bluesign® criteria for chemical assessment (Homologation)

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1 Introduction

1.1 Chemicals use in textile and leather supply chain

The textile and leather industry including its related branches is a diverse one, as much in the raw materials it uses as in the techniques it employs to make products. In order to impart the required functional and aesthetic properties desired by the consumer such as drape, hand and color, a fiber or a fabric as well as leather must be subject to different types of physical and chemical treatments. The negative impacts of these processes on the environment can be as numerous as they are varied.

The textile and leather supply chain utilizes hundreds of specific chemical substances to make chemical products that can be categorized into three groups:

- Basic chemicals (salts, acids, bases, etc.)
- Colorants (dyestuffs and pigments)
- Auxiliaries (surfactants, leveling agents, softening agents, non-creasing agents, etc.)

Specific chemical substances are defined by their Chemical Abstract Service (CAS) numbers. Chemical substances can be directly sold on the market as basic chemicals (e.g. sodium hydroxide, sodium chloride etc.) or they can be included in mixtures as additives, actives or impurities. Colorants and auxiliaries represent mixtures for which no CAS number can be assigned. Commercial chemical products usually consist of several intermediate mixtures (compare Fig. 1.1).

The chemicals used in the production of textiles and leather generally fall into two classes:

- Effect chemicals: designed to remain on the finished product ("be fixed", e.g. colorants, easy-care finishes, etc.); only very small amounts of these substances will be found in the wastewater effluent or the off-gas.
- Process chemicals: used to support the finishing processes (e.g. leveling agents, wetting agents) or to pretreat the raw material (e.g. detergents); may be completely introduced into the wastewater effluent during the production.

The possible consequences for the worker, consumer, and environment depend on which of the above categories the chemical belongs to. However, often not the active substances mentioned above but the additives (e.g. dispersing agent in a dye) or the impurities (e.g. monomer residue in polymer) are the reasons for a possible negative impact on people and the environment. Therefore the homologation procedure considers also these types of substances.
1.2 Chemical hazard and risk assessment

All chemical substances have an inherent hazard. The degree to which that hazard may present a risk to humans or the environment is a function of the inherent hazard and exposure:

\[ \text{RISK} = f(\text{HAZARD} \times \text{EXPOSURE}) \]

Following the precautionary principle, risk reduction should be accomplished by minimizing the inherent hazards of chemicals used in the production whenever it is possible to do this and maintain function. Where substitution of less hazardous chemicals is not possible, a risk assessment approach is used to calculate the nature and magnitude of possible health risks to worker, consumers, and the environment. The risk assessment approach is also used to determine the bluesign® chemical limits (compare Fig. 1.2).
In general, risk depends on the following factors:

- inherent toxicity (i.e. hazard) of the chemical substance
- concentration of the chemical substance
- level of exposure for a person or ecological receptor to the contaminated medium

**Note:**
Risk assessment related terminology used in this document is mainly based on:
2 Scope

The chemical assessment (hereinafter referred to as ‘bluesign® homologation’ or ‘homologation’) is one of the main focus areas of the bluesign® system. This document describes the process and criteria for this chemical assessment. The scope of bluesign® homologation are bluesign® system partners' chemical products for industrial use in the textile and leather industry as well as in other related industries (e.g. accessory manufacturing). The processes described are not unlike those used for risk assessments in other industries or for ecological risk assessments.

Note 1:
A homologation process is not carried out for basic chemicals (e.g. sodium hydroxide, acetic acid etc.). Basic chemicals are rated based on an actual MSDS which has to be reliable and appropriate. Basic chemicals can either be rated “accepted” (compliance is given) or “banned” (compliance is not given). “Banned” chemicals have to be phased out from manufacturing process. The bluesign® system partnership for a chemical company supplying only basic chemicals is not required.

Note 2:
The methodology of homologation procedure explained hereinafter is based mostly on the examples from the textile industry. The approach for other textile industry related branches (e.g. leather industry, accessory manufacturing), even though not explicitly stated in this document, is similar.

Note 3:
For nanoscale materials, flame retardants, biocidal products/antimicrobial active substances and chemical products for direct consumer use additional requirements including a lifecycle risk assessment performed by the bluesign® system partner are requested (see relevant annex documents).

Note 4:
Chemicals management is not the focus of this document. Requirements related to practices such as input stream management of raw materials and intermediates, storage, processing and discharge of chemicals at the chemical supplier and the down stream user level (i.e. textile manufacturer) are described in the bluesign® criteria for production sites and in relevant annexes.
3 Definitions

3.1 Homologation
Chemical assessment and rating of chemical products according to their environmental, health and safety aspects.

