients appeared for routine patch testing and Disperse dyes were included, prevalence values ranged from 0.4% to 6.7% (based on a literature review including Manzini et al, 1991; Seidenari et al, 2002; Ryberg et al, 2011). Prevalence values in patient populations known to be or very probably sensitised to Disperse dyes ranged from 5.5% to 100%.
- Isaksson et al (2015a) reports a frequence of positive reaction to TDM of 3.6% within 2,493 consecutive dermatitis patients in 9 dermatology clinics.
- Lazarov (2004) reports a prevalence of positive patch testing to standard tests (TRUE, TCFS + piece of textile) of 12.9%, within 644 patients tested with suspected textile ACD (441 female and 203 male).
- Lisi et al (2014) investigated 277 patients for suspected contact dermatitis from textile clothing. The patch tests performed included 22 allergens including disperse dyes[74], basic dyes, aromatic amines, formaldehyde resins and thiuram mix, as well as other substances such as DMFu, a chloromethylisothiazolinone/methylisothiazolinone mixture and 2-mercaptobenzothiazole (MBT). The results showed that 154 patients were sensitised to at least one allergen from the battery used. Disperse and basic dyes accounted for 81.8% of positive reactions. Textile dyes were suspected of being responsible for the skin problems observed in 46.3% of patients. The other agents responsible were formaldehyde resins used as textile sizes, with a frequency of 2.3%.

[74] Disperse dye: substance of low molecular weight, with an azo, anthraquinone or diphenylamine structure, used to dye synthetic fibres such as polyester (Mahapatra, 2016).

- Wentworth et al (2012) reviewed results in patients who underwent patch testing using a series of textile dyes and resins from 2000 to 2011. A total of 671 patients (mean age, 56.5 years; female, 65.9%) were patch tested with the textile series (42 dyes and resins). These patients were also generally tested with the standard patch test series (n = 620). Of the patients, 219 (32.6%) demonstrated allergic reaction to 1 or more textile dyes and resins, and 71 (10.6%) manifested irritant reactions. The most frequent allergens were disperse blue 106 (8.3%), disperse blue 124 (8.0%), and melamine formaldehyde (8.0%). Of patients tested with the standard series, 36 (5.8%) showed a positive reaction to the traditional textile screening allergen p-phenylenediamine 1%.
- It has to be noted that the results from Lisi et al (2014), Wentworth et al (2012) and Lazarov (2004) above maybe somehow not representative since, as mentioned in KemI (2016), the prevalence among patients with suspected allergy tends to be higher than in consecutive patients. In particular, the high numbers from Lisi et al (2014) (46.3%) and Wentworth et al (2012) (32.6%) may be outliers compared to all reported values from the other studies presented herein.
- A survey from Ryberg et al. (2009) showed that among 858 patients with contact allergy in Sweden and Belgium, 18 % of the patients suspected textiles as a cause of their skin problems, and that synthetic materials were the most common textiles to give skin problems.
- In Denmark, between 2% and 3% of the patients in the clinic react to the textile mix in the Baseline Series. In this group, the cause can be found to be textile related in 1 out of 3 cases. Out of 3,893 patients, 73 reacted on the textile mix (1.9% positive). Male:Female; 1:1. In 31 of the 73 cases (42%) textile articles were found relevant for the eczema. The allergy is found to be derived from shoes, scarfs, shirts, trousers, swimming suits, working cloths and gloves. In 30 % of the cases the patients also show a reaction towards PPD (KemI, 2016).
- Anses (2018) study carried out a review of studies exploring contact dermatitis caused by textile clothing or footwear between 2000 and 2016. Regarding textile, additionally to the studies presented above, ANSES reports that French data from the Dermato-Allergology Study and Research Group (GERDA) indicate positivity prevalences in patch tests for textile clothing ranging between 1 and 5% based on Bourrain (2016). Regarding allergies to footwear, several studies report positivity rates for tests as follows:
    - The frequency of contact dermatitis caused by allergens found in shoes is around 1.5% to 24.2% in patients subjected to patch tests according to the review from Matthys *et al.* (2014) (based on Freeman, 1997; Chowdhuri et al, 2007; Saha et al, 1993 and Rani et al, 2003). This variability is mainly due to perspiration, which can promote the release of allergens, as well as to seasonality and footwear manufacturing processes.
    - One of the most frequently identified allergens is potassium dichromate (a chromium VI compound). In a retrospective study in Sweden over a period of 10 years, involving 6,482 patients with an average age of 48 years presenting with allergic contact dermatitis, chromium was found with a positivity rate of around 3.6% (Lejding *et al.,* 2018). Geier et al (2000) also report a prevalence of positive reaction to potassium dichromate around 4% for men and 3.6% for women.
    - Studies have shown high levels of sensitisation to cobalt, whose salts are used as metal dyes, in the dyeing of leather and as catalysts for certain glues (INERIS, 2003). Leather is one of the main sources of consumer exposure to cobalt (Hamann *et al.,* 2014). Cobalt allergy is often associated with chromium-induced contact dermatitis (Geier *et al.,* 2000).
    - Rubber additives, such as thiurams, dithiocarbamates and/or mercaptobenzothiazoles and thioureas, can also cause contact dermatitis. Some studies have reported positive tests for diphenylthiourea, found in synthetic rubber and plastics due to its use as a stabiliser in the manufacture of PVC and as an accelerator in the production of neoprene (Samuelsson *et al.,*

2011). Reactions between these additives during vulcanisation can generate new compounds such as dimethylthiocarbamylbenzothiazole 189ulphide (DMTBS). Patch testing for DMTBS proved positive in Belgian and Dutch patients, induced by flexible canvas tennis shoes (Schuttelaar *et al.,* 2014).

- The para-tert-butylphenol-formaldehyde (PTBPF) resin used as an additive in rubber adhesives is found in neoprene suits and sport equipment such as shin pads. The patch tests that were positive for this substance in both adults and children demonstrated its ubiquitous use (Herro and Jacob, 2012). The role of 2-monomethylol phenol or 2-(hydroxymethyl)phenol, resulting from the condensation of the PTBPF resin in the shin pads, remains unexplained. A rare case of contact sensitivity was found with this compound (Ali *et al.,* 2009).
- Nardelli *et al.* (2005) conducted a retrospective study in Belgium in 1,168 patients suspected of footwear-induced contact dermatitis. The allergens detected were potassium dichromate and cobalt chloride (concomitant to the chromium), p-phenylene diamine, rosin and PTBPF resin. Individuals sensitised to MBT derivatives also reacted to this compound. Overall, 5.5% presented a positive reaction to one or more substances related to shoes.
- Hunasehally *et al.* (2010) conducted a retrospective study over 2001-2009 to investigate the correlation between the specific site of foot dermatitis and the allergens responsible. The most commonly found allergens were PTBPF resin (19%), chromium VI salts (19%), MBT (18%) and rosin (16%). Four patients were positive to their own shoe alone with no other causative allergen identified. Among the patients, the most frequently affected anatomical sites were the top of the foot (37%) and the sole (32%). The only prediction possible was that 72% of patients with contact dermatitis affecting the sole were allergic to rubber accelerators. Overall, 17% of patients presenting with foot dermatitis had a final diagnosis of foot-wear-related ACD.
- Bourrain (2016) reports a positivity prevalence in patch tests for shoes ranging between 3% and 11%.

- According to the BfR Textile Working Group 2006 report, between 1% and 2% of contact allergies in dermatological clinics in Germany are triggered by chemical substances in textile (Bfr, 2006). This value is also reported in RIVM (2008) and RIVM (2014).
- Outside Europe, a clinical study in Australia was conducted in 2069 patients in whom allergic contact dermatitis from clothing was strongly suspected. The authors showed that 157 patients (7.6%) responded to at least one allergen from a “textiles” battery. The most frequently implicated allergen was Basic Red 46, accounting for 20.6% of positive reactions. It was most often found in dark-coloured acrylic socks for men. The next most frequently implicated allergens were Disperse Blue 124 and Disperse Blue 106. Formaldehyde and the formaldehyde releasers tested were responsible for more than 30% of positive reactions (Slodownik *et al.,* 2011).

➔ **Regarding prevalence of ACDs related to textile and leather in children**, data are scarcer. Such as reported in Malinauskiene et al (2012):

- Zug et al (2008) didn’t report differences in prevalence between children and adults for ACDs to allergens and disperse dyes in particular: the North American Contact Dermatitis group compared sensitivity to Disperse Blue 106 in children and adults, and did not find a significant difference: the prevalence rate was 2.1% in children and 2.4% in adults.
- Bonitsis et al., 2011, also covers children’s sensitivity to several disperse dyes: Disperse Blue 124, Disperse Blue 106, Disperse Orange 3, Disperse Red 1, and Disperse Yellow 3. According to this review, the prevalence of positive reactions in at least 1% of tested children was found to be statistically significant only when they were positive to Disperse Blue 124 but not to other disperse dyes.

