bluesign® CRITERIA for chemical assessment

Version 3.0 | 2022-11

Content

1 Introduction

Chemical products are widely used in the manufacturing of consumer goods to optimize processes and to bring functional and esthetic properties to articles. Beside the intended functionalities, they have an impact on people and the environment that needs to be controlled. A thorough chemical assessment is therefore imperative to evaluate the impact of chemical products in the manufacturing, use and disposal phases.

The bluesign® CHEMICAL ASSESSMENT is a powerful tool to evaluate this impact, to eliminate substances of high concern and to support the development and use of safer alternatives.

1.1 Use of chemicals in the textile supply chain

The textile and leather industry, including its related branches, is diverse in terms of the many raw materials it uses and the techniques it employs to make products. To impart the required functional and esthetic properties desired by the consumer, such as color, drape and hand feel, a fiber or a fabric as well as leather must be subjected to different types of physical and chemical treatments.

The textile and leather supply chain utilizes many different chemical products that can be categorized into four groups:

- Basic chemicals (salts, acids, bases, etc.)
- Colorants (dyestuffs and pigments)
- Auxiliaries (e.g. surfactants, leveling agents)
- Finishing agents (e.g. softening agents, coatings)

Chemical products are composed of individual chemical substances, usually identified 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 can be included in mixtures as active substances, additives or impurities. Colorants, auxiliaries and finishing agents are mixtures of chemical substances. Commercial chemical products mostly consist of several intermediate mixtures (see Figure 1).

From the application point of view, chemicals used in the production of textiles and leather generally fall into two classes:

- Functional chemical products: designed to remain on the finished article ('be fixed', e.g. colorants, easy-care finishes, etc.); only very small amounts of these substances will be present in the wastewater effluent or the off-gas.
- Process chemicals: used to support finishing processes (e.g. leveling agents, wetting agents) or to pretreat the raw material (e.g. detergents); may be fully introduced into the wastewater effluent during production. Process chemicals are not intended to remain on the finished product.

The potential impact on workers, consumers and the environment depends on the chemical product category and the mode of use. In many cases it is not the active substances, but instead additives (e.g. dispersing agent in a dye) and/or impurities (e.g. monomer residue in polymer) that are responsible for a potential negative impact on people and the environment. For this reason, the bluesign® CHEMICAL ASSESSMENT also considers these types of substances.

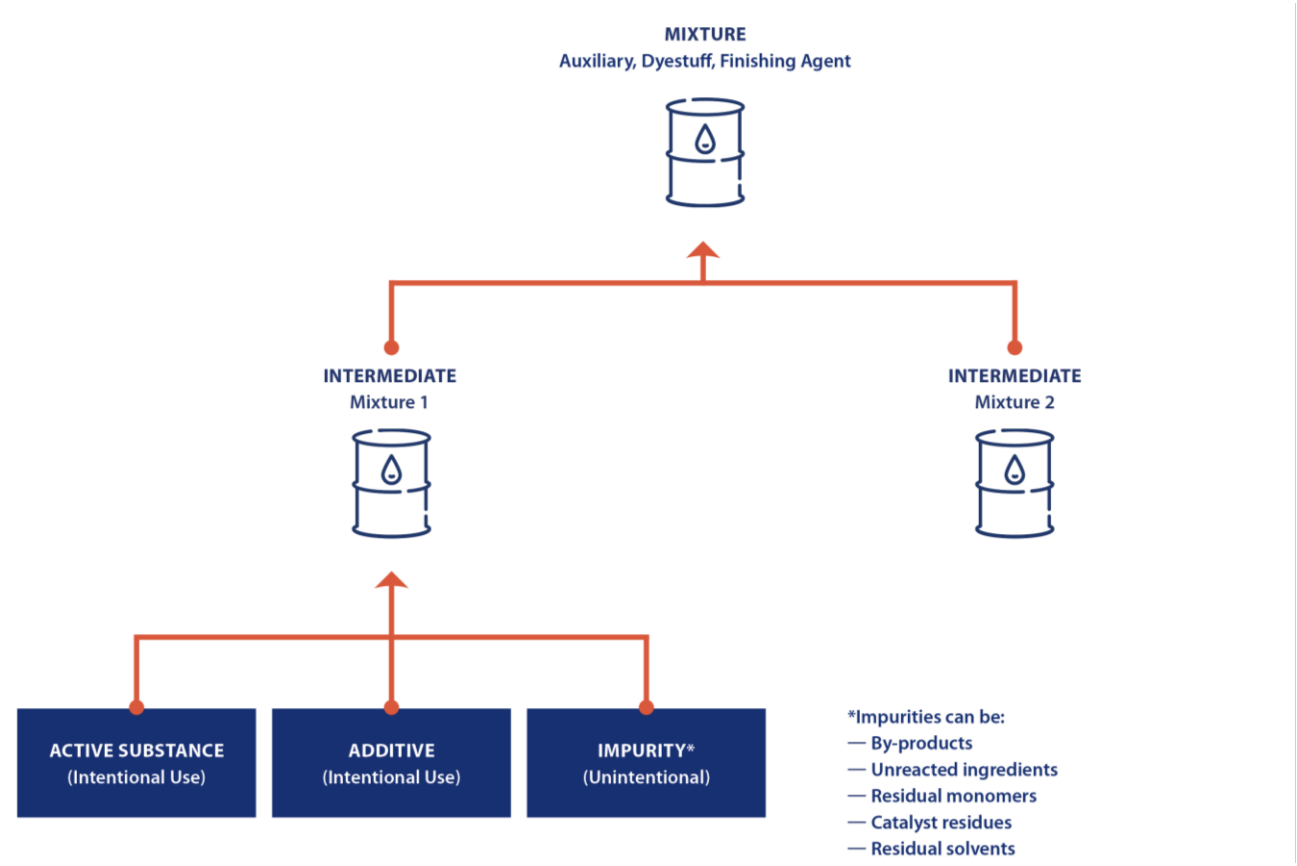


Figure 1: Chemical mixture and its components.

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 human or the environment is a function of the inherent hazard and the exposure:

RISK = f (HAZARD x EXPOSURE)

Following a purely hazard-based principle, risk reduction can be done by simply eliminating substances of high concern. This approach is useful in the case of highly toxic substances (such as carcinogens or mutagens) or - following the precautionary path - when insufficient information on the possible exposure is available. Bluesign uses the hazard-based approach to eliminate the most critical substances from the supply chain.

For all chemical substances that pass the purely hazard-based assessment, an additional exposure assessment is conducted to calculate the risk and keep it at a manageable and acceptable level. Bluesign applies a multidimensional risk assessment approach to calculate the nature and magnitude of possible health risks to workers and consumers and the negative impact on the environment (see Figure 2).

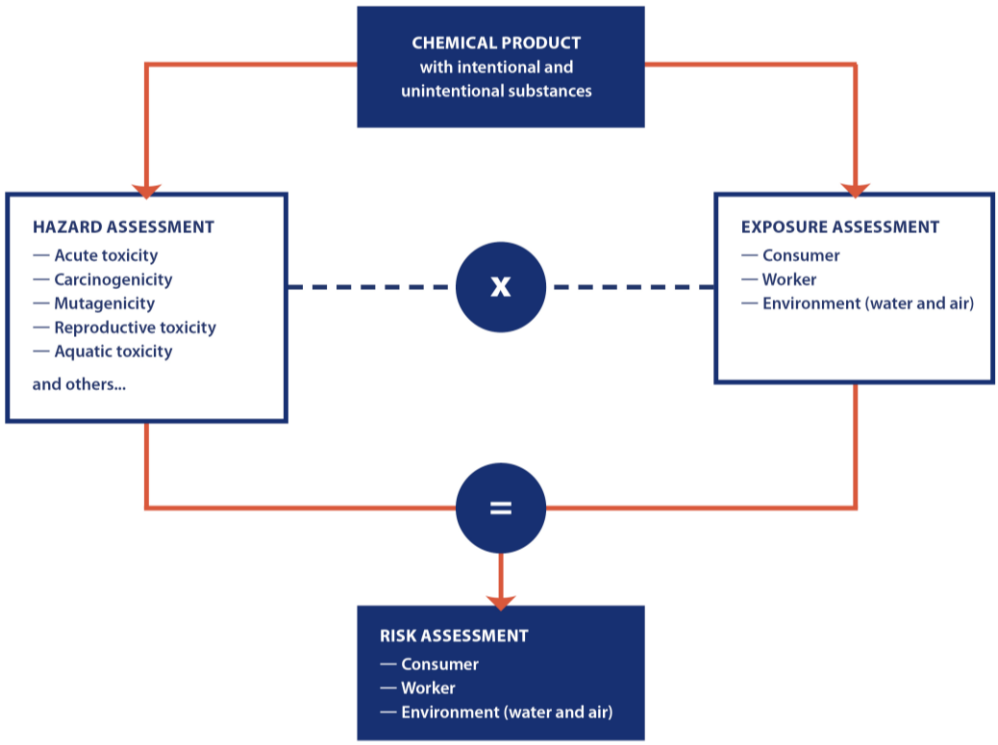


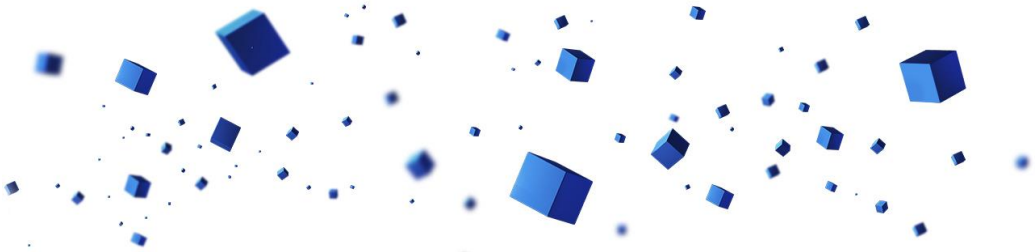
Figure 2: Risk assessment block diagram

In general, the risk depends on the following factors:

- Inherent toxicity (i.e. hazard) of the chemical substance
- Concentration of the chemical substance
- Level of exposure to the chemical substance for a person or ecological receptor

Note:

Risk assessment related terminology used in this document is mainly based on the following article: Nordlander K, Simon C-M, Pearson H, 2010. Hazard v. Risk in EU Chemicals Regulation, *The European Journal of Risk Regulation* 3: 239-250.