3.2 Hazard
An intrinsic potential of something to cause harm.

3.3 Exposure
A state of coming into contact with a chemical substance through inhalation, skin contact, ingestion or any other route.

3.4 Risk
A likelihood of harm to occur.

3.5 Usage ban
For several chemical substances or substance groups a usage ban is defined. For these substances or substance groups intentional use in manufacturing of articles is prohibited. That means that chemical products used for manufacturing of articles (e.g. colorants or textile auxiliaries) must not intentionally contain these substances or substance groups.

3.6 Blue rating
Rating of a chemical product from a bluesign® system partner. Blue rated chemical product may be used for all applications.

3.7 Grey rating
Rating for a chemical product from a bluesign® system partner. Grey rated chemical product may be used under one or more preconditions as listed in the bluesign® bluefinder.

3.8 Black rating
Rating for a chemical product from a bluesign® system partner which does not meet the bluesign® criteria for chemical assessment (homologation) and must be eliminated from the manufacturing process.

3.9 Usage range
Usage ranges classify consumer goods according to their consumer safety relevance. Three usage ranges (A, B, C) are defined, with A being the most stringent category concerning limit values/bans.

3.10 CAS number
A unique numeric identifier which designates only one chemical substance. Also referred to as CAS Registry Number.

3.11 Chemical
A commercial product which can be a chemical substance or a mixture.

3.12 Chemical product
See Chemical.

3.13 Chemical substance
A chemical element and its compounds with constant composition and properties. It is defined by the CAS number.
3.14 **Basic chemical**
A commercial product (normally without a trade name) consisting of one chemical substance or a solution of this substance (e.g. sodium hydroxide, acetic acid).

3.15 **Mixture**
A chemical product composed of two or more chemical substances. It can be, for example, a colorant or an auxiliary.

3.16 **Auxiliary**
A commercial product composed of two or more chemical substances.

3.17 **Colorant**
Can be a dye or a pigment. Colorant is characterized by its ability to absorb visible light.

3.18 **Pigment**
A colorant characterized by being practically insoluble in the media in which it is applied.

3.19 **Dye (also dyestuff)**
A colorant applied to various substrates from a liquid in which it is completely or at least partly soluble. In contrast to a pigment, a dye must possess a specific affinity to the substrates for which it is used.

3.20 **Manufacturer**
A company that produces textile articles (all processing levels), leather and accessories.

3.21 **Chemical supplier**
Any company that places under own trade name chemical products such as auxiliaries, dyestuffs and other chemical products for production of textiles, leather and accessories on the market. A chemical supplier may be a manufacturer, a formulator or a rebrander of chemical products. A producer of chemical products who directly uses the produced chemicals for down-stream processing of articles will also fall under the category chemical supplier.

3.22 **Downstream user**
A company or an individual who uses a chemical substance, either on its own or in a mixture, in the course of the industrial or professional activities.

3.23 **Endpoint**
A discreet, measured parameter or outcome in a study.
4 Concept

The textile and leather industry and industries related to the complex textile/leather supply chain use chemical intensive processes. The paramount idea of the bluesign® homologation process is to provide chemical suppliers as well as down-stream users with the tools to reduce or even eliminate harmful chemicals in consumer goods and to minimize emissions to the environment (Fig. 4.1).

The outcomes of homologation are

- the bluesign® system substances list (BSSL); around 900 substances are considered
- usage bans for chemical substances in manufacturing (for about 600 substances a usage ban is defined)
- limits for chemical substances in chemical products (documented in the bluesign® bluetool)
- blue, grey and black rating of chemical products
- limits for chemical substances in articles (consumer safety limits; see BSSL-consumer safety limits)
- web-based bluesign® bluefinder, a positive list of blue and grey rated chemical products

![Diagram of bluesign® homologation process](image)

Figure 4.1: bluesign® homologation process.
4.1 Assessment
Hazard identification and appraisal of exposure followed by a risk assessment of chemical substances that are contained intentionally or non-intentionally in the chemical products is one of the main fundamental pillars of the homologation procedure. Based on the detailed knowledge and data delivered by system partners from the chemical industry a well-founded assessment of the respective chemical products can be performed. The web based bluesign® bluetool serves as the assessment tool. In the next sections, the methodology behind the assessment procedure is explained in detail.

4.2 Restrictions and bans for chemical substances
As of 2014, the BSSL contains about 900 chemical substances. So far for about 600 substances a usage ban has been defined.