- The Portuguese Contact Dermatitis group, in a study performed in 1992, found a low prevalence of positive reactions to Disperse dyes – in 1.5% of 329 tested children (Gonçalo et al, 1992).
- Studies performed in Italy found that the most prevalent DD contact allergens in children are Disperse Blue 106 and Disperse Red 1, followed by Disperse Blue 124, Disperse Orange 3, and Disperse Yellow 3 with a positive rate of patch test reaction of 4.6% (Giusti, 2003). Seidenari et al. (1997) described the sensitivities of 23 DD-positive children. In their study, the most prevalent sensitizers were Disperse Red 1 and Disperse Orange 3.

Based on these data, there seems to be no significant difference in prevalence of contact allergies due to textile and leather (based on Disperse dyes testing in particular) between children and adults. It is also confirmed by experts in dermatology consulted as well as by ANSM (former AFSSAPS, the French agency for medicines and cosmetics safety) 2010 report on risks of cosmetics in children[75] (ANSM, 2010) that state that there is no reason that children would be more sensitive to contact allergies than adults. In ANSM 2010 report, the agency compared kids skin and adults skin in order to provide recommendations for risk assessment for cosmetics in children. It is thus reasonably assumed that what is valid for cosmetics is also valid for textiles to this respect. In section III.7. CONCLUSIONS – RECOMMANDATIONS of the ANSM 2010 report, the conclusion is that cutaneous tissue is mature at full term birth and comparable to adults in terms of defense capacity; There is an exception for premature babies (before 37 weeks) whom skin is not mature. **As a consequence, children and adults are addressed as a single population in this assessment (such as addressed in the risk assessment above).**

Tables below provide a summary of the prevalence data collected through the literature review performed for the purposes of this restriction proposal.

Table 37 : Overview of prevalence data on contact allergies from positive patch tests to chemicals contained in textile and/or footwear in adults and children

Source	Prevalence	Interpretation	Population of reference / Method
Prevalence of positive patch tests to chemicals contained in textile or footwear in adults			
Bfr, 2006	1 -2%	Prevalence of contact allergies from dermatological clinics	Germany
RIVM 2008 and RIVM 2014 (based on Bfr, 2006)	1 -2%	Prevalence of contact allergies from dermatological clinics	Germany
Lisi et al, 2014	46.3% (textile dyes) (considered as outlier in the analysis) 2.3% (formaldehyde and resins)	Prevalence of positive patch test to textile series (30 substances: disperse and basic dyes, finishing resins and other allergens)	277 Italian patients affected by textile dermatitis => 154 reacted to textile series (75.9% reacted to one or more ingredients)
Ryberg et al, 2011	2.6%	Prevalence of positive patch testing to textile dyes	2 049 patients consecutively tested from Sweden and 497 from Belgium
KemI 2016 RMOA (KemI, 2016)	2 -3%	Prevalence of positive patch testing with	3 893 patients tested

[75] https://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Evaluation-de-la-securite-des-produits-cosmetiques-destines-aux-enfants-de-moins-de-trois-ans-Point-d-information

		textile mix in the Baseline Series	
Malinauskiene et al, 2012	0.4 - 6.7%	Prevalence of positive patch testing to disperse dyes	Literature review
Zug et al, 2008	2.4%	Prevalence of sensitivity to Disperse Blue 106	9 670 patients tested aged 19 years and older
Ryberg et al, 2014	2.1 -6.9% (3.7% for TDM)	Prevalence of contact allergy to TDM	2 907 consecutively tested patients
Lazarov, 2004	12.9%	Prevalence of positive patch testing to standard tests (TRUE, TCFS + piece of textile)	644 patients tested with suspected textile ACD
Wentworth, 2012	32.6% (considered as outlier in the analysis)	Prevalence of positive patch tested patients reacted to textile series (42 dyes and resins)	671 patients tested over 2000-2011 with suspected textile ACD
Slodownik et al, 2011	7.6%	Prevalence of positive patch tested patients reacted to textile dyes, resins and formaldehyde	2069 patients with suspected allergic contact dermatitis from clothing
Isaksson et al, 2015a	3.6%	Prevalence of positive patch tested patients reacted to formaldehyde	2 493 consecutive dermatitis patients in 9 dermatology clinics were patch tested
Hatch et al. 2000	1.4 -5.8%	Prevalence of positive patch tested patients reacted to disperse dyes	Literature review
Bourrain, 2016	1 - 5%	Prevalence of positive patch tested patients for textile clothing	French data from the Dermato-Allergology Study and Research Group (GERDA)
Bourrain, 2016	3 - 11%	Prevalence of positive patch tested patients for shoes	French data from the Dermato-Allergology Study and Research Group (GERDA)
Matthys et al, 2014	1.5 - 24.2%	Prevalence of positive patch tested patients for shoes	Literature review
Geier et al, 2000	3.6 -4%	Prevalence of positive patch tested patients to potassium dichromate in shoes	28 577 women were patch tested with potassium dichromate
Nardelli et al, 2005	5.5%	Prevalence of positive patch tested patients to allergens in shoes	1 168 patients tested suspected of footwear-induced contact dermatitis
Hunasehally et al, 2010	17%	Prevalence of positive reactions to tests performed with the British Contact Dermatitis Group standard series and an in-house shoe series	328 patients patch tested over 2001-2009 with presented foot dermatitis
KemI, 2016	3.12 % (Females 3.31%; Males 2.68 %) varying between 0 % to 6.16 %	Prevalence for textile dye mix allergy in 2015.	2 531 tests performed in 15 dermatology departments in sweden

Heratizadeh et al, 2017	1.1%-5.1% p-aminoazobenzene (5.1%) p-phenylenediamine (PPD) (4.5%) Disperse Orange 3 (3.1%) Disperse Blue 124 (2.3%) Disperse Blue 106 (2.0%) Disperse Red 1.1%) Disperse Yellow 3 (1.1%)	Prevalence of positive patch tested patients tested with DKG textile and leather dyes series	1 628 patients tested (IVDK)
Lejding et al., 2016	3.6%	Prevalence of positive reactions to potassium dichromate in shoes	6 482 patients tested over 2005-2014
Manzini et al, 1991	1%	Prevalence of positive patch test to GIRDCA series (Trolab, germany)+textile dyes series (FIRMA, Italy)+17 textile dyes	569 patients patch tested with suspected ACD (6 reacted with some co-sensibilisations)
Seidenari et al, 1991	1.4 -5.8%	Prevalence of positive patch test to textile dyes + GIRDCA[76] series	100 patch tested patients
Prevalence of positive patch tests to chemicals contained in textile or footwear in Children			
Gonçalo et al, 1992	1.5%	prevalence of positive reactions to textile dyes	329 children tested aged 14 years of younger
Bonitsis et al, 2011	>1%	Prevalence of sensitivity to Disperse Blue 124, Disperse Blue 106, Disperse Orange 3, Disperse Red 1, and Disperse Yellow 3	Literature review over 1966-2010
Zug et al, 2008	2.1%	Prevalence of sensitivity to Disperse Blue 106	391 patients tested aged 0 to 18 years
Giusti, 2003	4.6%	Prevalence of positive patch testing to 7 disperse dyes	1 098 children tested over 1996-2000, including 667 with suspected ACD

Incidence data of contact allergy and allergic contact dermatitis

Information about incidence of contact allergy and allergic contact dermatitis is limited. As reported in Mortz et al (2002) for children and adolescents, most studies are cross-sectional, thus giving estimates of the prevalence only, and publications of follow-up studies in this age group are non-existent. Incidence figures are therefore not available. This observation also applies to the incidence data in adults. The few data collected in the literature are as follows:

- Saetterstrom et al (2014) reports an incidence rate of contact allergies of 4.5 per 1,000 inhabitants recognized by dermatologists each year in Denmark.

[76] Gruppo Italiano Ricerca Dermatiti da Contatto e Ambientali

- Schnuch et al (2002) reports an incidence of ACD between 1.7 and 7 per 1,000 per year for the general population, extrapolated from the number of patients eligible to patch testing and combined with patch test results from the Information Network of Departments of Dermatology (IVDK).

Table 38 : Incidence data of contact allergy and allergic contact dermatitis

Source	**Annual incidence rates**	**Population of reference /interpretation**
Saetterstrom et al (2014)	4.5/1 000 (0.45%)	General population in Denmark
Schnuch et al (2002)	1.7-7/1 000 (0.17%-0.7%)	General population in Germany

In conclusion, from the literature and from the dermatologists consulted during the preparation of this restriction proposal, and based on the above data:

- **The prevalence of contact allergy (ACD) in the general population (all causes) would range from 4.4% to 18.4% with a lifetime prevalence of around 15 - 20%.**
- **Annual incidence rates (new cases) for ACD in the general population (all causes) are between 0.17% and 0.7% per year.**
- **Prevalence studies (frequency) of positive patch tests from testing with chemicals contained in textile and leather in adults tested range from 0.4% to 17% with an average calculated by the Dossier Submitter around 5%.**
- **There seems to be no significant difference in prevalence of contact allergies due to textile and leather (based on Disperse dyes testing in particular) between children and adults.**

Based on the above prevalence and incidence data, the number of individuals already sensitised to chemical substances in textile and leather in the EU general population as well as the new textile and leather ACD cases have been estimated.