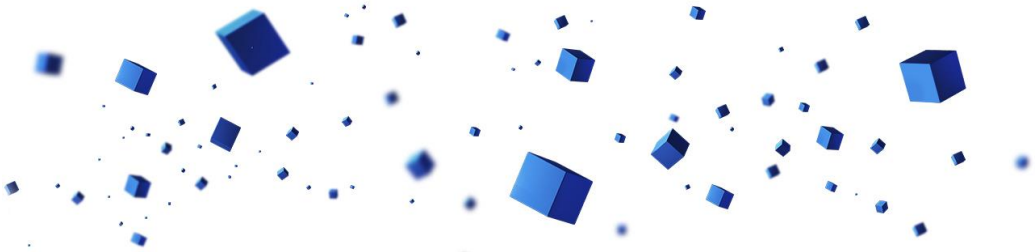
2 Scope

Chemical assessment is one of the main focus areas of the bluesign® SYSTEM. This document describes the process and criteria for the bluesign® CHEMICAL ASSESSMENT. The items relevant to this scope are bluesign® SYSTEM PARTNER chemical products for industrial use in the textile, footwear and leather industry. The methodology of the bluesign® CHEMICAL ASSESSMENT procedure described below is mainly based on examples from the textile industry, but this approach is flexible and can also be extended to other industries. Several use sectors aside from textile-related scopes are covered by the methodology, for example plastic, rubber, paper and metal.

For nano materials and biocidal products, additional requirements including a lifecycle risk assessment performed by the bluesign® SYSTEM PARTNER are applicable. The use of flame retardant products should be limited to those articles where it is needed for safety reasons. Depending on their hazard profile, additional requirements can be mandatory (see relevant Annex documents).

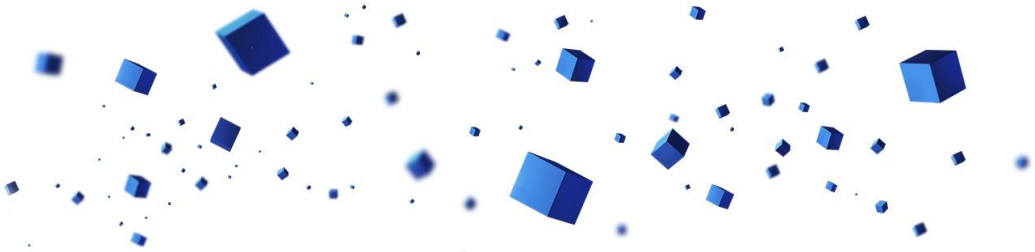
Chemicals management and chemicals change management are not the focus of this document. Requirements related to practices such as input stream management of raw materials and intermediates, storage, processing and discharge of chemicals at chemical suppliers and downstream user level (e.g. textile manufacturer) are described in the bluesign® CRITERIA for production sites, in relevant Annexes and in specific bluesign® Guidelines and Guidance Sheets.

Remark: Basic chemicals (see definition in Guidance Sheet 'Input stream management commodity/basic chemicals in textile production') are not rated via the methodology at hand. Basic chemicals are rated via input stream management at the manufacturing site, based on SDS and substance specifications as described in the bluesign Guidance Sheet Input stream management commodity/basic chemicals in textile production'.

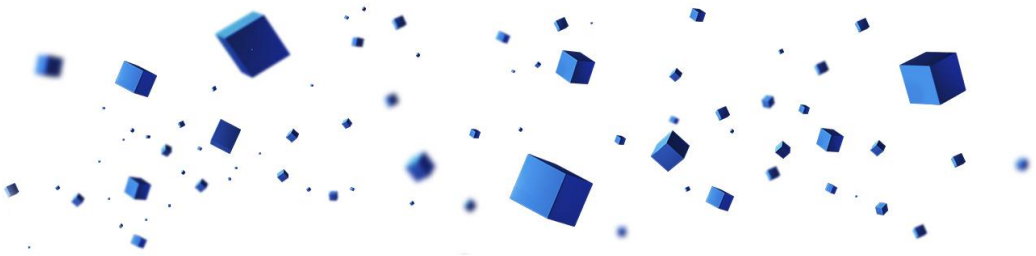


3 Definitions

Expression	Definition
A	
Antimicrobial active substance	Any substance used to destroy or suppress the growth of micro-organisms (bacteria, viruses, fungi) on inanimate objects and surfaces. In textile manufacturing, antimicrobial active substances are mostly used to control growth of odor-causing bacteria.
Article	An object composed of one or more substances given a specific shape, surface or design. In terms of a bluesign® certificate and registration in the bluesign® GUIDE, an article is characterized by a well-defined manufacturing process and by an article name/article code. It includes parts that can be easily detached from a product but are associated with its function, such as a rain cover or a separate hood. Extras that are not associated with the function of the article are not considered as part of the article, e.g. giveaways or hangtags.
Auxiliary	A commercial chemical product composed of two or more chemical substances (e.g. a levelling agent, coating agent or detergent)
B	
Basic chemical	A commercial product (normally without a trade name, sold under its chemical name) consisting of one chemical substance or a solution of this substance (e.g. sodium hydroxide, acetic acid)
bluesign® CHEMICAL ASSESSMENT (formerly: Homologation)	Chemical assessment and rating of chemical products according to their environmental and health and safety aspects
bluesign® COMPANY ASSESSMENT (formerly: Screening and Audit)	A bluesign® COMPANY ASSESSMENT is an assessment which includes on-site inspections of production sites. The assessment at a production site focuses on the management system, environmental and OH&S aspects, input stream management, chemicals change management (manufacturer) and product stewardship (chemical supplier). Compliance with the bluesign® CRITERIA is checked and measures for continuous improvement are evaluated.
BSBL (bluesign® SYSTEM BLACK LIMITS)	The *bluesign® system black limits (BSBL)* specifies threshold limits for chemical substances in finished chemical products such as auxiliaries or dyes. It includes all substances from the publicly available *bluesign® system substances list (BSSL) Consumer safety limits* for which a usage ban is defined. The BSBL is publicly available and updated yearly. Remark: Only Input Stream Management starting at the chemical supplier can ensure BSBL compliance. A bluesign® SYSTEM PARTNER shall not disseminate the BSBL to the supply chain with the only purpose of obtaining a compliance declaration.
BSSL (bluesign® SYSTEM SUBSTANCES LIST)	The BSSL specifies limits for chemical substances in articles (consumer safety limits). More than 1000 chemical substances are listed. The BSSL is publicly available and updated yearly. Remark: Only Input Stream Management and application of the appropriate processes at the article manufacturer can ensure BSSL compliance. A bluesign® SYSTEM PARTNER shall not disseminate the BSSL to the supply chain with the only purpose of obtaining a compliance declaration.
C	
CAS (Chemical Abstracts Service) Registry Number	A unique numeric identifier which designates only one chemical substance; also referred to as CAS number
Chemical	A commercial product which can be a chemical substance or a mixture
Chemical assessment	*Add definition as per glossary*
Chemical product	See Chemical
Chemical substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process with defined composition and properties. A chemical substance is usually defined by a CAS number.
Chemical supplier	A company that under its own trade name markets chemical products, such as auxiliaries, dyestuffs or other chemical products, for the production of textiles, leather and/or accessories. A chemical supplier may be a manufacturer, a formulator or a rebrander of chemical products. A producer of chemical products that directly uses the produced chemicals for downstream processing of articles is also considered to be a chemical supplier.
Colorant	Can be a dye or a pigment. Colorants are characterized by their ability to absorb visible light.
D	
Dye	See dyestuff



Expression	Definition
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 dyestuff must have a specific affinity to the substrates for which it is used.
E	
Exposure	A state of coming into contact with a chemical substance through inhalation, skin contact, ingestion, or any other route
Endpoint	A discreet, measured parameter (e.g. flash point or LD50 value) or outcome in a study addressing a certain hazard (e.g. flammability, acute toxicity)
G	
Global Harmonized System (GHS)	An internationally agreed-upon system created by the United Nations. It is designed to replace the various classification and labeling standards used in different countries by using consistent criteria for classification and labelling on a global level.
H	
Hazard	An intrinsic potential of something to cause harm
M	
Mixture	A chemical product composed of two or more substances. It can be, for example, a colorant or an auxiliary.
Manufacturer	A company that produces textile articles (at all processing levels), leather and/or accessories
O	
OEL (occupational exposure limit)	Occupational exposure limits are regulatory values which indicate levels of exposure that are considered to be safe (health based) for a chemical substance in the air of a workplace
OHS	Occupational Health & Safety
P	
Pigment	A colorant characterized by being practically insoluble in the media in which it is applied
R	
Rating - Blue	Rating of a chemical product from a bluesign® SYSTEM PARTNER for a specific application. Blue rated chemical products for a specific application are fully compliant with the bluesign® CRITERIA for chemical assessment.
Rating - Grey	Rating of a chemical product from a bluesign® SYSTEM PARTNER for a specific application. Grey rated chemical products for a specific application are fully compliant with the bluesign® CRITERIA for chemical assessment, but the user needs to follow certain guidance on safe use at the factory. Supporting information is given in the bluesign® FINDER.
Rating - Black	Rating of a chemical product from a bluesign® SYSTEM PARTNER which does not meet the bluesign® CRITERIA for chemical assessment for a specific application. The chemical product must be eliminated from the manufacturing process of articles.
Release rate	The release rates define an expected loss (weight %) of a substance from the wet textile during a process to water or air. They were developed by Bluesign in the context of specific models used in the chemical assessment and the applicability is limited to these processes. If no practical experience is available, release rates are determined based on physical/chemical substance properties and process parameter.
Release rate to water	This release type is only valid for water-based processes. The release rate to water for a dyestuff for example is related to the fixation degree (fixation degree of 90% correlates to a release rate of 10%). Release rates depend on physical/chemical properties considering the log K_{ow} of a substance and the ability to form hydrogen bonds (H-bridges) with the substrate. Solubility in water and the molecular weight can be supporting information too.
Release rate to air	The release rates to air refer to a substance release within a standard drying process. They are a function of the vapor pressure (at 150 °C) and the capability of the substance to form hydrogen bonds (H-bridges). Based on the different emission retention capacity, air release rates are defined for cotton and polyester. Molecular weight and solubility can be supporting information.
S	
SVHC (substances of very high concern)	Substances that may have serious and often irreversible effects on human health and the environment can be identified as substances of very high concern (SVHC). If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorization List (Annex XIV of the REACH regulations). Once a SVHC is listed in the authorization list, the substance is not allowed to be used anymore without granted an authorization from the ECHA.
U	



Expression	Definition
Usage ban	See BSBL and BSSL For several chemical substances or substance groups a usage ban is defined. For these substances or substance groups, intentional use in the manufacturing of articles is prohibited. This means that chemical products used for manufacturing of articles (e.g. colorants or textile auxiliaries) must not intentionally contain these substances or substance groups.
Usage range	See BSSL Usage ranges classify consumer goods products according to their consumer safety relevance. Three usage ranges (A, B, C) are defined, with A being the most stringent category with regard to limit values/bans
Usage range A	Articles with next-to-skin use and baby-safe articles
Usage range B	Articles with occasional skin contact
Usage range C	Articles with no skin contact

Table 1: Definitions

4 Concept

The paramount aim of the bluesign® CHEMICAL ASSESSMENT process is to provide chemical suppliers as well as down-stream users with the tools to reduce or even eliminate harmful chemical substances in consumer goods, to mitigate the impact on workers in production facilities, and to minimize emissions to the environment (Figure 3).