4.3 bluesign® rating
Chemical products supplied from bluesign® system partners are rated. Three rating scores can result: blue, grey or black. Chemical products that comply with the bluesign® criteria are divided into categories “blue” or “grey”:

- Blue chemical products entirely fulfill the requirements of the bluesign® criteria based on realistic worst-case exposure scenarios and may be used for all applications.
- Grey chemical products may be used in the production only under certain conditions. The principle of the Best Available Technique (BAT) applies in this case.

Chemical products that do not meet the strict requirements of the bluesign® criteria fall into the category “black” and must be eliminated from the manufacturing process.

4.4 bluesign® bluefinder - Positive list of blue and grey rated chemical products
The bluesign® homologation provides a foundation for developing a ‘positive’ list of blue and grey chemical products, which shall solely be used in the manufacturing process of bluesign® system partners. The list is available as a web-based information tool – the bluesign® bluefinder.

4.4.1 Usage ranges
Three usage ranges (A, B, C) are defined, with A being the most stringent category concerning limit values/bans:

- Usage Range A: Next to skin use and baby-safe (0 to 3 years)
- Usage Range B: Occasional skin contact
- Usage Range C: No skin contact
5 Data sources

5.1 Open data sources

Assessment of chemicals is based on the best available data. The following nationally and internationally recognized agreements, scientific literature and hazard lists are taken into consideration when identifying the substances of concern:

- national/international consumer safety regulations
- national/international regulations on environmental protection and occupational health
- voluntary agreements within the chemical and textile industry
- substances of concern listed in the so-called “Restricted Substances Lists (RSLs)” and “Manufacturing Restricted Substances Lists (MRSLs)” of various retailers and brands
- web tools/search engines

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<td>Data input to bluesign® bluetool</td>
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<td>Data Sets (CICADs)</td>
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<td>Germany</td>
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<td>DFG Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area</td>
<td>German Research Foundation (DFG)</td>
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### Others Europe

- **KEMI Databases**: Swedish Chemicals Agency (KEMI)  

### U.S.

- **EPA Laws and Regulations**: United States Environmental Protection Agency (EPA)  
  [www2.epa.gov/laws-regulations](http://www2.epa.gov/laws-regulations)
- **NIOSH Information on Chemicals**: The National Institute for Occupational Safety and Health (NIOSH)  
  [www.cdc.gov/niosh/topics/chemical.html](http://www.cdc.gov/niosh/topics/chemical.html)
- **OSHA Regulations**: United States Department of Labor Occupational Safety & Health Administration  
  [www.osha.gov](http://www.osha.gov)
- **OEHHA Regulations**: California EPA  
  [www.oehha.org/prop65.html](http://www.oehha.org/prop65.html)
- **OEHHA Toxicity Criteria Database**: California EPA  
  [www.oehha.org/tcdb/index.asp](http://www.oehha.org/tcdb/index.asp)
- **Design for the Environment Program (IRIS)**: United States Environmental Protection Agency (EPA)  
  [www.epa.gov/iris](http://www.epa.gov/iris)
- **Integrated Risk Information System (IRIS)**: United States Environmental Protection Agency (EPA)  
  [www.epa.gov/iris](http://www.epa.gov/iris)
- **NLM TOXNET**: United States National Library of Medicine Toxicology Data Network  

### Other sources

- **SIN List**: International Chemical Secretariat  
  [www.chemsec.org/what-we-do/sin-list](http://www.chemsec.org/what-we-do/sin-list)
- **Brand RSLs**: Brands worldwide  
  [several](http://several)
- **ETAD Regulations and Recommendations**: The Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD)  
- **58 Key Chemical Groups**: China’s 12th Strategic 5 Year Plan (2011-2015)  
  [China’s 12th Strategic 5 Year Plan (2011-2015)](http://China’s 12th Strategic 5 Year Plan (2011-2015))
- **Information on Chemicals**: Several testing labs  
  [several](http://several)
- **Other Eco Labels**: Several Organizations  
  [several](http://several)
5.2 Data input from chemical supplier system partners

With the help of the bluesign® bluetool all system partners from chemical industry are easily guided through the homologation procedure. The tool provides all the necessary information on the evaluation of chemical products. Information on both ecological and toxicological properties of a mixture and on the single substances in a mixture is provided by the system partners. The data input is carefully verified by bluesign technologies.

5.2.1 Information on chemical substances

Information on kind and amount of all relevant single chemical substances listed in the BSSL and contained in a mixture is provided by system partners.