- **The number of individuals** already sensitised in 2019 to chemical substances in textile and leather articles **in the EEA31 population[77] is estimated between 3.9 and 5.2 million (average 4.5 million),** calculated as follows:

  EEA31 population x ACD prevalence data (min 15%; max 20%) x prevalence of positive tests with textile and shoes series (average 5%)

  ⇨ Min : EEA31 population x 15% x 5% = 518 million x 0.8%≈ 3 885 000 individuals
  ⇨ Max : EEA31 population x 20% x 5% = 518 million x 1%≈ 5 180 000 individuals

  The prevalence of textile and leather ACD, such as calculated by the Dossier Submitter, is thus around 0.8%-1% in the general population. A sensitivity analysis has been performed on the value of 5% of positive patch tests (please see Annex E.5.1.5).

[77] According to Eurostats, the EEA31 counted 518 061 408 inhabitants on 01/01/2018.

According to the baseline scenarios developed in section 1.4 of the main report and Annex D, in 2023, these numbers will be between around 4 060 000 and 5 900 000 (see Table 17 in Annex D). These numbers are respectively rounded down to 4 000 000 and up to 6 000 000 for simplicity reasons in the following. Some significant proportion of these already sensitised individuals are expected to be protected with the adoption of this restriction proposal since skin sensitising substances (classified under CLP or in the list of concern) will no longer be used in textiles and footwear or will be used at a concentration which is considered as safe. The Dossier Submitter considered that this proportion would be between 70% and 90% (for further details please see below, Annex E.5.1.4).

- **The number of new textile and leather ACD cases are estimated between 45 000-180 000 per year (average 113 000) from 2019** calculated as follows:

EEA31 population x ACD incidence data (min 0.17%; max 0.7%) x prevalence of positive tests with textile and shoes series (average 5%)

⇨ Min : EEA31 population x 0.17% x 5% = 518 million x 0.01%≈ 45 000 individuals
⇨ Max : EEA31 population x 0.7% x 5% = 518 million x 0.04%≈ 180 000 individuals

These cases correspond to individuals that are newly sensitised every year and are expected to be prevented with the adoption of this restriction. The incidence of textile and leather ACD, such as calculated by the Dossier Submitter, is thus around 0.01%-0.04% in the EEA31 population.

As indicated in Annex D, the overall number of textile and leather ACD (prevalence and incidence) is thus expected to increase over time under the baseline.

Table 39 : Number of individuals already sensitised in 2023 to substances in textile and leather articles (in million)

	min	max	average
Number of individuals already sensitised to substances in textile and leather articles (0.8%-1% of EEA31 population) – based on prevalence	4	6	5

Table 40 : Number of annual new textile and leather ACD cases from 2023

	min	max	average

Number of newly sensitised cases from textile and leather articles per year (0.01%-0.04% of EEA31 population/year) – based on incidence	45 000	180 000	113 000

These Min/Max/Average values of prevalent and new cases of textile and leather ACD are the ones used to build the projections of prevalent and new cases under the baseline over 2023-2103 in Annex D and in Baseline section 1.4 of the main report.

E.5.1.4 Valuation of health impacts and benefits assessment

The valuation of the health impacts includes the following cost elements:

- Direct costs: treatment costs can become very high as the health effects are incurable and treatment is only palliative (symptom based). Daily treatment for contact allergy includes all activities related to managing the disease when the diagnosis is settled. This is the daily routine treatment of the disease. This may include medication, routine visits to GP, Medical specialists, Ambulatory services, Hospital services, etc. this may also include acute care.

- Indirect costs: skin allergies may hamper persons in their daily activities, cause inconveniences, and may also lead to absence of work because of the recurring effects. Indirect costs may also thus be borne by patients due to the loss of working days in case of invalidating symptoms and sick leaves. The indirect costs are usually assessed based on production losses (costs of lost working days).

- Welfare (intangible) costs: depending on the severity of the contact allergies, the quality of life may be more or less affected. In that case, the loss of quality of life can be assessed.

The literature does not provide many economic studies documenting and assessing the disease burden of contact allergies. A literature review has been done and about 60 papers have been pre-selected based on keywords such as “dermatitis”, “contact dermatitis”, “allergic contact dermatitis”, “skin allergy”, “skin sensitization” associated with “cost”, “disease burden”, “economic burden”, “benefits” and “willingness to pay”. After screening, 18 papers have been selected for further scrutiny (for example, papers addressing the efficiency of a specific dermatological medicine or atopic dermatitis or psoriasis have been discarded). Finally, 4 studies have been considered to be relevant for this case: Saetterstrom et al (2014); the 2012 restriction proposal on chromium VI in leather (mainly based on CowI, 2004); ECHA willingness-to-pay report (2014) and ECHA revised willingness-to-pay report (2016).

These studies are used as the basis of the benefits assessment for this restriction proposal.

Saetterstrom et al (2014)

Saetterstrom et al (2014) assessed the direct and indirect costs of contact dermatitis in a register-based cost-of-illness study. They investigated the effects of contact dermatitis on labour market affiliation and societal costs in terms of healthcare costs and production loss. A total of 21 441 patients patch tested either in hospital departments or at dermatological

clinics in the period 2004–2009 were included in the study. The analyses were stratified by children (age 0–15 years), occupational contact dermatitis (age 16–65 years) (out of the scope of this restriction), and non-occupational dermatitis (age ≥16 years). Controls were selected from a 30% random sample of the population. Individual encrypted data were retrieved on healthcare utilization, socio-demographics, education, labour market affiliation and transfer payments from public registers in Denmark for cases and controls. As explained by the authors, since the exact onset of disease was not determinable within the group of patients, it was not possible to be certain whether costs were entirely attributable to the disease until the patient had been tested. Therefore, an approach was chosen whereby yearly 'attributable' costs were estimated from 4 years prior to patch testing until 1 year after patch testing, although, for children, it was only 1 year before and 1 year after patch testing, because children included newborns. It was assumed that this period would cover the majority of attributable costs incurred, and that, as the date of patch testing was approached, the frequency of disease in the case group would increase, hence increasing the rate of costs attributable to the disease. Healthcare costs and productivity loss for cases and controls were determined for each year and compared.

- Healthcare costs included utilization of primary (fees paid from the public health insurance to healthcare professionals for visits and other services) and secondary healthcare services and prescription medicine (based on market price was used, including both reimbursement and co-payment parts). The attributable healthcare costs for 4 years prior to patch testing for adults and the year after patch testing were €1 794 for non-occupational dermatitis discounted at 3% (ie €360/year). The dossier Submitter notes that since healthcare provision (primary and secondary care) in Denmark is to a great extent publicly funded (85% of healthcare costs are financed through taxes), this part of the healthcare costs may be somehow underestimated.

- Productivity loss: for individuals in the labour market force (aged 18–65 years and excluding individuals who have taken early retirement, retired individuals, and pensioners), the authors included for the assessment of the productivity costs only long-term sickness exceeding 24 days in a row, assuming that the entire period of benefits represented 100% lost productivity. Since contact dermatitis may mainly cause shorter (and potentially repetitive) sick leaves, this assumption may be underestimating since sick leaves longer 24 days may be actually rare when it comes to non-occupational dermatitis (as recognized by the authors themselves). According to the human capital method, productivity losses were valued at the average earnings of €37.4 per hour worked (available from Statistics Denmark), which corresponds to €280.5 for a working day of 7.5 hours. Productivity costs for the entire period (5 years) were €3 074 for non-occupational contact dermatitis (for adults only) discounted at 3% (ie €615/year). It has to be noted that this figure is highly dependent on the quality of the data used and the actual costs in different countries. As a comparison and as noted by the authors themselves, in Germany the cost of one lost working day used for calculations was estimated to range from €400 to €700 (Diepgen, 2006). Saetterstrom et al's figure may thus be underestimating to this respect.

The 2011 restriction proposal on chromium VI in leather

In their restriction proposal, the Dossier Submitter assessed the direct, indirect and intangible costs of contact allergies to chromium VI containing in leather articles. The Dossier Submitter note that monetary valuations of health impacts are subject to significant uncertainty. This study presents a comprehensive assessment and by updating relevant key unit costs to the current price level and to reflect a EU27 average, an order of magnitude monetary value of

the health benefits has been estimated. The COWI (2004) study presents an estimate of the costs of contact allergy. The effects of chromium allergy were considered as more severe by the Dossier submitter and some of the key assumptions have been adjusted (on expert judgements). The healthcare costs include diagnosis costs (incurred once) and direct healthcare costs after diagnosis; the indirect costs include production value loss; the intangible costs are assessed from the value of avoiding a symptom day.

- Diagnosis costs: diagnosis includes all activities related to diagnosing the patient. This is done at the GP, Medical Specialist or at hospital ambulatory (visits as well as tests). The assumptions for an average person who is diagnosed with contact allergy is an age of 40 years old at the time of the diagnosis (based on expert judgement) and an average expected remaining lifetime of 42 years. The cost estimated amounts to € 123 per diagnosis and is presented in Table 41.