4.1 Assessment methodology

Hazard identification and assessment and appraisal of exposure, followed by multidimensional risk assessments, are fundamental pillars of the bluesign® CHEMICAL ASSESSMENT procedure. Chemical substances that are contained intentionally or unintentionally (impurities) in chemical products are considered (see section 4.4). Based on detailed knowledge and data provided by bluesign® SYSTEM PARTNERS from the chemical industry, a well-founded assessment of chemical products can be performed. Assessments are done using the web-based application bluesign® TOOL.

The main elements of the bluesign® CHEMICAL ASSESSMENT are:

- Hazard assessment of chemical products with regard to threshold values of the most hazardous and relevant substances (BSBL). If a threshold is exceeded, the chemical product is black rated and cannot be bluesign® APPROVED.
- A hazard assessment of a chemical product with regard to the most impactful hazard classes and categories (e.g. classification as CMR: Carcinogenic, Mutagenic or Toxic to reproduction) according to the GHS (Globally Harmonized System). If a chemical product is classified as CMR, it is black rated and cannot be bluesign® APPROVED.
- Assessment of a chemical product with regard to the presence of substances listed on the SVHC candidate list of the ECHA. If a chemical product contains a SVHC substance exceeding the threshold, it is black rated and cannot be bluesign® APPROVED.
- Risk assessment of a chemical product according to all hazard classes and categories of the GHS (Globally Harmonized System). Exposure strongly depends on application parameters.
- Risk assessment of a chemical product with regard to workplace exposure to certain hazardous substances during manufacturing processes. Several scenarios are covered. Compliance with relevant occupational exposure limits is checked by model calculations.
- Risk assessment with regard to consumer safety (use of finished articles). Compliance with consumer safety limits (BSSL) for relevant hazardous substances is checked by model calculations.
- Assessment of air emissions (volatile organic substances) considering the use of a chemical product in manufacturing processes.
- Assessment of a chemical product with regard to selected environmental parameters (e.g. Adsorbable Organic Halogens)
- An overall rating for a chemical product expressed as blue, grey or black.

Blue or grey rated chemical products can be published in the bluesign® FINDER, a positive list of safe chemistry. In chapter 5 the methodology and the different assessment modules built into the bluesign® TOOL are explained in more detail.

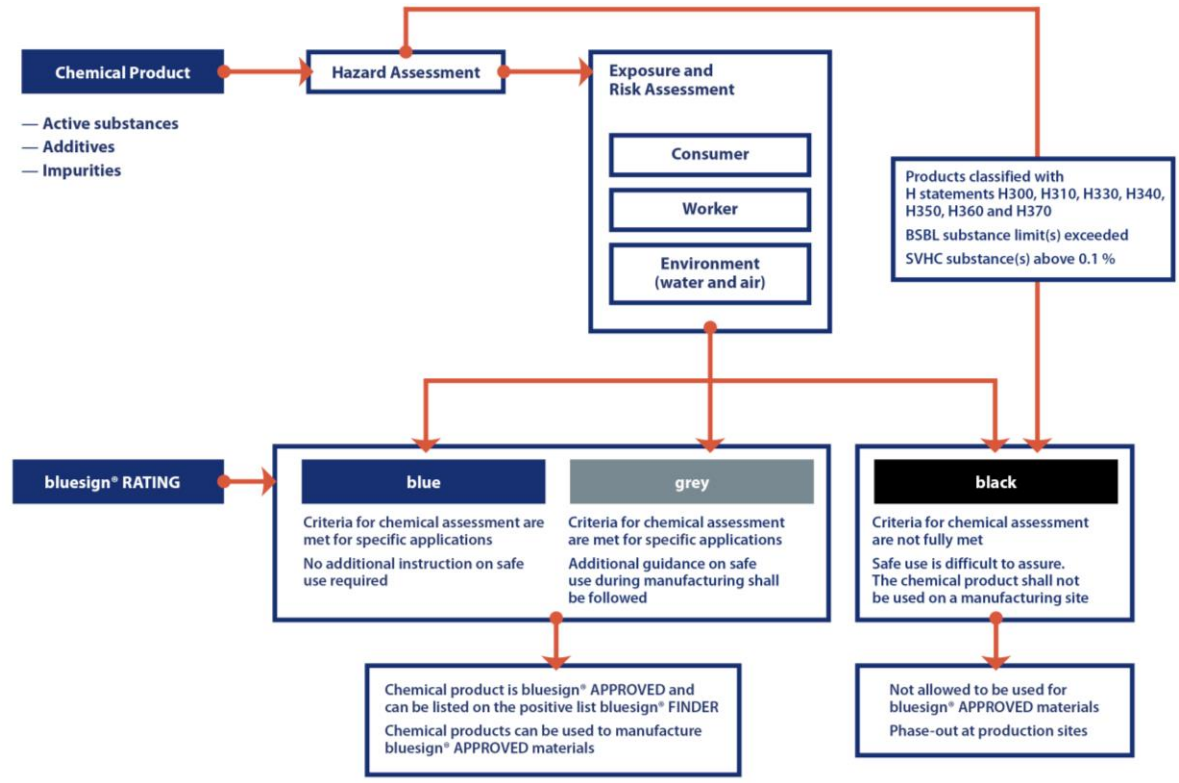


Figure 3: bluesign® CHEMICAL ASSESSMENT

4.2 bluesign® RATING

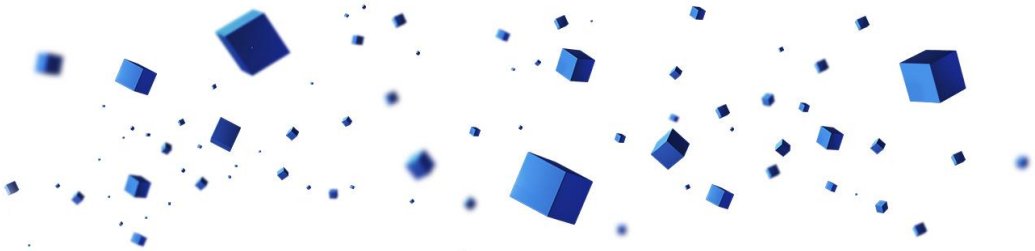
Chemical products supplied from bluesign® SYSTEM PARTNERS are rated according to the bluesign® CRITERIA for chemical assessment for specific claimed applications. The rating is valid only for those specific applications. There are three possible rating results: blue, grey or black. Chemical products in applications that comply with the bluesign® CRITERIA are considered as bluesign® APPROVED and are divided into the categories 'blue' and 'grey':

- Blue rated chemical products fulfill the requirements of the bluesign® CRITERIA for chemical assessment based on realistic worst-case exposure scenarios and can be used for specific applications without further conditions.
- Grey rated chemical products are fully compliant with the bluesign® CRITERIA for chemical assessment for specific applications, but the user needs to follow certain guidance on safe use in the factory.

Chemical products that do not meet the requirements of the bluesign® CRITERIA for chemical assessment fall into the category 'black' and must be eliminated from the manufacturing process.

In addition, the bluesign® RATING provides information on which usage ranges the chemical product can be used for. Those usage ranges are defined as A, B and C, with A being the most stringent category in terms of 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



4.3 bluesign® FINDER - Positive list of blue and grey rated chemical products

The bluesign® CHEMICAL ASSESSMENT is the foundation for the 'positive' list of blue and grey rated bluesign® APPROVED chemical products. Only bluesign® APPROVED chemical products should be used in the manufacturing processes of bluesign® SYSTEM PARTNERS. The list of bluesign® APPROVED chemicals is available as a web-based information platform - the bluesign® FINDER.

4.4 Information on chemical product composition

The chemical composition of the chemical products intended to be registered as bluesign® APPROVED shall be provided, including:

- Active substances
- Additives
- Impurities (e.g. by-products, unreacted ingredients, residual monomers, catalyst or solvent residues)
- Substances that may be released during application (e.g. blocking agents used for polyurethane)

Bluesign reserves the right to ask for full disclosure of formulation recipes and composition at substance level. Full disclosure means information on all unintentional ingredients above a concentration of 100 mg/kg (or lower if required to prove compliance with BSSL or BSBL limits) and intentionally added substances without any concentration limits.

4.5 Data verification

All relevant data for the bluesign® CHEMICAL ASSESSMENT is provided by authorized system partners from the chemical industry by means of the bluesign® TOOL, the interface between the chemical supplier and Bluesign. A chemical company must suitably fulfill the requirements laid down in the bluesign® CRITERIA for production sites, the ANNEX for chemical suppliers and the Product Stewardship Guideline before registration of chemical products in the bluesign® TOOL and the bluesign® FINDER is possible. Criteria compliance of the chemical company production site is checked through the bluesign® COMPANY ASSESSMENT.

The chemical assessment methodology described at hand is the backbone of the bluesign® TOOL. Via the bluesign® TOOL all necessary calculations according to the methodology are conducted, resulting in a chemical product rating 'blue', 'grey' or 'black'. The completeness and plausibility of transferred data are checked by specialists for chemical assessment at Bluesign. A thorough expert check is always performed before a chemical product can be registered in the bluesign® FINDER. In cases where the assessment models and default parameters do not fit with the claimed application, the final rating may be concluded by expert judgement.

During regular on-site assessments the chemical supplier´s capability to provide appropriate and complete data sets is monitored by spot-checking selected registered products in detail. On a yearly basis, Bluesign checks whether the mutually agreed testing plan (raw material testing and chemical product testing) is followed by the system partner.