5.2.2 Information on ecological and toxicological properties of a mixture

There are many parameters that may be required during the homologation process. The parameters listed below are used to review the toxicological, ecological and physicochemical properties of a mixture. A combination of certain core parameters influences the final rating score of a mixture. Those parameters that are not utilized for purposes of a rating procedure are used for example for the determination of an ecological impact (e.g. total nitrogen and phosphorus calculations in the wastewater).

- Biodegradability
- COD (chemical oxygen demand)
- TOC (total organic carbon)
- BOD₅ (biochemical oxygen demand)
- P total (total phosphorous content)
- N total (total nitrogen content)
- Sulphite
- Sulphate
- Aliphatic hydrocarbons
- Sulfide
- Aquatic toxicity (fish, daphnia, algae, bacteria)
- AOX (adsorbable organic halogens)
- Irritancy skin
- Irritancy eye
- Sensitization skin
- Acute oral toxicity
- Acute dermal toxicity
- Mutagenicity Ames test
- Chromosome aberration test
- Air emission (emission factors for total-C and specific substances)

5.3 Chemical Working Group

bluesign® Chemical Working Group - an association of product stewardship experts from chemical sector - provides the professional expertise and advice concerning chemical substances and products utilized in the textile industry and related branches.
6 Hazard assessment

6.1 Hazard Identification
When identifying and characterizing a hazard, the nature and severity of the possible adverse effects that a chemical substance can have on humans (carcinogenicity, eye irritation etc.) or on the environment (effects on fish, vegetation etc.) shall be determined. Hazard identification is based on the intrinsic properties of the chemical substance and the adverse effects associated with its properties.

The following hazard endpoints and environmental parameters are considered when identifying and prioritizing supply chain relevant substances:

- **Human toxicity:**
  - carcinogenicity
  - mutagenicity/genotoxicity
  - reprotoxicity
  - developmental toxicity
  - neurotoxicity
  - endocrine disruption
  - mammalian toxicity
  - skin/eye irritation and corrosivity
  - skin and respiratory sensitization

- **Environmental toxicity and fate**
  - persistence
  - bioaccumulation
  - biodegradation
  - aquatic toxicity
  - ozone depletion
  - green house gas effect

6.2 Dose-effect relationship
The hazard of a chemical substance is generally characterized in terms of the dose of that chemical which causes or may cause a particular adverse effect. The dose-effect relationship of a chemical substance may vary depending upon the route of exposure and the specific adverse effect. In the course of the homologation process bluesign technologies do not generate these data in the own labs but refer to data from system partners and from other data sources (compare Chapter 5).
7 Exposure assessment

The hazard assessment, while focusing solely on the intrinsic properties of a chemical substance, does not take into account the possibility, nature or extent of any actual human or environmental exposure to that chemical substance. Therefore the characterization of human or environmental exposure is an important step to evaluate whether human or environmental receptors are exposed to the properties that are linked to the possible adverse effects.

Exposure assessment includes the following exposure pathways:

- Consumer exposure
- Worker exposure with focus on inhalative exposure route
- Environment exposure (air emission and water emission)

![Exposure pathways diagram](image)

Figure 7.1: Exposure pathways.

7.1 Consumer exposure

Consumer can be exposed to the chemical product via three main routes:

- Dermal
- Oral
- Inhalative

and three kinds of usage ranges for the end product (A, B, C).

7.2 Worker exposure

Occupational exposure scenarios considered at the workplace include:

- undiluted auxiliary (open barrel)
- dyeing machine
- stenter, coating or printing machine

7.3 Environment exposure

Air and water are treated as two separate media for assessing exposure pathways.
8 Risk assessment

There are two ways to perform a risk assessment of a chemical product:

- Perform a risk assessment of the ecological properties of a mixture (e.g., dyestuff, auxiliary) as a whole
- Perform a risk assessment of the properties of each individual chemical substance (intentionally or non-intentionally used) that is part of a mixture

Figure 8.1: Methodology of risk assessment.

Each assessment pathway can lead to blue, grey or black classification for the mixture. The final rating, i.e., an outcome of an assessment for both a mixture and its single substances, is always decided by the worse of the two results.

8.1 Single substances in a mixture

The goal of assessing a risk for single substances in a mixture is to set concentration limits for these substances. The identification of substances of concern is based on the approach described in Chapter 5.

Risk assessment, which follows main exposure pathways described in detail in Chapter 7, considers two scenarios for the application and consequently the exposure to the chemical product:

- Realistic worst case scenario
- Real scenario
The realistic worst-case scenario is based on the default values that are conservative, in other words, they assume the highest hazard and the highest potential for exposure. The real scenario is based on the test results for exposure, the knowledge on distribution behavior between textile/water/air and on the data provided in the Technical Data Sheet.