Table 41 : Assumptions and diagnosis costs assessed in the restriction on Cr VI

Service	Number	Costs, €	Total costs, €
Diagnosis at GP			
GP Consultations	2	12	24
Allergy test	1	19	19
Total costs			43
Percentage of patients at GP	70%		
Expected costs of diagnosis at GP			**30**
Diagnosis by Specialist (MS) (Dermatologist)			
1st consultation MS	1	55	55
2nd consultation MS	1	30	30
Subsequent consultations MS	2	15	30
Other services	1	8	8
Total costs			123
Percentage of patients at MS	29%		
Expected costs of diagnosis by Specialist			**36**
Diagnosis at Hospital Out Patients clinic			
Visit to Out Patients clinic	3	147	441
Other services	1	33	33
Total costs			474
Percentage of patients at Hospital ***Out Patients clinic***	12%		
Expected costs associated with Hospital *Out Patients clinic*			**57**
Direct total costs			**123**

Sources: Restriction proposal on chromium VI in leather articles and COWI (2004)

The assumptions are mainly based on direct information from experts and hospital sector (Duus and Ménné, 2003). The percentages of patients going to visit their GPs vs. specialists vs. hospitals are thus uncertain. Nevertheless, considering that only 29% of patients go to consult a specialist seems to be in line with the dermatologist's judgement consulted during the elaboration of this restriction proposal who explained that all (potentially a significant part of) patients suffering from a contact dermatitis will not visit a dermatologist (see the 'disease course' above). This observation is also confirmed by the literature that contact allergies are overall under-reported and under-diagnosed. Moreover, in the table above it is assumed that, when consulting a specialist, patients would visit him/her 4 times (2 consultations +2

subsequent consultations), which is not far from the dermatologist's judgement consulted during the elaboration of this restriction proposal (3 consultations).

- Direct healthcare costs (after diagnosis): in the restriction proposal on chromium VI in leather articles, the annual treatment costs are assessed based on annual costs of visits to the GPs and specialists and the patient's costs for medication (ointments, lotions, creams, etc.).

Table 42 : Assumptions and annual treatment costs assessed in the 2012 restriction proposal on Cr VI

Service	Number	Costs, €	Total costs, €
GP Services			
GP Consultations	2	12	24
Total costs			24
Percentage of patients at GP	70%		
Expected GP costs			**17**
Services of specialist doctors (Dermatologist)			
1st consultation MS	1	55	55
2nd consultation MS	1	30	30
Subsequent consultations MS	2	15	30
Total costs			115
Percentage of patients at MS	10%		
Expected Specialist costs			**12**
Hospital out patient services			
Out patient visit	2	147	294
Total costs			294
Percentage of patients at Hospital out patients clinic	2.8%		
Expected costs at Hospital Out patient clinic			**8**
In- Patient Hospital Services			
Average costs per discharge	1	2,580	2,580
Percentage of patients	2.8%		2,580
Expected costs of Hospital Services			**72**
Total costs of health care services			**109**
Medication			
Topical steroids	1	27	27
Percentage of patients using topical steroids	69%		
Total costs of topical steroids			19
Specialists (MS) Dermatologist	12	5.5	66
Percentage of patients using emollients	85%		
Total costs of emollients			56
Lotions etc	12	24	288
Total costs of medication etc.			**363**
Direct total costs			**472**

The annual costs for GPs and hospital costs are estimated to be about €109. It is assumed that each patient has monthly average expenses for ointments, emollients and topical steroids of a little more than €30, i.e. €363/year. As a whole, the direct healthcare costs are estimated at €472/year per case (€9 650 discounted at 4% over lifetime).

The assumptions are based on Keiding (1997) and direct information from experts and hospital sector (Duus and Ménné, 2003).

- Indirect costs: the next cost element valued in the restriction proposal on chromium VI in leather is the possible loss of production value due to restricted activity days. It is based on expert estimates assumed that a person with contact allergy on average is absent from work 7 days per year, taking into account that the Cr(VI) allergy is quite severe. As a comparison, in the COWI 2004 report, 1.6 days has been used as the average absence from work due to contact allergy is (based on Flyvholm and Burr (2001)) but is admitted by the authors to be too low. The costs associated with this absence from work are estimated based on average EU27 salaries (€21.84 per hour; 7.5 hours a day). It is assumed to be €170 per day so the total production loss per year is €1 190 (€18 590 discounted at 4% over lifetime). Compared to Saetterstrom et al (2014), the cost per working day lost is lower due to higher salaries in Denmark (€280.5 for a working day of 7.5 hours) but overall the indirect cost is lower because, as mentioned above, Saetterstrom et al. only took into account sick leave exceeding 24 days. To this respect, the dermatology expert consulted during the elaboration of this restriction proposal confirmed that a duration of 7 days is considered to be representation of absence to work in case of invalidating contact allergy. Finally, in 2017, average hourly labour costs were estimated at €26.8 in the EU28 (although this average masks significant gaps between EU Member States, with hourly labour costs ranging between €4.9 and €42.5)[78].

- Intangible cost/welfare loss: this cost reflects the individual's loss of welfare due to the discomfort of having contact allergy. At the time of the chromium VI restriction proposal there were no specific studies on the individual's willingness to pay (WTP) for avoiding this disease. The ECHA reference values recommended in 2014 and revised in 2016 were not published yet. In their proposal, the Dossier submitter thus assessed this cost based again on COWI (2004) which included a discussion of using the benefit transfer approach and suggested applying a WTP to avoid a symptom day as value indicator. The value for WTP used was €15/day, considered as conservative (compared to other later studies such as the one from AEA Technology Environment in 2005 on air pollution with an avoided symptom day up to €38). Regarding the number of symptoms days, the Dossier Submitter assumed that 73 days of symptoms such as proposed by COWI (2004) was not representative enough and reassessed it upwards, based firstly on the fact that chromium allergy is a very severe form of contact allergy and secondly on the fact that patients with a chromium allergy may be able to avoid some exposure to leather and over time their symptom days could be reduced. The Dossier Submitter thus assumed that the number of symptom days will gradually decrease over a 20 year period from an initial level of 200 days/year to 100 days per year and then remain at 100 days per year for the rest of the patient's life. Finally, an average number of symptoms days of 125 has been used for the welfare loss assessment; giving an annual welfare loss of €1 875/case (€ 37 850discounted at 4% over lifetime). A sensitivity analysis was performed with 50% of the symptom days (reduced at 63) giving an annual welfare loss of 940€ /case.

ECHA 2014 and 2016 reports on willingness-to-pay

In their report on *stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the*

[78] Eurostat: https://ec.europa.eu/eurostat/statistics-explained/index.php/Hourly_labour_costs

European Union, published in 2014, ECHA recommends reference values for willingness-to-pay to be used in restriction proposals and in authorisation applications. *Part I: sensitization & dose toxicity* of the report proposes reference values specifically for skin sensitization from chemicals, based on the observation that there is a lack of comparable values of skin sensitization in the literature. In 2016, ECHA revised some of these values in *Valuing selected health impacts of chemicals - Summary of the Results and a Critical Review of the ECHA study*.

In close cooperation with medical experts and ECHA, several profiles of contact dermatitis were drafted and pretested for the stated preference valuation study. Allergic dermatitis is understood as an allergic inflammatory defence reaction of the body that seeks to eliminate the irritant and to minimize harmful effects. ECHA defines one profile for acute sensitisation (named 'Illness A') with 2 weeks symptoms, occurring once on less than 10% of the body and one profile for chronic sensitisation with lifetime permanent symptoms on less than 10% of the body but more than 10% during flare-up, flare-up lasting about 2 weeks twice a year (named 'Illness B').

In our view, the 'Illness B' profile (represented below) best corresponds to the contact allergies due to textile and leather. It describes a severe allergy, with a source that may be difficult to identify and a hardly avoidable exposure. Even though all contact allergies to textile and leather may not be severe, this profile fits to our case because identifying the exact cloth or shoe responsible of the allergy may be very complex since textiles and footwear articles often contain a high number of various chemicals that may be found in most of the articles in contact with the skin; in those circumstances, the exposure avoidance is difficult or even impossible in some cases and in the meantime, the patients' quality of life may be heavily affected. The 'illness B' profile may show however some extreme characteristics such as injectable corticosteroids and phototherapy in case of flare-ups. As indicated above, these treatments may be indeed prescribed by specialists but only for a few patients and not routinely. Nevertheless, in our view, these uncertainties are reflected in the associated large range of costs estimated by ECHA at €2 000-€12 000/year (ECHA, 2016).

Table 43 : 'Illness' B profile (chronic skin sensitisation) according to ECHA (2014) report

Symptoms of illness	• permanently: • itchy, burning skin • red rashes, small blisters • massive swelling, skin lesions, scabs and scales during flare-up
Area	• permanently: less than 10% of your body • more than 10% of your body during flare-up
How long?	• for the rest of your life • flare-up lasting about 2 weeks
How often?	• flare-up twice a year for the rest of your life
Treatment	• permanently: daily application of skin creams and local corticosteroids • one-week hospitalisation during flare-up with oral or injectable corticosteroids and phototherapy
Quality of life impact	• permanently: • skin soreness from scratching • sleep disturbance • medical side effects such as drowsiness • inability to work in certain types of occupation • during flare-ups: • unpleasant and unsightly appearance

	• limits to leisure activities

Overall, the economic values taken from the literature to assess the disease burden of contact allergies are summarised in the table below.