An obligation to provide non-routine information to Bluesign and the customer also exists in case of non-compliance of bluesign® APPROVED items, especially if legal requirements in the market of origin or target markets are infringed. In case of any non-conformity with respect to the bluesign® CRITERIA, chemical products can be deleted from the bluesign® FINDER.

5 Assessment Modules

Bluesign® CHEMICAL ASSESSMENT is performed with the expert software bluesign® TOOL. It contains six assessment modules that address physical, health and environmental hazards in which hazard and risk-based evaluations are applied. The modules are:

- Hazard based modules with gatekeeper function (BSBL module and SVHC module)
- GHS module (partly hazard based with gatekeeper function)
- Consumer Safety module (BSSL)
- Occupational Health module
- Air emission module
- Environment module

How the modules relate to processes and impacts at a manufacturing site is shown in Figure 4. Possible rating options (see overview in Figure 5), evaluation principles and calculations within the modules are explained in the following chapters.

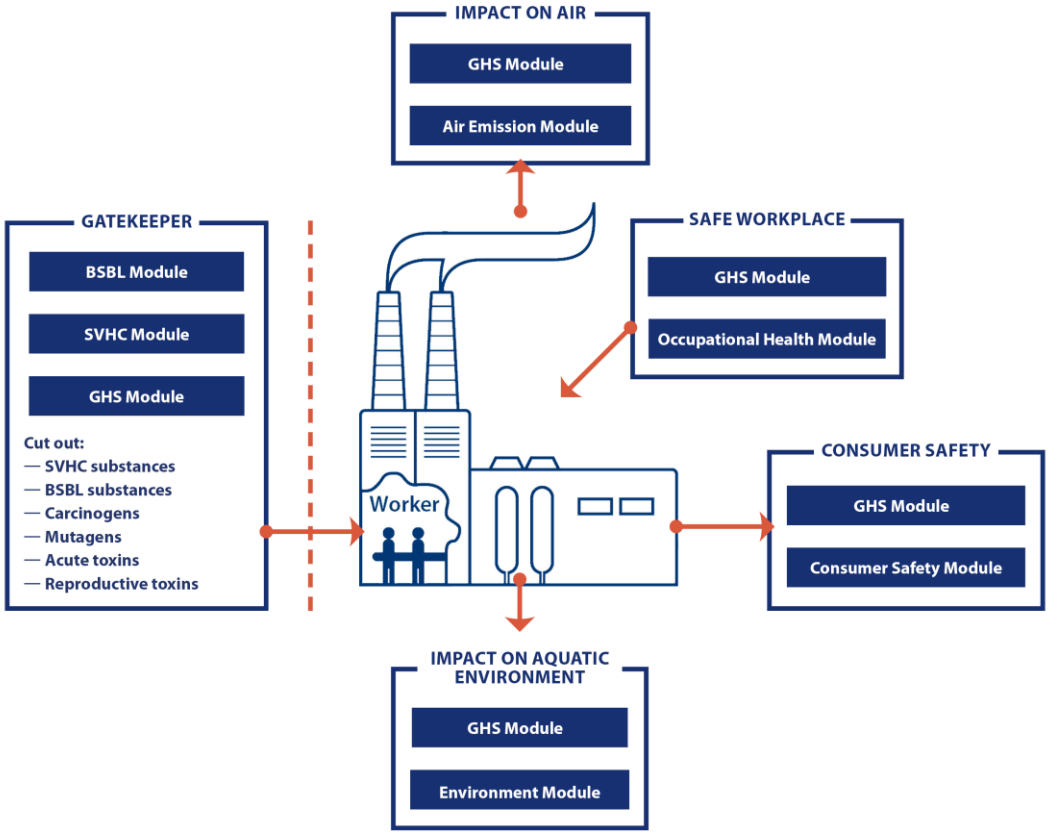


Figure 4: Chemical assessment modules in context with impacts on factory level

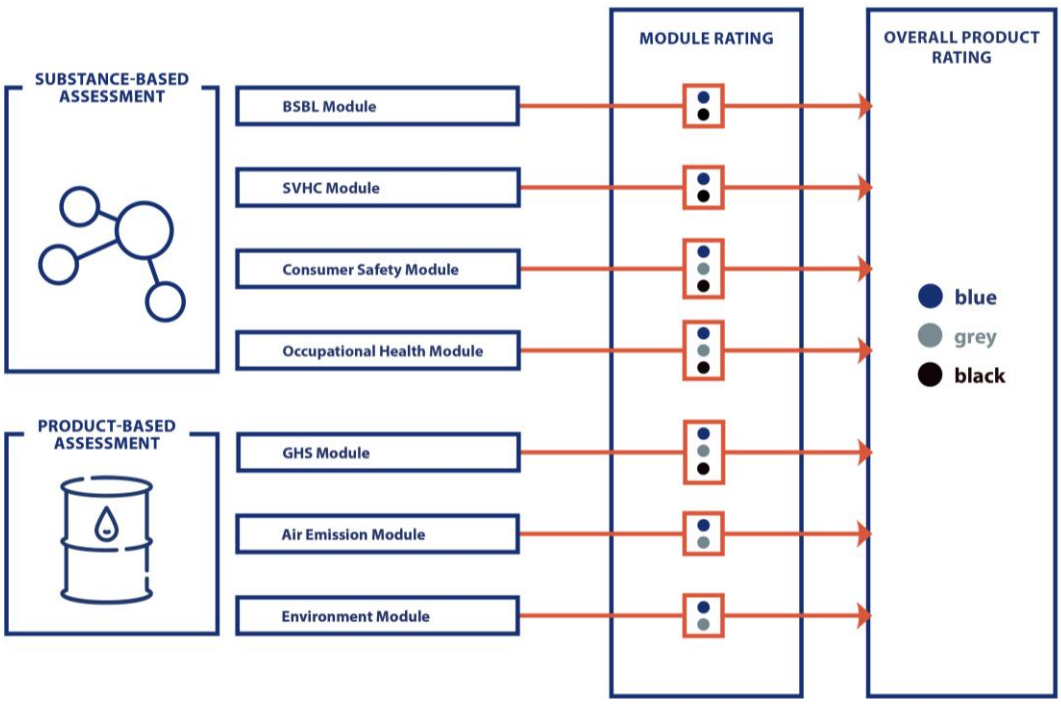


Figure 5: Possible rating options in each rating relevant assessment modules

5.1 Categorization

In order to apply the correct model calculations, a categorization needs to be assigned that essentially describes WHERE (sector of use, e.g. textile, leather, plastic articles), WHAT (what function does the chemical product have) and HOW (in which process the chemical product is used). The following categorization must therefore be made (refer also to Figure 6):

- Assign the sector of use (WHERE)
- Assign the product category (WHAT)
- Assign the product subcategory (WHAT)
- Assign the process category (HOW)
- Assign the process subcategory (HOW)

Figure 6: Categorization dimensions (WHERE, WHAT, HOW)

Examples of the categories are listed in Table 2. The full set of values in each category is documented as an Annex to the bluesign® TOOL user manual.

Sector of use (SU)	Product category (PC)	Product subcategory (PSC)	Process categories (PROC)	Process subcategories (PROSC)
Manufacture of textile products including fabrics, laminates and non-wovens	Dyes and pigment preparations	Disperse dyes	Dyeing	Batch processing
Manufacture of textile products including fabrics, laminates and non-wovens	Textile auxiliaries and functional agents	Softening agents	Finishing	Pad processing
Manufacture of leather products	Coating compounds, paints, lacquers, coatings, thinners, paint removers and process aids (for all uses)	Crosslinking agents for coating compounds; water-based	Leather finishing	Roll coating

Table 2: Categorization examples

The categorization controls the relevance of modules to a chemical product, the validity of calculation models, the risk characterization for exposure and release as well as the application of special rules, specific limits and necessary exceptions in BSSL and BSBL. Proper categorization is therefore mandatory for the correct outcome of the chemical assessment. Beside this, the categorization allows chemical assessment to be extended to other industries. The bluesign categorization system is similar to the descriptor system used in the REACH regulation, but is adapted to the needs of the bluesign® CHEMICAL ASSESSMENT.

Depending on the scope of application, the same chemical product could be rated differently (see Figure 7). In other words, a particular rating is only valid for a specific application. Application parameters are usually defined in the technical data sheet for a chemical product. The same chemical product can be bluesign® APPROVED for different applications with different ratings.

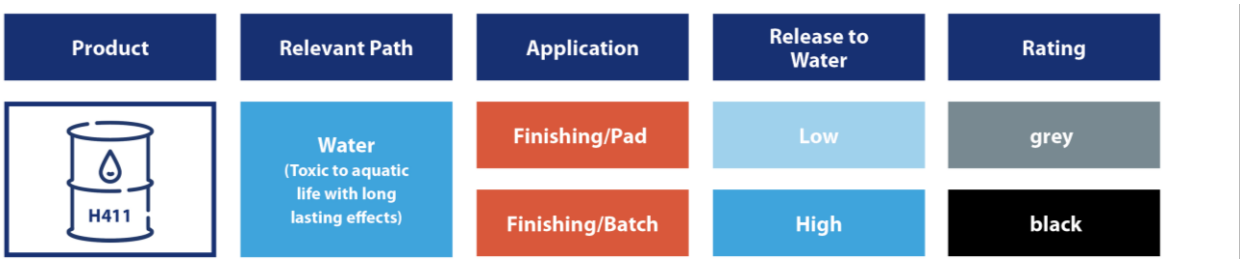


Figure 7: Different ratings for one product in two applications

5.2 Hazard-based modules (BSBL and SVHC)

5.2.1 BSBL module

5.2.1.1 Purpose and description

The purpose of the BSBL module is to check the compliance of chemical products with the BSBL limits. It relates to a hazard-based approach and acts as a 'gatekeeper' preventing most hazardous substances from being present in the chemical product in critical concentrations. Within this module the substance composition of a chemical product - including intentional and unintentional substances (impurities, e.g. residual monomers, by-products, catalyst residues, cross contamination) - is checked against relevant substance threshold limit values in the BSBL.

5.2.1.2 Required data

The chemical supplier shall provide

- Full categorization (Sector of use, product category and sub-category, process category and sub-category)
- Information on all BSBL listed substances that are or could be contained (intentionally or unintentionally) in a chemical product.

Relevant substances need to be reported with corresponding concentration limits/specifications. For relevant impurities, evidence by testing shall be provided. Intentionally added BSBL listed substances always need to be declared independent of concentration.