As a consequence two concentration limits for substances in mixtures result (Fig. 8.2):

- blue/grey limit
- grey/black limit

The blue/grey limit is a fixed limit based on the default values valid for the realistic worst case scenario. The grey/black limit is a dynamic limit, which depends on the real application data and emission behavior for the relevant chemical product. If data for calculation of real exposure scenarios is not available the realistic worst case scenario values are used. Chemical substances with usage bans are characterized only by a fixed limit; no dynamic limit applies in this case.

![Figure 8.2: Concentration limits for substances in a mixture.](image)

As a consequence, the risk assessments can result in

- a blue rating
- a grey rating
- a black rating

Finally, it has to be noted that the limit for a chemical substance in a mixture is indicated by the lowest limit calculated for each exposure pathway.
The supplement to this document contains a compendium (non-exhaustive) of formulas and default values used for the risk assessment. The default values are based on the Technical Guidance Documents on Risk Assessment (EC, 2003), German Federal Institute for Risk Assessment BfR Opinion No. 041/2012 Introduction to the problems surrounding garment textiles and the database of the German Institute for Work Safety (IFA), former BIA. All relevant BSSL substances are assessed using the approach described in Chapter 8 and in the Supplement.

8.1.1 Consumer
Risk assessment calculations, given in the Supplement, are performed for the following exposure routes:
- Dermal
  - acute
  - chronic
- Oral
  - mouthing (contact with or in the mouth for an extended period of time)
  - swallowing
- Inhalative
  - acute
  - chronic

Inhalation scenarios include among others: space inside a tent, baby inside baby baggy, window curtains in a room, textile in a car, etc.

Knowing typical application scenarios and emission pathways for the down-stream use of the chemical products (e.g. in the textile manufacturing) a conclusion on concentration limits of a substance in a chemical product (in mg substance per kg mixture) can be drawn based on the concentration of a substance in a textile (in mg substance per kg textile). In other words, the calculated consumer safety limit of the substance on the textile is triggering the limit for this substance in the chemical product.

Realistic worst case default values for back-calculation from consumer safety limits to concentration limits of a substance in a mixture are described in the Supplement.

8.1.2 Worker
For each of the exposure scenarios listed in section 7.2 and based on the maximum allowed concentration of a chemical substance in the workplace atmosphere, a concentration limit value for a substance in a chemical product is calculated. The calculation is based on Raoult’s law and diffusion controlled equation. The formulas and input parameters are listed in the Supplement.

8.1.3 Air
The emission factor concept (compare bluesign® criteria for production sites / annex: Textile Manufacturer) stands behind the risk assessment for air exposure pathway. It is used to estimate off-gas loads and off-gas concentrations. If data on substance specific emission factors is available, an exact calculation can be carried out (see Supplement). In all other cases, default values are used.

8.1.4 Water
In most cases the properties of and the behavior of a chemical product in the industrial process are taken into consideration when evaluating a risk for the water path. The PEC/PNEC ratio between the Predicted Environmental Concentration (PEC) and the Predicted No-Effect Concentration (PNEC), i.e. concentration below which unacceptable effects on organisms will most likely not appear, can be used as the indication of the likelihood of the adverse effects to occur.
PEC calculations (see Supplement) are carried out on the basis of real data in cases where chemical substances with high aquatic toxicity are involved. PNEC can be derived from laboratory NOEC (No Observable Effect Concentration) and/or L(E)C50 (50% Lethal or Effect Concentration) values by applying an assessment factor.
8.2 Ecological properties of a mixture

The assessment of ecological risk of a mixture is based on the correlation between biodegradation and aquatic toxicity (Fig. 8.3). Mixtures that have low aquatic toxicity and are readily biodegradable will be rated as blue. A high aquatic toxicity and a low biodegradation degree will lead to a black rating. The grey rating can also be supported by an additional parameter - bacteria toxicity.

The aquatic toxicity and biodegradation are used to determine the rating of only those mixtures that are not intended to be fixed on textiles. The ecological impact of chemical products that are intended to be fixed on textiles (e.g. dyestuffs, finishing agents, after treatment agents with fiber affinity) is assessed by an on-site inspection. These chemical products are designed to guarantee long-term functionality or color resistance of the textile, which is equal to an inherent low biodegradation behavior. Biodegradability of a chemical product can be assessed according to the methods: OECD 302 B, OECD 310, OECD 301 A-F or OECD 303 A.