Table 44 : Economic values available to assess the disease burden of contact allergies

Source	Annual Direct costs / case (healthcare costs)	Annual Indirect cost/ case (productivity loss)	Annual Intangible cost / case (welfare loss)
Saetterstrom et al (2014)	€360 (adult)	€615 (adult) (long-term sick leaves; €2 80.5/day – DK data)	-
Restriction proposal on Chromium VI in leather	€472 (after diagnosis) (€ 9 650 over lifetime)	€1 190 (€18 590 over lifetime) (7 working days lost; € 170/day – EU27 data)	€1 875 (€37 850 over lifetime) (125 symptom days; € 15/day)
ECHA (2016)	-	-	€2 000-€12 000 (severe, chronic sensitisation)

One can notice that, although they are based on different indicator values, the intangible costs from the restriction proposal on chromium VI in leather and the lower bound from ECHA (2016) are comparable. The indirect cost estimated by Saetterstrom et al (2014) is almost twice lower than the one assessed in the restriction on chromium VI: as already mentioned above, it seems however that Saetterstrom et al's evaluation is underestimated due to the fact that they only considered long sickness exceeding 24 days in a row, which are rare and don't occur for most cases of contact allergies. The indirect cost from the restriction on chromium VI is thus considered in what follows as a better estimate for our case (updated with EU28 2017 hourly labour cost). Regarding the direct costs, the cost from the restriction on chromium VI is a bit lower but comparable to Saetterstrom et al's for adults (€472 vs €360. For the assessment, the interval €400-€500 is used for the direct costs.

In summary, the annual economic values used in this evaluation are the following:

- **Direct costs: €400-€ 500 (based on the restriction on chromium VI and Saetterstrom et al 2014)**
- **Indirect costs: €1 400 (based on the restriction on chromium VI, adjusted with EU 28 2017 hourly labour cost)**
- **Intangible costs: €2 000 - €12 000 (based on ECHA (2016 report) and similar value for the lower bound from the restriction on chromium VI)**
  -> This leads to a total annual costs per new case between €3 800 and €13 900.

Based on these economic values, the estimation performed herein includes the following benefits:

- The benefits (cost savings) expected from the restriction due to the protection of a significant proportion of already sensitised individuals who currently suffer from textile and leather contact allergy. These benefits are estimated on the basis of the following:

- As mentioned above, literature reports that around 2/3 (e.g. 70%) of all textile related cases of allergy are attributed to disperse dyes (reported in Bfr (2006); RIVM (2008) and RIVM (2014), based on Hatch and Maibach (1995; 2000) and Lazarov (2004)). The estimate of this proportion covers a certain degree of uncertainty since it is based on the frequency of positivity of patch tests performed on patients and not on an overall and comprehensive prevalence study of textile and leather ACD in the EU general population (which, as already explained, does not exist to date). Given the fact that current textile-specific patch tests, such as *Textile Colours & Finish Series TF-1000* (see Table 33) mainly contain dyes and disperse dyes and that the Textile Dye mix (TDM) (Mx30, see Table 35) only contain disperse dyes, these substances are currently one of the most investigated: as a consequence, the frequency of positivity of patch tests in patients due to disperse dyes may not be representative of most of the actual cases of ACD and the proportion of 2/3 reported in the literature may be somehow biased and overestimated. Nevertheless, this information from the literature still gives an indication that a significant proportion of ACD may be due to disperse dyes (being 70% or lower) which is valuable information to be used.
- For the other substances of the scope, the attribution of textile and leather ACD to specific substances cannot be estimated precisely since no specific information is available. As a result, although the exact proportion of allergy cases attributed to these substances cannot be quantified precisely, the Dossiers Submitter considers that additional current cases would be protected by this restriction proposal:
  - For these substances for which a concentration limit (considered as safe) has been derived from substance-specific elicitation thresholds to the substances, it is considered that the already sensitised individuals will be protected.
  - For these other substances for which a generic concentration limit has been proposed due to a lack of data on their elicitation and/or migration, it is assumed that some proportion of the attributed cases will be protected.
  - These individuals who are already sensitised to skin sensitisers in the scope would still suffer from them due to other sources of exposure but these sources are out of the scope of this restriction proposal and cannot be included in the human health impact assessment.
- As a whole, **the proportion of already sensitised individuals to the substances of the scope that would be protected with the restriction is estimated at least at 70%**, due to the proposed ban of allergenic disperse dyes and due to the restriction of additional allergenic substances at low or very low levels considered as safe (see Annexes B.10.2 and B.10.3) **and up to 90%** is considered to be protected by additional restriction of remaining substances in the scope. The remaining 10% of these individuals potentially not protected reflect uncertainties due to the proportion of highly sensitised individuals that may still trigger allergy at very low exposure limit (lower than the concentration limits considered as safe by the Dossier Submitter) and due to uncertainties that some individuals may still get sensitised to the substances falling under the 'generic approach' (concentration limits being 110 mg/kg in leather or 130 mg/kg in textile, see above sections B.10.1.3 and B.10.2.3.).

- The benefits (cost savings) expected from the restriction due to avoided new cases (constant number per year of avoided new cases which leads to increased accumulated cost savings): since the induction of sensitisation occurs at higher doses than elicitation, a large proportion of the naïve population (not yet sensitised) will also be

protected by the proposed restriction. For the same reasons as above, **it is assumed that between 70% and 90% of new cases would be avoided.** It has to be noted however that the Dossier Submitter expects that this proportion would be even larger, since the doses needed for induction are higher than for elicitation. Using 70%-90% may thus be a conservative assumption here (and a potential source of underestimation of the benefits). To 70%-90% of the number of new cases estimated above are then applied the annual costs per case such as selected above (and summarised in the following table). These benefits are calculated over 2023+80 years, taken as the average life expectancy in the EEA31.

To evaluate the benefits associated to current cases, the annual costs per case are applied to the proportion of 70% (standing for 2.5-4.1 million cases protected) and 90% (standing for 3.6-5.3 million cases protected). Since these individuals wouldn't be exposed to allergens in textile and leather from 2023, they would no longer bear the costs associated to their diseases each year and until the end of their life. As a result, the benefits associated to these avoided costs are estimated also on an annual basis. These individuals include young people, middle-aged people as well as elder people. Therefore, the calculation period for these benefits is 30 years, considered by the Dossier Submitter as a good approximation of the average remaining lifetime of already sensitised individuals from 2023. Moreover, direct costs borne by already sensitised individuals are expected to be lower than the direct costs borne by new allergy cases since one can reasonably expect that the diagnosis has already been done for the former and the disease better managed (at least for those who have consulted a specialist). **The Dossier Submitter thus applied a decrease of 20% on the direct costs for the already sensitised individuals: associated annual costs being therefore €3 700-€13 800 for those.**

As explained also in the main report, it has to be noted that the Cr VI restriction does not include the diagnosis cost in the direct healthcare costs which are annual, compared to the diagnosis cost which is incurred once. As explained in the Annex, the diagnosis cost is estimated at €123 in the Cr VI restriction and is one-shot. As a comparison, Saetterstrom et al, 2014 include diagnosis cost in their direct costs (to the Dossier Submitter's understanding, they assessed as a whole the cost of patch testing and the consultations until the diagnosis and the subsequent treatment and follow-up costs). In principle, the cost of diagnosis shouldn't be included in the evaluation for prevalent cases since they are supposed to be already diagnosed. Regarding new cases, the cost of diagnosis should be included in principle. In the assessment done by the Dossier Submitter, the interval of direct costs is based on both the Cr VI restriction and Saetterstrom et al., 2014 values (and applied to both current and new cases): it thus does not include diagnosis cost in the lower bound of direct costs but it does include it in the upper bound. Nevertheless, the Dossier submitter considers that the interval of these values is still reasonable to be used in the assessment for both current and new cases. Moreover, as mentioned above, the Dossier Submitter applied -20% to the direct costs associated to current cases to reflect their better knowledge and management of their disease (and somehow the diagnosis cost already borne).

Human health benefits: results

Table 45 below provides a summary of the number of cases and the economic values used for the HHIA.

Table 45 : Summary of the number of cases and economic values used for the HHIA

	Total annual	Number of annual new	Total annual costs per ACD	Number of current ACDs

	costs per ACD case (for new cases)	ACDs cases prevented from 2023 (between 70%-90%)	case (for current cases)	cases protected from 2023 (between 70%-90%)
Min values	€3 800	30 000-125 000	€3 700	2.8-3.6 million
Max values	€13 900	40 000-160 000	€13 800	4.1-5.3 million

Based on these data, the annual benefits expected from the restriction have been assessed with 4 sensitivity scenarios, discounted over 2023-2103 for the new cases and over 2023-2053 for the current cases (at 2.5% over 2023-2053, then 0.5%). These sensitivity scenarios are all possible combinations of the number of new and current cases of ACDs and the associated annual costs per case; these combinations are detailed in the main report in section 2.4.2.3.

As a result, the total benefits expected from the restriction, discounted at 2.5% over 2023-2053 and then 0.5% until 2103 are as follows:

Using a discounting rate of 4% is common practice to estimate present values for typical financial assessments. However, when dealing with human health assessment, a decreasing discounting rate of 4% over 2023-2053 (first 30 years) and then 2% (for benefits occurring after 30 years) can be used in order to take into consideration intergenerational equity when human health benefits occur over long-term beyond 30 years[79]. Moreover, it is considered that the value of preventing a fatality has a constant utility value over time and it is therefore uprated in real terms each year by real GDP per capita growth. An uprating factor, usually based on GDP per capita growth and income elasticity, estimated around 1.5%, based on OECD forecasts[80] was used in this restriction proposal. Therefore, when combined with a 4% (2% for benefits occurring after 30 years) discount rate, it gives an 'effective' discount rate for health benefits of 2.5% over 2023-2053 and 0.5% for benefits occurring after 2053.