5.2.1.3 Rating

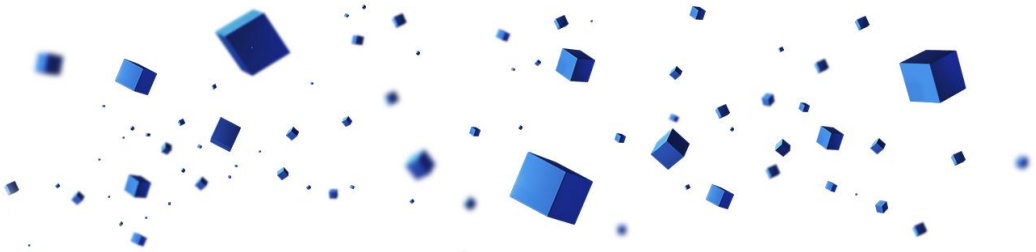
Reported concentration limits of BSBL substances relevant to a chemical product are directly compared with the limit values in the BSBL. If one or more BSBL limits are exceeded, the chemical product is rated 'black' and cannot be bluesign® APPROVED. If all relevant substance threshold limit values are complied with, the chemical product is rated 'blue' within this module. For a few BSBL substances where the limit type is defined as 'monitoring', a grey rating is possible (see also Table 3). Those substances are subject to observation and are candidates for a usage ban or restriction. Evidence for a black limit is not yet considered sufficient regarding substances with the limit type "monitoring'.

Limit type	Substance concentration	Rating
'Usage ban' or 'Usage restriction'	≤ BSBL limit	blue
'Usage ban' or 'Usage restriction'	> BSBL limit	black
'Monitoring'	≤ BSBL limit	blue
'Monitoring'	> BSBL limit	grey

Table 3: Rating rules for the BSBL module

5.2.1.4 Exceptions

BSBL limits are independent of application parameters (purely hazard-based approach). In some cases, specific limits or exceptions are defined in the BSBL (e.g. for some solvents in solvent coating) to account for important industry needs and currently available technology. These exceptions are indicated by comments in the BSBL. All exceptions are summarized in the 'ANNEX: Exceptions'.



5.2.2 SVHC (substances of very high concern) module

5.2.2.1 Purpose and description

All SVHC substances that have been identified as relevant for the textile and related industries are included in BSSL and/or BSBL and are restricted by the corresponding modules (BSBL module, Consumer Safety module). The purpose of the SVHC module is to detect SVHC substances in chemical products that are not yet included in BSSL or BSBL and to provide an overview of all SVHC substances in a chemical product. In the rare event that an SVHC substance is identified that is not covered by the BSBL and/or BSSL, a rating is assigned by expert judgement during the bluesign® CHEMICAL ASSESSMENT.

5.2.2.2 Required data

The chemical supplier shall report on all SVHC substances that may be present in the mixture above 100 mg/kg unless BSSL or BSBL limits require a lower reporting limit for a particular substance.

5.2.2.3 Rating

The substance composition of a chemical product - including intentional and unintentional substances such as impurities and by-products - is checked against the most updated SVHC (Substances of Very High Concern) candidate list for authorization from the ECHA. If a substance listed as SVHC exceeds a concentration of 0.1% (1000 mg/kg) the legal reporting limit is reached. The corresponding substance will be added to the candidate list for the next BSSL/BSBL revision (if not already listed), which includes an evaluation on limits for safe use. Bluesign approval is generally not possible if a substance classified as SVHC is present in a concentration above 0.1%, i.e. the product becomes black rated.

5.3 GHS module

5.3.1 Purpose and description

The GHS (Globally Harmonized System) module addresses health hazards, environmental hazards and physical hazards and includes both a purely hazard based precautionary approach (for certain hazard classes/categories) and an exposure affected risk-based path. The goal is to exclude chemical products with a high risk for humans or the environment from the manufacturing process, to point out the risk of using hazardous chemicals, and to encourage the use of safer alternatives where possible.
Hazard classifications come with the relevant hazard statement (H-statement) as defined in the UN GHS[1]. The hazard statement is used in the bluesign® CHEMICAL ASSESSMENT to define the rating. All hazard classes and categories according to UN GHS version 8 are covered by the bluesign® CHEMICAL ASSESSMENT.

5.3.1.1 Likelihood of exposure and release

For a risk-based assessment the degree of exposure needs to be determined or estimated. The likelihood of exposure of a chemical product with a certain hazard strongly depends on how the chemical product is used or applied. These application conditions are accounted for by the categorization described in section 5.1. Depending on the process categorization which defines a clear process and subprocess description, the exposure/release level can be:

- No release (release of substances e.g. to water/air is avoided)
- Low (low likelihood of exposure or release)
- Moderate (moderate likelihood of exposure or release)
- High (high likelihood of exposure or release)
- Industrial

Here the term 'exposure' is used when describing the level of impact on humans and 'release' is used for when describing the level of impact on the environment.

The exposure category 'industrial' has been created for all physical hazards (all H-statement codes starting with 2xx) and for health hazards with oral exposure. Physical hazards classified as 'industrial' need to be controlled by adequate industrial safety measures (e.g. sufficient ventilation and explosion-proof machinery when working with flammable liquids or gases). For health hazards with oral exposure, 'industrial' has been assigned as it is normal industrial practice/hygiene not to ingest chemical products, i.e. the likelihood of exposure does not depend on the process.

A process– exposure matrix has been created to reflect the expected degree of exposure/release depending on the processes applied. An example regarding physical and health hazards is shown in Table 4. The example illustrates that for a finishing process the likelihood of dermal exposure ranges from low to high depending on the process subcategory: batch processing (moderate), continuous processing (low) or spray application (high). In the same way the possible release to water (no release, low, moderate, high) and air (yes, no) related to the application processes is defined in a matrix as well (see example in Table 5).

[1] https://unece.org/about-ghs

Process category (PROC)	Process subcategory (PROSC):	Physical hazard risk	Health hazard - Oral exposure	Health hazard - Dermal exposure	Health hazard - Inhalative exposure
Finishing	Batch process	Industrial	Industrial	Moderate	Moderate
Finishing	Continuous process	Industrial	Industrial	Low	Low
Finishing	Pad process	Industrial	Industrial	Low	Moderate
Finishing	Spray process	Industrial	Industrial	High	High

Table 4: Likelihood of exposure depending on process categorization (for physical and health hazards)

Process category (PROC)	Process subcategory (PROSC):	Release to water	Release to air
Finishing	Batch process	High	Yes
Finishing	Continuous process	High	Yes
Finishing	Pad process	Low	Yes
Finishing	Spray process	No release	Yes

Table 5: Likelihood of release depending on process categorization (for environmental hazards)

5.3.2 Required data

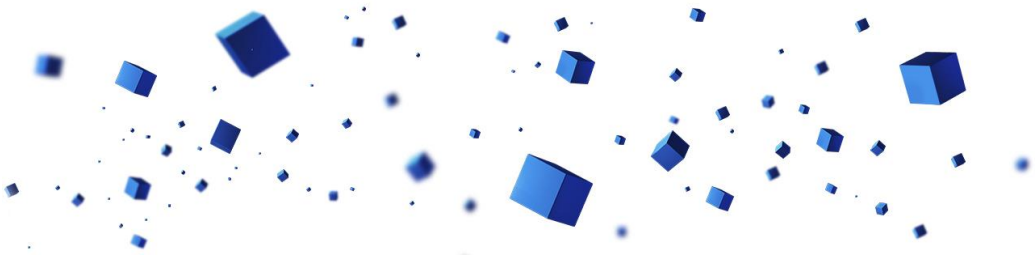
The data required to perform the assessment in the GHS module consists of:

- Full categorization (Sector of use, product category and sub-category, process category and sub-category)
- Product classification and related H-statement codes (backed by a valid and correct SDS in GHS format), as a minimum all hazard classes and categories according to CLP plus Aquatic Acute Categories 2 and 3 shall be covered
- Declaration of all substances that are classified and contained in the chemical product above the generic cut-off values listed in Table 1.1 of Annex I to Regulation (EC) No. 1272/2008
- Exposure route for specific H-statements if needed (oral, dermal, inhalation)

5.3.3 Rating

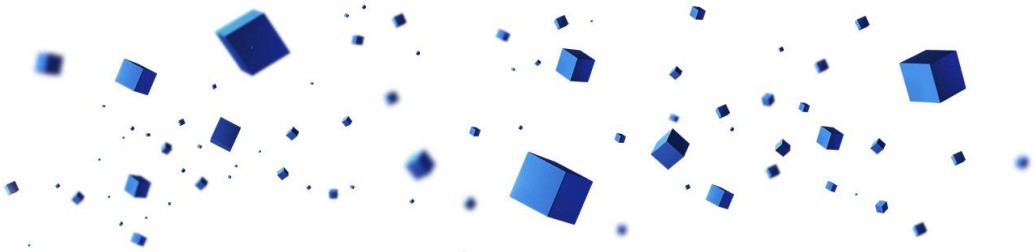
5.3.3.1 General rating principle

The bluesign® RATING in the GHS module - expressed as 'blue', 'grey' or 'black' - depends mainly on the H-statement (representing the inherent hazard) and exposure/release. In general, it can be said that the worse the hazard and the higher the exposure/release, the higher the likelihood of a black rating. Dependencies between all H-statements, exposure scenarios and resulting ratings are laid down in the ANNEX: GHS rating matrix (see an excerpt of the matrix in Table 6). Not all ratings depend on the exposure/process parameters. Those cases are specifically explained in the following sections.