![Diagram of rating mechanism based on OECD 302 B](image)

Figure 8.3: Rating mechanism – biodegradability and aquatic toxicity relationship – based on OECD 302 B.
9 Validity

This document comes into effect from April 01, 2014. It replaces Chapter 6 of the bluesign® standard, edition 1.2 from March 2010.

This document is subject to changes. Changes will come into effect after prior notice and defined transition time.

10 Other applicable documents

- bluesign® system (effective version)
- bluesign® system substances list (BSSL; effective version)
- bluesign® criteria for chemical assessment (homologation) | Annex: Biocidal products and antimicrobial active substances (effective version)
- bluesign® criteria for chemical assessment (homologation) | Annex: Flame retardants (effective version)
- bluesign® criteria for chemical assessment (homologation) | Annex: Nanoscale materials/structures (effective version)
- bluesign® criteria for bluesign® approved chemical products for direct consumer use (effective version)
11 Supplement

This supplement contains risk assessment calculations for consumer safety, occupational safety and air/water emissions.

11.1 Consumer

11.1.1 Dermal exposure

- Acute dermal exposure

\[
C_{\text{textile}} = \frac{l_{\text{dermal acute}} \times BW \times 100 \times 100 \times 1000 \times 1000}{A_{\text{dermal}} \times SW_{\text{textile}} \times MOS \times F_M \times F_P}
\]

- Chronic dermal exposure

\[
C_{\text{textile}} = \frac{l_{\text{dermal chronic}} \times BW \times 100 \times 100 \times 1000 \times 1000}{A_{\text{dermal}} \times SW_{\text{textile}} \times MOS \times F_M \times F_P \times N_{\text{event}}}
\]

where

- \(l_{\text{dermal acute}}\) [mg/kg bw] Acute toxic value (LD50 value)
- \(l_{\text{dermal chronic}}\) [mg/kg bw/day] Chronic daily value (NOAEL or results from acknowledged risk assessment studies*)
- \(C_{\text{textile}}\) [mg/kg] Concentration of substance on textile
- \(SW_{\text{textile}}\) [g/m²] Specific textile weight
- \(A_{\text{dermal}}\) [m²] Exposed skin area
- MOS Margin of safety
- \(F_M\) [%] Migration portion out of textile
- \(F_P\) [%] Absorption portion
- \(BW\) [kg] Body weight
- \(N_{\text{event}}\) [1/day] Number of events per day

* NOAEL value is used together with the respective MOS value. If the results from risk assessment, e.g. IRIS reference dose (RfD), are used then MOS is automatically included in the calculation.

11.1.2 Oral exposure

- Oral exposure, swallowing

\[
C_{\text{textile}} = \frac{l_{\text{oral (swallowing)}} \times BW \times 100 \times 100 \times 1000}{F_{\text{oral}} \times Q_{\text{oral}} \times MOS \times N_{\text{event}}}
\]

- Oral exposure, mouthing

\[
C_{\text{textile}} = \frac{l_{\text{oral (mouthing)}} \times BW \times 100 \times 100 \times 1000}{F_{\text{oral}} \times Q_{\text{oral}} \times F_M \times MOS \times N_{\text{event}}}
\]
where

\[ I_{\text{oral}} \] (mg/kg bw/day)  Recommended daily intake from acknowledged risk assessment studies or NOAEL*

\[ C_{\text{textile}} \] (mg/kg)  Concentration of substance on textile

\[ Q_{\text{oral}} \] (g)  Weight of exposed textile

\[ F_{\text{oral}} \] (%)  Fraction absorbed

\[ F_{\text{M}} \] (%)  Migration portion

MOS

\[ N_{\text{event}} \] (1/day)  Number of events per day

\[ BW \] (kg)  Body weight

* NOAEL value is used together with the respective MOS value. If the results from risk assessment, e.g. IRIS reference dose (RfD), are used then MOS is automatically included in the calculation.