Table 46 : Total annual human health benefits expected from the restriction: assuming 70% of prevalent and new cases protected.

	Total annual benefits associated to new cases avoided (in million €)	Total annual benefits associated to prevalent cases protected (in million €)	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	83	7 004	**7 087**
Sensitivity Scenario 2: Min; Max	310	25 980	**26 290**
Sensitivity Scenario 3: Max; Min	340	10 190	**10 530**
Sensitivity Scenario 4: Max; Max	1 200	37 800	**39 000**

[79] It has been done in the restriction proposal for BPA in thermal paper for example.

[80] OECD long-term forecast estimates a growth in GDP per capita between 1.92% in 2019 and 1.35% in 2060 (forecasts not available after 2060) (http://knoema.fr/iuacek/euro-area-gdp-growth-forecast-2013-2015-and-up-to-2060-data-and-charts) and the elasticity recommended to be used by OECD is 0.8 +-0.4.

Values discounted over 2023-2103 for the new cases and over 2023-2053 for the current cases (at 2.5% over 2023-2053, then 0.5%)

Table 47: Total annual human health benefits expected from the restriction: assuming 90% of prevalent and new cases protected)

	Total annual benefits associated to new cases avoided (in million €)	**Total annual benefits associated to prevalent cases protected (in million €)**	**Total annual human health benefits expected from the restriction proposed (RO1a) (in million €, rounded up)**
Sensitivity Scenario 1: Min; Min	100	9 000	**9 100**
Sensitivity Scenario 2: Min; Max	400	33 000	**33 400**
Sensitivity Scenario 3: Max; Min	450	13 000	**13 450**
Sensitivity Scenario 4: Max; Max	1 600	48 600	**50 200**

Values discounted over 2023-2103 for the new cases and over 2023-2053 for the current cases (at 2.5% over 2023-2053, then 0.5%)

In conclusion, the total annual human health benefits expected from the restriction amount between 7 and 50 billion € from 2023 with "reasonable" estimate (based on scenarios 2 and 3, considered as "reasonable" compared to the extreme scenarios 1 and 4) between 10.5 and 33.4 billion € (discounted over 80 years from 2023 and 2103 for the new cases and over 30 years from 2023 and 2053 for the current cases ; at 2.5% over 2023-2053, then 0.5%).

Based on the lowest and highest values, the sensitivity scenarios (Min; Min) and (Max; Max) may be respectively underestimating and overestimating. Uncertainties surrounding these estimates are presented in Annex F.

E.5.1.5 HHIA: Sensitivity analysis

A sensitivity analysis (SA) has been performed on the following parameters: the prevalence of patch tests positivity to textiles (considered to be on average 5% in the main calculation), the prevalence of contact dermatitis in the general population all causes (considered to be 15%-20% in the main calculation), the proportion of current and new cases of textile and leather ACD prevented (assumed to be 70%-90% in the main calculation), the assessment period (assumed to be 30 years for current cases protected and 80 years for new cases prevented) and the prevalence of textile-related ACDs in the general population (considered to be 0.8%-1% in the main calculation).

The benefits would respectively vary as follows. The sensitivity analysis SA 1 to SA 7 have been performed assuming 70% of current and new cases protected.

Table 48 : Total annual human health benefits expected from the restriction – SA 1: the average prevalence/frequency of positivity patch tests to textiles assumed to be 10%

	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	14 000
Sensitivity Scenario 2: Min; Max	53 000
Sensitivity Scenario 3: Max; Min	21 000
Sensitivity Scenario 4: Max; Max	78 000

Table 49 : Total annual human health benefits expected from the restriction – SA 2: the average prevalence/frequency of positivity patch tests to textiles assumed to be 0.5%

	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	**708**
Sensitivity Scenario 2: Min; Max	**2 629**
Sensitivity Scenario 3: Max; Min	**1 053**
Sensitivity Scenario 4: Max; Max	**3 900**

Table 50 : Total annual human health benefits expected from the restriction – SA 3: the average prevalence/frequency of positivity patch tests to textiles assumed to be 1%

	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	1 400
Sensitivity Scenario 2: Min; Max	5 200
Sensitivity Scenario 3: Max; Min	2 100
Sensitivity Scenario 4: Max; Max	7 800

Table 51 : Total annual human health benefits expected from the restriction – SA 4: the prevalence of contact dermatitis in the general population, all causes, assumed to be 8%-12%

	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	3 900
Sensitivity Scenario 2: Min; Max	14 600
Sensitivity Scenario 3: Max; Min	6 900
Sensitivity Scenario 4: Max; Max	27 500

Table 52 : Total annual human health benefits expected from the restriction – SA 5: the number of current and new cases of textile and leather ACD in the general population protected assumed to be 50%.

	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	5 000
Sensitivity Scenario 2: Min; Max	18 700
Sensitivity Scenario 3: Max; Min	7 500
Sensitivity Scenario 4: Max; Max	27 900

Table 53 : Total annual human health benefits expected from the restriction – SA 6: the assessment period assumed to be 30 years for both current and new cases protected/prevented (discounted until 2053 at 2.5%).

	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	7 081
Sensitivity Scenario 2: Min; Max	26 260
Sensitivity Scenario 3: Max; Min	10 504
Sensitivity Scenario 4: Max; Max	38 950

Table 54 : Total annual human health benefits expected from the restriction – SA 7: the assessment period assumed to be 10 years for both current and new cases protected/prevented (discounted until 2033 at 2.5%).

	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	9 450
Sensitivity Scenario 2: Min; Max	35 000
Sensitivity Scenario 3: Max; Min	14 000
Sensitivity Scenario 4: Max; Max	51 900

Table 55 : Total annual human health benefits expected from the restriction – SA 8: the prevalence of textile-related ACDs in the general population, assumed to be between 0.8% (the DS' calculated lower bound) and 2% (taking into account the upper bound from Bfr, 2006)

	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)
Sensitivity Scenario 1: Min; Min	7 087
Sensitivity Scenario 2: Min; Max	26 290
Sensitivity Scenario 3: Max; Min	19 500

Sensitivity Scenario 4: Max; Max	72 200

E.5.2. Environmental impacts

As the rationale for this restriction proposal is human health, the environmental impacts arising from substances in textile and leather articles and their comparison with those of the alternatives are not discussed further.

E.6. Risk reduction capacity, practicability and monitorability

The restriction proposed is considered to be practical and monitorable. See section 2.4.4. in the main report.

E.7. Distributional impacts

The restriction proposed is expected to cause distributional impacts among industry of textile and leather (inside an outside the EEA) and consumers (inside the EEA). See section 2.4.3. in the main report.

E.8. Proportionality

Given that the approach performed in this restriction proposal to assess impacts follows a semi-quantitative cost-benefit approach, the proportionality of the restriction proposed is appreciated by comparing the costs and the benefits expected when quantified. The restriction proposed is considered to be proportionate. See section 2.4.4. in the main report.

E.9. Comparison of Restriction Options

Two other restriction options (RO2 and RO3) have been further assessed to be compared with RO1a which is the restriction proposed. RO2 is assessed under section 2.5 in the main report; RO3 is assessed under section 2.6. in the main report and these restriction options are compared with RO1a under section 2.7 in the main report.

Annex F: Assumptions, uncertainties and sensitivities

Table below lists the assumptions, uncertainties and sensitivities of the assessment done to support this restriction proposal and their overall impact.

Table 56 : Assumptions, uncertainties and sensitivities

Section	Source of uncertainties	Overall Impact on the restriction proposal
Scope	Substances included may not be used anymore in textile and leather articles	None since in that case, no impact is expected from the restriction of a substance that is not used
	Irritant and corrosive substances not included in the scope	Under estimation of the number of individuals impacted
	Non classified substances not included if they are not in the list of concern	Under estimation of the number of individuals impacted
Risk assessment	**Migration**. The Dossier submitter has assumed that migration takes place for all substances in the scope. However, information on specific migration factors for the majority of substances was not found. The migration depends on many factors, e.g. inherent chemical/physical properties of the substance, how the substance is incorporated into the textile, the type of fibre the substance is incorporated in, the handling of the textile (by the consumer) and the quality of the manufacturing process (KemI, 2014). For leather articles, the Dossier submitter assumes that the same factors are of importance for the migration potential.	A generic migration factor was used for substances for which no specific migration factor was found. It was selected as an upper range of reported migration factors. This will likely overestimate the migration in many cases. However, in some cases this could also be an underestimation.
	Exposure. The Dossier submitter assumes there is potential for exposure to all substances in the scope, if present in the textile or leather. Based on current data it is not possible to draw conclusions about the *absence* of migration potential for any of these substances in any event. In addition, since the substances in the scope are known skin sensitisers these have potential to penetrate the skin.	The exposure assessment used in this restriction proposal may result in an over-estimation of the exposure for substances that do not migrate from textile or leather.
	Use pattern. There is a lack of data regarding use patterns for different textile and leather articles. The usage depends, for example, on the type of article and individual use patterns. The Dossier Submitter used a worst case scenario setting a frequency of “3” uses per 24 hours to cover most exposure situations. In the case of leather a frequency of 2 was used, since the use pattern was regarded different from textile.	The frequency factor of 3 or 2 will likely overestimate the risk.
	Residual monomers in textiles. The information on the	Because of data gaps regarding levels of unreacted monomers in textile the