Hazard statement code	H-statement	Classification (UN GHS)	Exposure route	Rating depending on exposure		
				Low	Moderate	High
H310	Fatal in contact with skin	Acute toxicity, Category 1 & 2	dermal	black	black	black
H311	Toxic in contact with skin	Acute toxicity, Category 3	dermal	grey	grey	black
H312	Harmful in contact with skin	Acute toxicity, Category 4	dermal	blue	grey	grey
H313	May be harmful in contact with skin	Acute toxicity, Category 5	dermal	blue	blue	blue
H314	Causes severe skin burns and eye damage	Skin corrosion/irritation, Categories 1, 1A, 1B & 1C	dermal	grey	grey	grey
H315	Causes skin irritation	Skin corrosion/irritation, Category 2	dermal	blue	grey	grey
H316	Causes mild skin irritation	Skin corrosion/irritation, Category 3	dermal	blue	blue	blue
H317	May cause an allergic skin reaction	Skin sensitisation, Categories 1, 1A &1B	dermal	grey	grey	black
H318	Causes serious eye damage	Serious eye damage/eye irritation, Category 1	dermal/eye	grey	grey	grey
H319	Causes serious eye irritation	Serious eye damage/eye irritation, Categories 2 & 2A	dermal/eye	grey	grey	grey
H320	Causes eye irritation	Serious eye damage/eye irritation, Category 3	dermal/eye	blue	blue	blue
H330	Fatal if inhaled	Acute toxicity, Category 1 & 2	inhalative	black	black	black
H331	Toxic if inhaled	Acute toxicity, Category 3	inhalative	grey	grey	black
H332	Harmful if inhaled	Acute toxicity, Category 4	inhalative	blue	grey	grey
H333	May be harmful if inhaled	Acute toxicity, Category 5	inhalative	blue	blue	blue
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled	Respiratory sensitisation, Categories 1, 1A & 1B	inhalative	grey	grey	black
H335	May cause respiratory irritation	Specific target organ toxicity - SE, Category 3	inhalative	blue	grey	grey
H350i	May cause cancer by inhalation	Carcinogenicity, Categories 1, 1A & 1B	inhalative	black	black	black

Table 6: Excerpt of the ANNEX: GHS rating matrix



5.3.3.2 Health hazards - Hazard approach

For a few H-statements that represent very severe health hazards a purely hazard based approach applies. A chemical product will always be rated 'black' if classified as such, independent of the exposure scenario. Those H-statements and related GHS classifications are summarized in Table 7.

H-statement code	H-statement	Classification (UN GHS)	Rating
H300	Fatal if swallowed	Acute toxicity, oral - Category 1 & 2	black
H310	Fatal in contact with skin	Acute toxicity, dermal - Category 1 & 2	black
H330	Fatal if inhaled	Acute toxicity, inhalation - Category 1 & 2	black
H340	May cause genetic defects	Germ cell mutagenicity - Category 1, 1A & 1B	black
H350[2]	May cause cancer	Carcinogenicity - Category 1, 1A & 1B	black
H360[3]	May damage fertility or the unborn child	Reproductive toxicity - Category 1, 1A & 1B	black
H370	May cause damage to organs	Specific target organ toxicity, single exposure - Category 1	black

Table 7: H-statements that trigger 'black' rating of a chemical product in the GHS module independent of the exposure scenario

5.3.3.3 Health hazards - Exposure approach

For health hazards (except the ones with oral exposure route and those mentioned in section 5.3.3.2) the bluesign® RATING matrix applies. H-statements relevant to the chemical product combined with the likelihood of exposure (low, moderate or high) lead to a 'blue', 'grey' or 'black' rating. Due to the extent of the matrix it is not displayed here. Details are described in the 'ANNEX GHS rating matrix'.

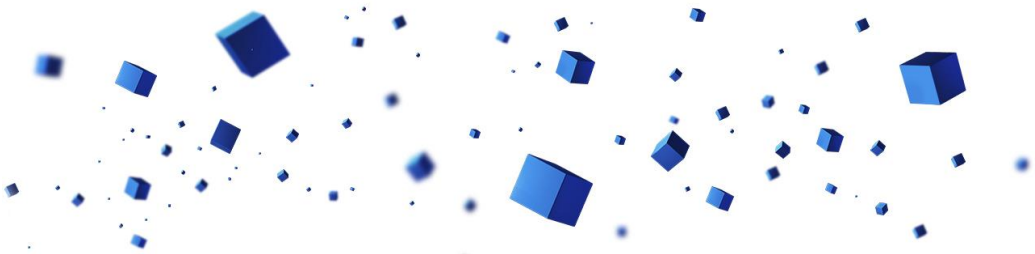
[2] Also includes the specified H-statement H350i (according to CLP)
[3] Also includes the specified H-statements H360F, H360D, H360FD, H360Fd and H360Df (according to CLP)

5.3.3.4 Health hazards with oral exposure

For health hazards with oral exposure the rating only depends on the H-statement (allocation to high, moderate or low exposure is not applicable, see Table 8). As described in section 5.3.1.1, health hazards with oral exposure are assigned an 'industrial' risk which can be controlled by common sense and trained workers respecting industrial hygiene principles (ingestion of chemicals is unlikely). Important note: The same hazard statement with dermal or inhalative exposure can in fact lead to different process-dependent ratings (see section 5.3.3.3), in the worst case (e.g. in spray applications) a 'black' rating. The H-statements in Table 7 are always rated 'black' independent of the exposure route.

Hazard statement code	Hazard statement	Classification (UN GHS)	Rating
H301	Toxic if swallowed	Acute toxicity, oral - Category 3	grey
H302	Harmful if swallowed	Acute toxicity, oral - Category 4	blue
H303	May be harmful if swallowed	Acute toxicity, oral - Category 5	blue
H304	May be fatal if swallowed and enters airways	Aspiration hazard - Category 1	grey
H305	May be harmful id swallowed and enters airways	Aspiration hazard - Category 2	blue
H336	May cause drowsiness or dizziness	Specific target organ toxicity - single exposure - Category 3	blue
H341	Suspected of causing genetic defects	Germ cell mutagenicity - Category 2	grey
H351	Suspected of causing cancer	Carcinogenicity - Category 2	grey
H361	Suspected of damaging fertility or the unborn child	Reproductive toxicity - Category 2	grey
H362	May cause harm to breast-fed children	Reproductive toxicity - effects on or via lactation, additional category	grey
H371	May cause damage to organs	Specific target organ toxicity - single exposure - Category 2	grey
H372	Causes damage to organs	Specific target organ toxicity - repeated exposure - Category 1	grey
H373	May cause damage to organs	Specific target organ toxicity - repeated exposure - Category 2	grey

Table 8: H-statements with related rating for health hazards with oral exposure in the GHS module



5.3.3.5 Environmental hazards

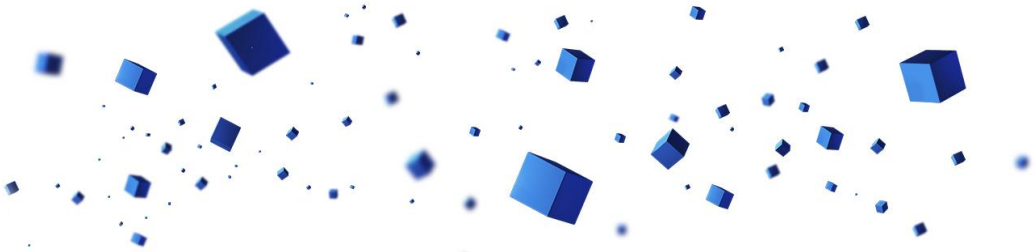
Acute and chronic aquatic toxicity are the most important hazard classes in this sub-module. The possible process-dependent exposure scenarios are 'no release', 'low', 'moderate' and 'high'. The resulting ratings as a function of H-statement and exposure are shown in Table 9. If a chemical product is classified as 'Hazardous to the ozone layer' (H420) it will be rated 'grey' independent of the release scenario.

Hazard statement code	H-statement	Classification (UN GHS)	Rating depending on release			
			No release	Low	Moderate	High
H400	Very toxic to aquatic life	Hazardous to the aquatic environment, acute hazard - Category 1	grey	grey	grey	black
H401	Toxic to aquatic life	Hazardous to the aquatic environment, acute hazard - Category 2	blue	blue	grey	grey
H402	Harmful to aquatic life	Hazardous to the aquatic environment, acute hazard - Category 3	blue	blue	blue	grey
H410	Very toxic to aquatic life with long lasting effects	Hazardous to the aquatic environment, long-term hazard - Category 1	grey	grey	grey	black
H411	Toxic to aquatic life with long lasting effects	Hazardous to the aquatic environment, long-term hazard - Category 2	blue	grey	grey	black
H412	Harmful to aquatic life with long lasting effects	Hazardous to the aquatic environment, long-term hazard - Category 3	blue	blue	grey	grey
H413	May cause long lasting harmful effects to aquatic life	Hazardous to the aquatic environment, long-term hazard - Category 4	blue	blue	blue	grey
Hazard statement code	**H-statement**	**Classification (UN GHS)**	**Rating (independent of release)**			
H420	Harms public health and the environment by destroying ozone in the upper atmosphere	Hazardous to the ozone layer - Category 1	grey			

Table 9: Risk-based rating of chemical products with environmental hazards in the GHS module

5.3.3.6 Physical hazards

As described in section 5.3.1.1, physical hazards are assigned an 'industrial' risk which can be controlled by adequate industrial safety measures. A degree of exposure expressed as 'low', 'moderate' or 'high' is not assigned. All H-statements of physical hazard classes (as per CLP) result in a 'grey' rating (refer also to the 'ANNEX: GHS rating matrix').



5.3.4 Exceptions

There are a few exceptions where the standard assessment within the GHS module would lead to a 'black' rating but a 'grey' rating is allowed due to industrial state of the art. Examples of these exceptions are:

- Isocyanates in reactive hotmelts
- DMF/DMAC in solvent coating applications
- Respiratory sensitizing dyes in textile and leather dyeing
- Substances (e.g. cyanides) in galvanic processes

Specific safety measures are to be implemented at a manufacturing site which for bluesign® SYSTEM PARTNERS is verified during bluesign® COMPANY ASSESSMENTs. Advice on safe use shall be communicated via SDS (Safety Data Sheets) and TDS (Technical Data Sheets). In addition, valuable information for safe use is provided in the bluesign® TOOL and bluesign® FINDER. An overview of all exceptions is summarized in the 'ANNEX: Exceptions'.

If a chemical product is rated grey because of H-statement H317 (May cause an allergic skin reaction), the application for usage range A is by default not allowed to protect consumers from sensitizing substances on the textile. Exceptionally, usage range A may still be allowed if:

- the sensitizing substance is not intended to remain and does not remain on the fiber (all process chemicals);
- the sensitizing substance is bonded to the fiber in a way that eliminates the sensitizing effect (e.g. reactive dyes).

For details see the 'ANNEX: Exceptions'.