11.1.3 Inhalative exposure

- Acute inhalative exposure

\[
C_{\text{textile}} = \frac{C_{\text{inh}} \times V_{\text{room}} \times E_{\text{air}} \times T_{\text{contact}} \times \frac{100}{F_{\text{inh}}} \times \frac{100}{E_{\text{eff}}}}{(1 - \left(e^{(-1 \times 0.69312 \times HLT^{-1}) \times T_{\text{contact}}})\right) \times Q_{\text{textile}}}
\]

- Chronic inhalative exposure

\[
C_{\text{inh}} = \frac{I_{\text{inh}}}{MOS} \times \frac{BW}{Q_{\text{inh}}} \times \frac{100}{F_{\text{inh}}}.
\]

\[
C_{\text{textile}} = \frac{C_{\text{inh}} \times V_{\text{room}} \times E_{\text{air}} \times E_{\text{exposure}} \times \frac{100}{E_{\text{eff}}} \times \frac{24h}{E_{\text{daily exposure}}}}{Q_{\text{textile}}}
\]

where

\[ C_{\text{textile}} \] (mg/kg)  Concentration of substance on textile

\[ C_{\text{inh}} \] (mg/m³)  Concentration of substance in air

\[ Q_{\text{textile}} \] (kg)  Amount of textile

\[ V_{\text{room}} \] (m³)  Volume of room

\[ E_{\text{air}} \] (1/h)  Air exchange rate

\[ T_{\text{contact}} \] (h)  Duration of exposure

\[ F_{\text{inh}} \] (%)  Absorption of the inhaled air

\[ E_{\text{eff}} \] (%)  Emission efficiency

\[ HLT \] (h)  Half-life time

\[ I_{\text{inh}} \] (mg/kg bw/day)  Daily intake value (NOAEL or results from acknowledged risk assessment studies)

\[ Q_{\text{inh}} \] (m³/h)  Inhalation rate

\[ BW \] (kg)  Body weight

\[ E_{\text{exposure}} \] (h)  Chronic time exposure

\[ E_{\text{daily exposure}} \] (h)  Daily time exposure

MOS

* NOAEL value is used together with the respective MOS value. If the results from risk assessment, e.g. IRIS reference dose (RfD), are used then MOS is automatically included in the calculation.
11.1.4 Back calculation for the limit of a substance in a chemical product

- **Pre-treatment/dyeing (exhaust processes)**

\[ C_{\text{sub}} = \frac{C_{\text{textile}}}{C_{\text{liquor}} \times LR \times 1000} \times \frac{100}{R} \]

- **Finishing**

\[ C_{\text{sub}} = \frac{C_{\text{textile}}}{C_{\text{liquor}} \times P_{\text{up}} \times 1000} \times \frac{100}{R} \]

- **Coating**

\[ C_{\text{sub}} = \frac{C_{\text{textile}}}{C_{\text{liquor}} \times P_{\text{up}} \times 1000} \times \frac{100}{R} \]

where

- \( C_{\text{sub}} \) [g/kg] Concentration of substance in auxiliary
- \( C_{\text{textile}} \) [mg/kg] Concentration of substance on textile
- \( C_{\text{liquor}} \) [kg aux/kg liquor] Concentration of auxiliary in liquor
- LR [kg liquor/kg textile] Liquor ratio
- \( P_{\text{up}} \) [kg liquor/kg textile] Pickup of liquor on textile
- R [%] Residue on textile after process

11.2 Worker

11.2.1 Undiluted auxiliary or dying machine

The calculations for assessment of the worker’s safety in the dyeing kitchen and at the dyeing machine are based on the Raoult’s Law and Avogadro equation (Atkins P.W., *Physical Chemistry*, 1990).

11.2.2 Stenter/Coating or Printing Machine

The assessment of the worker’s safety at the stenter follows the bluesign® modelling based on the diffusion controlled evaporation.

The following input data are required for the calculation of the concentration of a substance in auxiliary [g Sub/kg Aux]:

- Maximum concentration in air [mg/m³]
- Molecular weight of substance [g/mol]
- Molecular weight of solvent [g/mol]
- Working time [h]
- Air exchange rate [1/h]
- Room volume [m³]
- Air flow [m³/h]
- Source Room Relation [-]
- Activity coefficient in solution [-]
- Vapor pressure of substance 20 °C [mbar]
11.3 Air

11.3.1 Air emission stenter / coating

\[ C_{sub} = \frac{f_i}{P_{up} \times C_{liquor}} \times \frac{F}{100} \times \frac{100}{S} \]

where

- \( f_i \) [g Sub/kg Tex] Emission factor limit
- \( P_{up} \) [kg liquor/kg textile] Pickup of liquor on textile
- \( C_{liquor} \) [kg aux/kg liquor] Concentration of auxiliary in liquor
- \( F \) [%] Correction factor
- \( S \) [%] Emission ratio of the limit
- \( C_{sub} \) [g Sub/kg Aux] Share of single substance to emission factor limit

11.4 Water

The formula for obtaining PEC values is based on REACH RUH Project (www.reach-helpdesk.info).