	amount/levels of unreacted monomers in textile articles is limited, but levels are assumed to be low. This may be relevant for substances like diisocyanates and (meth)acrylates. Based on such assumptions, consequently the exposure is expected to be very low.	proposed concentration limit may be overly protective.
	Elicitation. The generic elicitation value used as elicitation dose, 0.8 µg/cm^2, is the median EC10 -value based on 15 elicitation studies and on 8 different skin sensitisers (Fischer et al 2011). The range of elicitation doses was 0.025–20.1 µg/cm^2, indicating differences depending on the substance. The median value, 0.8 µg/cm^2, has been used as a generic elicitation dose for regulating concentrations of skin sensitisers in cosmetics. This dose was selected for use in the calculations since it was considered appropriate also for skin sensitisers in textile therefore used in our calculations. For certain substances, such as dispersive dyes specific elicitation doses were found and were used in calculations. Furthermore, the exposure when using patch tests (as basis for generating a generic elicitation dose) may not correlate well with real life exposures in causing elicitation – which is typically induced at lower doses.	Depending on the specific substance, the use of a generic elicitation dose may over- or underestimate the risk.
	ROAT versus Patch tests. The generic elicitation dose used in this restriction proposal (0.8 µg/cm^2) has been calculated using data from patch tests (Fischer et al. 2011). However, elicitation doses generated by ROAT (Repeated Open Application Test) are usually lower.	The generic elicitation dose used may be too high and may underestimate the risk for certain substances. This could lead to a too high concentration limit (and less protective) in textiles/leather. However, this may be counteracted by the worst case scenarios used in the calculations.
	Content of substance in textile and leather versus migration. Migration depends on the content of substance in the textile and leather, but also on other factors, as described above. The exact relation between content and migration potential is uncertain.	The uncertainties and assumptions used in the calculations will have an effect on the concentration limits proposed. Since conservative assumptions have been used, the concentration limits calculated are assumed to be protective. However, there may be cases, when the assumptions used may not be protective enough.
	Risk characterisation. The calculations to generate concentration limits in textile and leather are based on worst case scenarios for migration and exposure frequency.	Based on the calculations used in this restriction proposal, the concentration levels proposed for textile and leather are likely to be sufficiently protective in case of most substances.
Analysis of Alternatives	First substances may have been missed in the original search done by the Dossier Submitter.	This can in turn lead to the inclusion or exclusion of substances if/when the estimated mg/kg limits are

	Secondly the estimation of the mg/kg limits done in KemI (2019) can be an over- or underestimation since it is based on assumptions and best available knowledge (which the consultants themselves also discuss).	reassessed once better information arrives in the public consultation process. It is hard to estimate the magnitude of this uncertainty but the Dossier Submitter do anticipate that a restructure of the estimated mg/kg limits will occur due to new and better information in the public consultation process. This will in turn lead to an inclusion and exclusion of the substances for which the restriction will be binding or not.
Economic Impacts/substitution Costs	Uncertainties also follows due to the lack of adequate information on the use of some substances, their requirement in the process (or not: are there practices that would allow to diminish or get rid of those) and their potential substitute that still persist in certain areas despite substantial efforts (call for evidence, questionnaire to industry and KemI (2019)). Looking at table 18 in the main report, it can be seen that the uncertainties differ in origin for the different substances (even though there are some general uncertainties as well). Below are summarised some of these specific uncertainties: **Lack of information:** For the metals, Phenol, 4-(1,1-dimethylethyl)-Plasticiser and Antioxidant and Antimicrobial, the source of uncertainty is a lack of information on substitution, cost of substitutes and their technical feasibility. **Intermediates and Solvents:** For the intermediates and the solvents, it is estimated that substitution is not technical possible, but there is some uncertainty as to if changes in practice (for solvents) can reduce the concentration of the substances in articles at point of sale. **Diisocyanates:** For the diisocyanates there is some uncertainty regarding whether best practice is required to comply with the proposed restriction, and there is substantial uncertainty about the	For the cases where substitution cost has not been assessed due to information gaps, there is a substantial risk that there are some important substitution costs, which has not been assessed properly. For these cases the Dossier Submitter hopes that better information can be presented in the public consultation process. Feedback from the industry and better information in the public consultation process will be needed to take the analysis further. For intermediates the information at hand, based on industry's feedback, indicates that substitution may be hard. The same for solvents, but best practice is indicated as a possible way forward for solvents. Cost could therefore be high if intermediates and solvents are restricted without substitutes. The number of companies not using best practice and the average cost of moving towards best practice is lacking. This makes the substitution cost (if substitution is needed) of diisocyanates uncertain.

	cost of moving towards best practice (no cost data available).	
	Regrettable substitution: For a number of substances there is indication from industry that the identified substitutes may be considered as regrettable in one aspect or another. For rosins, Phthalates, plasticiser for neoprene for instance, there is an uncertainty as to whether or not substitutes exist with a better health / risk profile.	If better substitutes are not identified, restricting the substances may be harder, according to the industry consulted.
	Rubber accelerators: For rubber accelerators a source of uncertainty is the fact that the number of articles in need of reformulation has not been estimated, which makes the total cost for this reformulation uncertain.	This creates an uncertainty with regard to the number of articles in need of reformulation, it may lead to an underestimation of the costs. Feedback from industry in the public consultation may hopefully clarify this.
	Chromium VI and Glutaraldehyde: There are 2 interlinked sources of uncertainty: one is associated to the stricter concentration limit for chromium VI from 3 mg/kg to 1 mg/kg and the other one is associated with the restriction on glutaraldehyde. For chromium and moving from 3 mg/kg to a more stringent 1 mg/kg target, the uncertainty lies in whether or not this stricter limit implies that usage of chromium will be rendered impossible in the upstream tanning process. At the moment, chromium tanning is possible in the upstream tanning process and the concentration in articles at point of sale can be kept below 3 mg/kg. Three mg/kg was the detection limit at point of (2012) restriction proposal for chromium VI. At present point in time test methods are better and detecting 1 mg/kg can be possible for chromium VI. It is however not known if this will make usage of chromium in the upstream tanning impossible, which might imply large costs. This is therefore considered a source of uncertainty. Although uncertain, indications late in the process give that industry may be able to comply with the lower 1 mg/kg limit without problem. For glutaraldehyde there is an uncertainty as to how a restriction	If a stricter concentration limit for chromium VI in articles at point of sale makes usage of chromium VI in the upstream tanning process impossible, then large costs might follow. At the moment this is however uncertain. More information is needed in the public consultation in order to mitigate this uncertainty. It might lead to large additional costs, especially if the supply of vegetable tanning is insufficient for the large volumes of leather where glutaraldehyde is used today. Since glutaraldehyde is a substitute for chromium the consequences might be even larger if the usage of both are restricted.

	would affect the industry. Information is lacking with regard to substitution costs of glutaraldehyde as well as on the concentration of glutaraldehyde in articles at point of sale. According to the chromium VI (2012) restriction proposal, glutaraldehyde seems to be the main substitute for chromium VI in leather. It is mainly used in the car industry, but also for shoes and other articles. It is uncertain as to whether or not the supply of vegetable tanning and other substitutes to glutaraldehyde are available in large enough quantities. This is an uncertainty. The combined aggregated uncertainty connected to both a stricter limit for chromium VI and glutaraldehyde may also be greater than the sum of the two uncertainties in separate. This follows since glutaraldehyde is a substitute for chromium VI.-	
Total substitution costs	There is an uncertainty that follows from the fact that the total cost calculations are based on the price difference of the substance used and the alternative assuming that all factors (for example volume and quality) are held constant. For the sensitivity analysis for total reformulation cost connected to rubber accelerators there is an uncertainty since the number of reformulations needed due to this restriction in the low-medium-and high scenario are based on assumptions.	This may be considered to result in an underestimation of the total costs. This can lead to both an underestimation and an overestimation of the total cost of reformulations for rubber accelerators.
Human health impact assessment	Occupational contact dermatitis not taken into account	May be a source of underestimation of benefits
	Chemicals-induced urticarial cases not quantified	May be a (probably slight) source of underestimation of benefits
	Irritation contact dermatitis cases (likely to be the preliminary signs of sensitisation) not quantified	May be a source of underestimation of benefits as eliminating substances leading to irritation through textile would stop it
	The calculated prevalence of textile and leather ACDs is *inter alia* based on diagnosed sensitisation from positive patch tests but sensitisation are known to be under-diagnosed and under-reported	May be a source of underestimation of benefits