5.4 Consumer Safety module (BSSL)

5.4.1 Purpose and description

The goal of the consumer safety module is to predict whether articles that are treated with a chemical product comply with the consumer safety limits (BSSL). The module therefore calculates predicted concentrations of relevant restricted substances on or in an article and compares them to the substance-specific limits laid down in the BSSL. Substance concentrations on or in an article depend on multiple factors, such as:

- How much chemical product is used per kg material (AddOn)
- Substance concentration in the chemical product
- Applied process (e.g. exhaust, pad application, extrusion)
- Function of the applied chemical (effect chemicals or process chemicals)
- Affinity of the substance to the fiber
- Other process parameters (e.g. temperature)

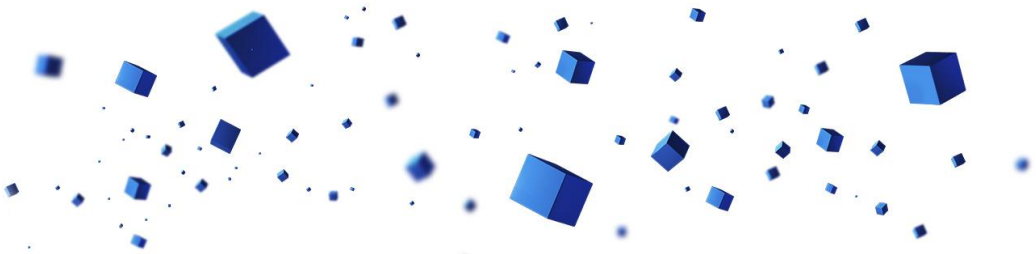
Three different process scenarios are considered with separate calculation models:

- Textile application - Batch (exhaust) or continuous
- Textile application - Pad application or coating
- Direct application - Chemical product directly processed into an article (e.g. extrusion, spinning)

Model assignment is done according to a categorization matrix by defining the Sector of Use, Process Category and Process Subcategory (see also Table 10). Whether release to water and/or air is relevant within the textile application modules is also determined in a categorization matrix (see Table 11) .

Sector of Use (SU)	Process category (PROC)	Process subcategory (PROSC)	Model – Textile Application	Model – Direct Application
Manufacture of down and feather products	Finishing	Batch processing (exhaust)	Yes	No
Manufacture of down and feather products	Finishing	Spray processing	Yes	No
Manufacture of fibers/yarns	Extrusion	No process subcategory available	No	Yes
Manufacture of fibers/yarns	Fiber/yarn preparation	Batch processing (exhaust)	Yes	No

Table 10: Model assignment (consumer safety) based on categorization of 'sector of use', 'process' and 'subprocess'



Sector of Use (SU)	Process category (PROC)	Process subcategory (PROSC)	Direct water release during process	Air release during drying process
Manufacture of textile products including fabrics, laminates and non-wovens	Aftertreatment	Batch processing (exhaust)	Yes	Yes
Manufacture of textile products including fabrics, laminates and non-wovens	Aftertreatment	Continuous processing	Yes	Yes
Manufacture of textile products including fabrics, laminates and non-wovens	Aftertreatment	Pad processing	No	Yes
Manufacture of textile products including fabrics, laminates and non-wovens	Aftertreatment	Spray processing	No	Yes

Table 11: Relevance of release to water and air based on categorization of sector of use, process and subprocess

5.4.2 Parameters for calculation of residual substance concentration on articles

Parameter	Unit	Description
AddOn	kg CP/kg material	Weight of chemical product (CP) applied per weight of material to be treated
CP	-	Chemical product
$C_{Sub,CP}$	mg/kg	Concentration of a substance in a chemical product
$C_{Sub,corr}$	mg/kg	Substance concentration corrected by correction factor $F_{corr,.met}$. Only relevant for metals
$C_{Sub,initial}$	mg/kg	Substance concentration in or on material (e.g. a fabric) without consideration of release to water or air
$C_{Sub,wet}$	mg/kg	Substance concentration after a wet processing step (exhaust)
$C_{Sub,final}$	mg/kg	Substance concentration after subtraction of relevant releases to water (wet processing) and air (drying) as applicable
Fix	wt %	Share of chemical product intended to remain on the material after processing, regardless of fixation degree
F_{corr}	-	Correction factor for high AddOn based on amount of fixed active substance; factor to consider the weight increase after treatment
$F_{corr,.met}$	-	Correction factor to account for incomplete extraction of metals from a substrate
Liquor	-	The liquid/fluid that is used to treat a material (e.g. a fabric). The liquid is usually a solvent such as water in which the active substance (e.g. a dyestuff) and auxiliary substances (e.g. dispersing agent) are dissolved.
$R_{release,water,}$	wt %	Substance specific release rate to the water phase in weight percentage during wet processing
$R_{release,air}$	wt %	Substance specific release rate to the air from a synthetic or natural fiber in weight percentage during drying process

Table 12: Parameters for calculation of residual substance concentration on articles

5.4.3 Calculation models

5.4.3.1 Textile application model (exhaust and continuous)

This model builds on the assumption that substances are fully ab/adsorbed by the substrate and then released through wet processing to the water phase and released to the air through a drying process.

In a first step the initial theoretical substance concentration $C_{Sub,initial}$ on the dry material is calculated. It is determined by multiplying the add-on of the chemical product (CP) per kg material with the substance concentration in the chemical product. A correction factor is introduced to account for the weight increase of the fabric by fixation of a certain percentage of the chemical product.

$$C_{Sub,initial} = AddOn \cdot C_{Sub,CP} \cdot F_{corr}$$ Equation 1

With the correction factor being

$$F_{corr} = \frac{1}{\left(1 + AddOn \cdot \frac{Fix}{100}\right)}$$ Equation 2

The correction factor depends on the share of chemical product intended to remain on the material after processing (Fix) and reflects the dry weight increase of the article after it was treated with the chemical product. The factor can be significant in case of a high AddOn to material (e.g. coating); for process chemicals or other products that remain mainly in the water path the factor is very close to 1.

The initial concentration is then reduced by estimated substance-specific release rates. Release rates are either based on experience from industrial processes or are estimated based on the physicochemical properties of the substance, considering also relevant process parameters. Within bluesign model calculations, release rates to water ($R_{release,water}$) are assumed to depend on the substance parameters 'hydrogen bonding potential' with the substrate and the distribution coefficient between octanol and water (log K_{ow}). Release rates to the air depend on the hydrogen bonding potential with the substrate and on the vapor pressure. Pre-calculated release rates for each BSSL substance are available in the bluesign® TOOL. The reference temperature for release rate calculation is chosen to be 150°C for drying steps. Release rates to air are distinguished between natural fibers (represented by cotton) and man-made fibers (represented by PES). If release rates for specific substances can be derived from experimental studies, these may replace the release rates determined via model calculations.

Depending on the selected process and sub-process, there can be one or two wet processing/drying steps. For each relevant process step the substance concentration is reduced according to the substrate-specific (natural or synthetic fiber) release rates ($R_{release,water}$ and $R_{release,air}$). A possible sequence would be as follows (e.g. for batch process dyeing) where the calculated substance concentration after the wet processing step is $C_{sub,wet}$ and the final substance concentration after drying is $C_{Sub,final}$.

Wet processing step:

$$C_{Sub,wet} = C_{Sub,initial} \cdot \left(1 - \frac{R_{release,water}}{100}\right)$$ Equation 3

Drying step:

$$C_{Sub,fnal} = C_{Sub,,wet} \cdot \left(1 - \frac{R_{release,air}}{100}\right)$$ Equation 4

The final concentration $C_{Sub,final}$ is used for comparison with the BSSL limit values as described in chapter 5.4.5.

If the substance is a metal and the relevant limit in the BSSL is related to an 'extractable' method where the recovery rate of extraction is known, the substance concentration needs to be corrected as follows:

$$C_{Sub,corr} = C_{Sub,final} \cdot F_{corr,met}$$ Equation 5

In Equation 5, $F_{corr,met}$ is the extraction rate of a particular metal according to the referenced analytical method as given in the BSSL. This correction is necessary for adequate comparison of the calculated substance concentration with the limit value for the extractable amount.

5.4.3.2 Textile application model (pad and coating application)

This model builds on the assumption that substances are fully ab/adsorbed by the substrate and then released to the air during a drying processes according to the applicable substance- and substrate-specific release rate ($R_{release,air}$). Only one drying step is considered in this module. Module assignment is made based on process and sub-process categorization (e.g. process: coating, sub-process: roll coating). The initial substance concentration $C_{Sub,initial}$ on the material is calculated as per Equation 1 with consideration of the correction factor as per Equation 2. After drying the final substance concentration on/in the material $C_{Sub,final}$ is

$$C_{Sub,final} = C_{Sub,initial} \cdot \left(1 - \frac{R_{release,air}}{100}\right)$$ Equation 6

If the substance is a metal and the relevant limit in the BSSL is related to an 'extractable' method a correction factor is applied as per Equation 5.

5.4.3.3 Direct application

Direct application is a process where a chemical product is only converted into another shape (e.g. an extruded polymer), thereby becoming an article. The substance concentrations before and after the process are assumed to be identical; release is not considered. Module assignment is made based on process and sub-process categorization. If the substance of concern is a metal and the relevant limit in the BSSL is related to an 'extractable' method a correction factor is applied as per Equation 5.

5.4.4 Required data

The data required to perform the assessment in the consumer safety module consists of:

- Full categorization (Sector of use, product category and sub-category, process category and sub-category)
- Expected maximum concentrations of all relevant BSSL substances in the chemical product, i.e. specifications for all relevant BSSL substances
- Evidence that the expected maximum concentration of relevant BSSL substances in the chemical product are kept (e.g. test report, supplier CoA)
- AddOn of chemical product (in kg) per kg material
- Share of chemical product intended to remain on the material after processing (parameter 'Fix')

5.4.5 Rating

Calculated substance concentrations are expressed as a percentage of the BSSL limit; the final rating ('blue', 'grey' or 'black') depends on three main factors.

- The AddOn expressed as chemical product (in kg) per kg material (≤0.1 kg/kg or >0.1 kg/kg)
- The BSSL limit type ('usage ban', 'usage restriction', 'monitoring')
- Whether there are individual limits for usage range A, B and C or not

A ‘black’ rating can result even when the calculated substance concentration on the finished article is below 100% of the BSSL. This margin of safety is required because only one chemical product is considered in the model, but in reality, the textile is treated with several chemical products and a certain amount of the same substance could be on the textile from another processes. With an AddOn of ≤ 0.1 kg/kg the probability that other chemicals are used additionally is higher than with an AddOn of > 0.1 kg/kg, so the safety margin is higher with AddOn ≤ 0.1 kg/kg. The detailed rating decision logic is shown in Figure 8 (in case there is only one limit for usage range A/B/C) and in Figure 9 (in case there are individual limits for usage ranges A/B/C).