\[ PEC_{local} = \frac{Q_{chem.prod} \times C_{sub} \times F_{nx} \times (1 - Red_{min}) \times (1 - (F_{bio} + F_{ads}))}{Q_{water}} \]

where

- \( PEC_{local} \) [µg/l] Predicted local environmental concentration
- \( Q_{chem.prod} \) [kg/d] Amount of the chemical product used per time
- \( C_{sub} \) [mg/kg] Concentration of a substance in chemical product
- \( F_{nx} \) [-] Portion not fixed on a textile
- \( Red_{min} \) [-] Effectiveness of additional emission decrease measures
- \( F_{bio} \) [-] Degree of biodegradability
- \( F_{ads} \) [-] Sludge adsorption factor
- \( Q_{water} \) [m³/d⁻¹] Receiving water

11.5 Default values

The following default values were used for calculations:

11.5.1 Consumer safety
- baby weight: 3 kg
- adult weight: 60 kg
- textile weight - baby: 300 g/m²
- textile weight - class A (next to skin): 300 g/m²
- textile weight - class B (occasional skin contact): 300 g/m²
- textile weight - class C (tent use, 50% of the floor are covered): 500 g/m²
- exposed skin area
  - baby: 0.5 m²
  - class A: 1.5 m²
  - class B: 1.5 m²
  - class C: 1.0 m²
- absorption portion dermal: 100 % (worst case scenario)
- migration portion out of textile: 100 % (dermal acute), 5 % (dermal chronic, sweat management), 2 % (dermal chronic, hydrophilic agents) 10 % (mouthing)
- fraction absorbed (oral): 100 % (worst case scenario)
- area of textile (swallowing): baby 10 cm², adults 25 cm²
- area of textile (mouthing): baby 100 cm², adult 400 cm²
- margin of safety: 1000 (when NOAEL value used) or 1 (when risk assessment value used)
- half-life time depends on the vapor pressure at 30 °C
- absorption of the inhaled air: 100 % (worst case scenario)
- emission efficiency: 100 % (worst case scenario), also outside baby buggy: 50 %
- air exchange rate
  - normal usage: 0.5 l/h
  - tent: 1.0 l/h
  - baby buggy: 1.5 l/h
- inhalation rate
  - adult: 0.83 m³/h
  - child: 0.42 m³/h
  - baby: 0.19 m³/h
- duration of exposure: 24 h (worst case scenario)
- chronic time inhalative exposure: 90 days

**Note:**
If a substance is classified as carcinogenic according to the regulations (e.g. EU, US-EPA IARC or CEPA) the cancer risk is included in the chronic exposure scenarios.

11.5.2 Realistic worst case default values – back calculation
- conc. of auxiliary in liquor: 0.02 kg/kg (dyeing), 0.1 kg/kg (finishing), 0.25 kg/kg (coating)
- liquor ratio: 1:10 (kg textile/kg liquor)
- pickup of liquor on textile: 0.75 kg/kg (finishing), 1 kg/kg (coating)
- residue on textile after process: depends on vapor pressure of a substance at 20 °C and the ability of a substance to build hydrogen bridges. In case of dyeing it depends on water solubility.

11.5.3 Worker
- solvent type: water
- vapor pressure of substance at a given temperature: 20 °C (undiluted auxiliary), 50 °C (dyeing machine), 20 °C (stenter/coating or printing machine)
- dilution factor used for the amount of gas inside barrel - max. 50 dm³ disperse to 1000 dm³ (worst case): 20
- normal pressure: 1013.25 mbar
- molar volume: 24.1 l/mol
- working time: 8 hours
- air exchange rate: 8 l/h
- room volume: 250 m³
- source room relation: 2
- activity coefficient in solution: 2
- temperature: 20 °C
- evaporation surface: 40 m² (stenter), 20 m² (coating)
- velocity surface liquid/air: 0.1 m/s
- concentration of auxiliary in coating/printing paste: 0.1 kg/kg
- concentration of auxiliary in exhaust process: 0.02 kg/kg

11.5.4 Air
- emission factor limit: 0.4 g substance/kg textile or 0.8 g C/kg textile
- conc. of auxiliary in liquor: 0.1 kg/kg (finishing, 0.25 (coating)
- pickup of liquor on textile: 0.75 kg/kg (finishing, 1 kg/kg (coating)
- correction factor depends on vapor pressure of a substance at 20 °C and the ability of a substance to built hydrogen bridges.
- share of single substance: 25 % (four-substance mixture) (see Supplement: Emission Factor Concept in Annex: Textile Manufacturer)