	ACD is not always confirmed after patch testing, with positive test results relating to past episodes of ACD or having uncertain clinical relevance in these cases	May be a source of underestimation of benefits
	New substances and new dyes are continuously introduced into textile industry	The restriction may not captured these potentially hazardous new substances (at least as long as they are not proven to be skin sensitizers and classified as such under CLP regulation) – may be a source of overestimation of the benefits
	The number of new textile and leather ACD prevented each year is assumed to be constant over time until 2103	May be a source of underestimation of benefits since the EEA31 population increases over time (and so does the number of individuals exposed to allergens contained in textile and leather under the baseline)
	Assumption that 70%-90% of new cases of textile and leather ACD would be avoided: the Dossier Submitter expects that this proportion would be even larger, since the doses needed for induction are higher than for elicitation. Using 70%-90% may thus be a conservative assumption here	Maybe a source of underestimation of the benefits
	The healthcare costs are partly assessed from Saetterstrom et al (2014). However, healthcare provision (primary and secondary care) in Denmark is to a great extent publicly funded (85% of healthcare costs are financed through taxes), so the healthcare costs maybe somehow underestimated.	May be a source of underestimation of benefits
	Prevalence of contact dermatitis in the general population estimated between 15%-20%	These data are considered robust since they are taken from the literature from thorough studies. However, the Dossier Submitter acknowledges that this prevalence may be decreasing due to the regulations adopted since the past few years on different skin allergens such as nickel and chromium. The Dossier Submitter has carried out a sensitivity analysis on this parameter but are confident in their result Moreover, the prevalence of contact dermatitis in the general population may differ from one country to another within the EEA31 due to e.g. cultural clothing habits or local fashions, etc. The Dossier Submitter however couldn't assess whether these potential differences would be a source of underestimation or overestimation.
Others	In addition to this, there is an uncertainty as to how the dynamic connection with CLP will evolve (see section 1.1.4.3 in the main report).	The potential consequences of this uncertainty is however difficult to anticipate: any new information (e.g. on substances used in textile and

	In cases where newly (after restriction implementation) identified substances (with a harmonised classification as skin sensitizer and with a mg/kg level for articles at point of sale, above the allowed), do not coincide with the groups and substances analysed in the SEA, the benefit cost ratio might very well be different from what is assessed.	leather articles) from the public consultation may help mitigate it.

Annex G: Stakeholder information

This annex aims at transparently documenting the consultations of stakeholders that have been carried out for the elaboration of this restriction proposal and how their views have been taken into account.

The current proposal targets at restricting chemical substances with known skin sensitising properties and which may be present in the finished textile and leather articles at point of sale. The Dossier Submitter developed a list of substances with a possible use in textile or leather applications. To gather information on the substances in the list and to understand their purpose in the applications relevant for the scope, ECHA launched a call for comments and evidence. The Dossier Submitter also prepared a questionnaire with targeted questions to selected stakeholders. This consultation mainly focused on the substances known to be present in the finished textile and leather articles at point of sale, though the restriction includes some substances that might not be used (difficult to confirm, so include for completeness). In parallel a consultancy study was initiated during which expert stakeholders were contacted. During the preparation of this restriction proposal, stakeholders were also consulted directly by the Dossier Submitter by e-mails or telephone calls. More information on these activities are presented below.

Call for comments and evidence

Between May 2018 and September 2018 ECHA hosted a call for comments and evidence on their website to allow interested parties to signal their interest and express their views and concerns on the restriction. Specific questions asked in the call concerned information on use of the approximately 340 prelisted substances by KemI and Anses (as those substances were indicated to be present in the finished textile and leather articles at point of sale) to understand their uses in the textile and leather supply chain, if they may remain in the finished articles, human health exposure data, potential alternatives available, and relevant socio-economic information for the preparation of this Annex XV restriction proposal. The background note for the call is available at: https://www.echa.europa.eu/web/guest/previous-calls-for-comments-and-evidence/-/substance-rev/19718/del/50/col/synonymDynamicField_523/type/desc/pre/1/view

In total, 45 comments were received from individual companies as well as industry and trade associations. The information received has been included to the extent applicable and relevant in this report. For confidentiality reasons, the name of individual companies providing information as part of the call for evidence has not been identified.

Questionnaire

As a complement to the call for comments and evidence, a questionnaire with targeted questions to selected stakeholders was prepared by the Dossier Submitter. The aim was to reach a deeper and better understanding of skin sensitisers in textiles, their usage (substance use, quantities and place in supply chain), technical functions of substances as well as substitutes and cost of substitution. The questionnaire is provided at the end of this Annex, (Annex G1).

The questionnaire was sent to in total 90 different companies, trade organisations and organisations in July 2018 (the list of recipients can be provided upon request). Until November 2018, the Dossier Submitter received 3 replies with additional information. However some companies and organisations have chosen to give information in the call for

evidence process instead. The information provided has been included to the extent applicable and relevant in this report.

Consultancy study

In May 2018, the Swedish Chemicals Agency initiated a consultancy study with the purpose to:

- Identify substances that are used in the production of textiles, leather, furs and hides, and that are likely to be present in any of the finished articles, based on (like the call for comments and evidence) use of the approximately 340 prelisted substances by KemI and Anses in the textile and leather supply chain.
- Gather information about levels in formulations, use patterns and potential consumer exposure
- Estimate approximate volumes, identify if and how the substances can be substituted, and the approximate costs of substitution.

The following questions were used:

- Is it used in textile or leather manufacturing?
- Is it used in upstream agriculture?
- Is it used in upstream chemical synthesis?
- Does the wet processor deliberately use the substance during textile or leather processing?
- Does a chemical formulator deliberately include it in a formulation?
- Is the chemical unintentionally present in a formulation?
- Is the substance indented to stay on the product?
- Is the chemical substance present in a finishing formulation and intended to stay on the product?

The chosen consultants were Amanda Cattermole from Cattermole Consulting and Phil Patterson from Colour Connections. They are both colour and textile chemists with over 25 years of experience in the textiles and leather industry and a deep knowledge of textile formulations and textile and leather supply chains.

The consultants consulted several experts from the following organisations:

- The ZDHC technical working group
- The AFIRM Group
- TEGEWA (trade association representing the German Chemical Industry)
- ETAD (Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers
- Nimkartec
- Bluesign
- VF who own the ChemIQ data – test data on textile formulations.

The final report and presentation was submitted to the Swedish Chemical Agency in September 2018.

Much of the information that were gathered in the consultancy study has been used by the Dossier Submitter to prepare the current restriction proposal, particularly for those parts that are related to the manufacture and uses, the cost impact assessment and the analysis of alternatives. The information were in most cases considered best available data, but in those cases the Dossier Submitter had information from other sources, that specific information were used, since the conclusions in the consultancy study were based on expert judgment.

The consultant study is published on KemI's website (www.kemi.se).

Direct consultation with stakeholders

Many stakeholders were also consulted directly by the Dossier Submitter during the preparation of this restriction proposal. The contacts are listed in Table 56 below.

Table 57 : List of Stakeholders consulted by the Dossier Submitter in the preparation of the restriction proposal

Name	**Type of organisation** Company/association/national authority/regional or local authority/Laboratory/Academic institution	**Response received** Yes/no	**Mode of contact** E-mail/phone call/Personal communication/etc
RISE IVF chemical group	Association and Laboratory	Yes	Membership meeting/E-mail. Personal communication.
RISE	Association and Laboratory/ CEN TC248/WG26	Yes	Personal communication/ e-mail
SSEI	Association	Yes	E-mail/personal communication/network meeting
Nimkartek	Laboratory	Yes	Personal communication
IFTH	Laboratory	Yes	Personal communication
Nordeconsult	Laboratory	Yes	Personal communication

Experts consulted

During the elaboration of this restriction proposal, ANSES consulted 2 experts in dermatology and dermatochemistry (Dr Catherine Pecquet and Jean-Pierre Lepoittevin) in order to get better knowledge about the skin sensitisation, the contact allergy course, symptoms and treatments. The numerous exchanges have been done by emails, direct interviews and discussions by phone or during physical meetings. The information collected has been used as a support for the analysis of the prevalence and incidence data, collected from the literature as well as for the risk assessment and the assessment of the human health impacts.

Anses also consulted its Experts Committee on REACH and Experts Committee on Consumer Products as a support of the risk assessment (with the assistance in particular of Dr Jean-Pierre Lepoittevin, chemico-dermatologist, Dr Catherine Pecquet, dermatologist, Luc Belzunces, Environmental Laboratory Director and François Clinard, epidemiologist), the analysis of the alternatives and the socio-economic impacts (with the assistance in particular of Dr Laura Maxim, economist).

Rubber consultant: KemI has also consulted a rubber expert (Dr Mats Ericson from the consultant firm “Lysmask innovation AB”). He has assisted KemI with expert information on seven different rubber accelerators. Information has been provided on function with regard to textiles and mg/kg levels in textile articles at point of sale. Dr Mats Ericson has also given valuable information on substitution, cost of substitution and more specifically on reformulation costs for rubber accelerators to be used for textile applications. Dr Mats Ericson has provided the information during face to face interviews, over email and in the form of excel sheets and other documents.

Annex G1 Questionnaire

Included is the questionnaire sent to textile stakeholders.

Microsoft
Excel-kalkylblad

Annex G2 KemI, 2019 report (consultancy)

https://www.kemi.se/global/pm/2019/pm-1-19-skin-sensitising-skin-corrosive-and-skin-irritating-substances-in-textiles-leather-furs-and-hides.pdf

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