5.4.6 Exceptions

There are exceptions where the consumer safety model would not lead to realistic substance concentrations on materials, e.g. for reactive systems and solvent based systems. For those applications a test on the finished material shall be done to confirm compliance with the BSSL limits. Exceptions are summarized in the ‘ANNEX: Exceptions’.

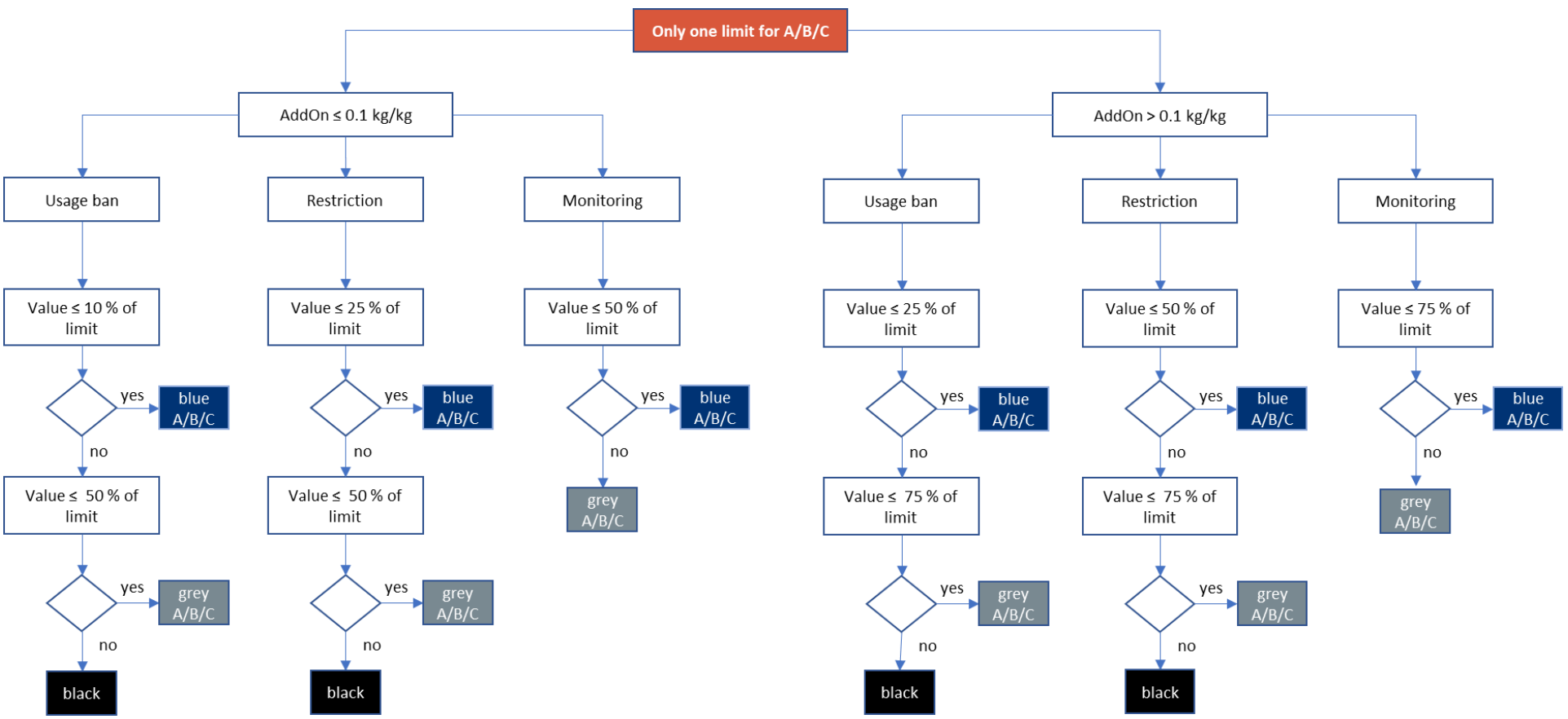


Figure 8: Rating rules in the consumer safety module when the BSSL substance only has one limit for usage ranges A, B and C

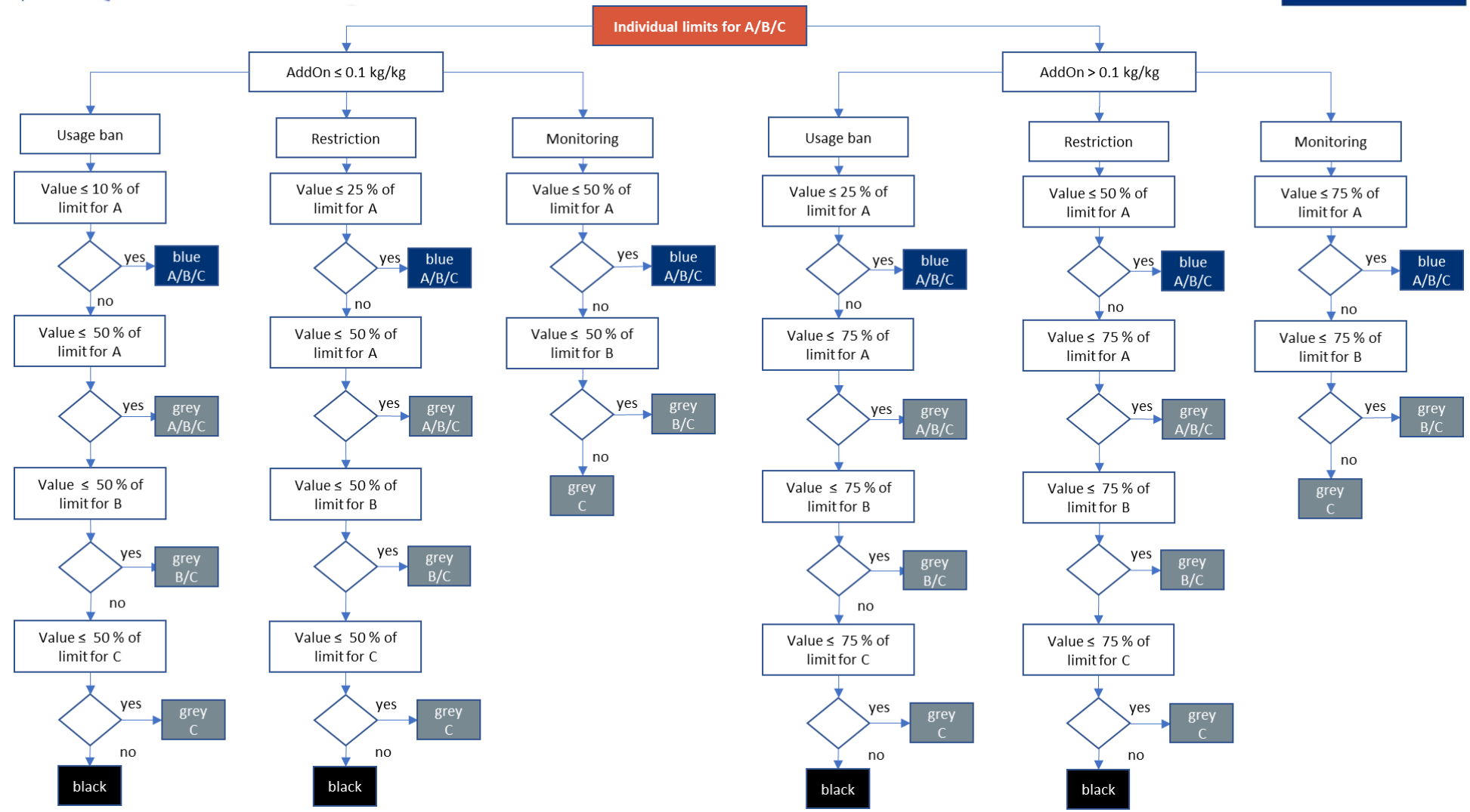


Figure 9: Rating rules in the consumer safety module when the BSSL substance has individual limits for usage ranges A, B and C

5.5 Occupational Health module

5.5.1 Purpose and description

The purpose of the occupational health module is to protect workers in textile and related industries by ensuring a safe workplace atmosphere.

Protection of workers is one of the key aspects of the bluesign® SYSTEM. Especially when it comes to volatile substances, the risk is often low for consumer use but high for workers. Ensuring a safe workplace atmosphere is a prerequisite for compliance with the bluesign® CRITERIA. The top priority within the hierarchy of controls for chemicals at production sites is substitution (see figure below).

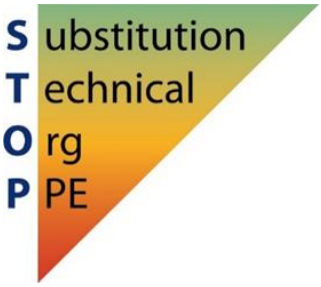


Figure 10: S.T.O.P principle. Hierarchy of controls. Refer also to the bluesign® CRITERIA for production sites (v3.0), chapter 12

For this reason, the chemical assessment includes the OH module to prevent the use of chemical products that pose a risk for workers from the beginning.

The OH module calculates, for selected industrial exposure scenarios, a predicted concentration of chemical substances in the workplace atmosphere and checks compliance with international legal occupational exposure limits (OEL). This is based on legal lists from China (GBZ 2.1), Germany (TRS 900 and 910) and the USA (OSHA). If more than one applicable limit exists, the lowest limit is considered for the rating.

5.5.2 Required data

The data required to perform the assessment in the occupational health module consists of:

- Full categorization (Sector of use, product category and sub-category, process category and sub-category)
- Concentration of all substances contained (intentional or unintentional) in the chemical product (refer also to section 4.4) with an occupational exposure limit in the regulations listed under 5.5.1

5.5.3 Scenarios and calculation

Five, mainly textile industry related scenarios are defined where a worker in normal operating procedures can come into contact with chemical substances. Depending on the kind of application, one or more scenarios for relevant substances with an OEL limit are calculated.

The scenarios are:

- Opening barrel
- Opening dyeing machine
- Batch application with drying process at stenter
- Pad application with drying process at stenter
- Coating application with drying process

The models are based on physicochemical rules for evaporation, using the vapor pressure (at different temperatures), Raoult's law or diffusion from wet surfaces.

Validity: All models are only valid for water-based systems. They are not applicable for solvent-based or solid products. For such products no OH calculation takes place. For solvent-based products, on-site measures are required in any case (see bluesign® CRITERIA for production sites).

Additional scenarios for other industrial applications may be developed in future.

5.5.3.1 Parameters for scenario calculations

Parameter	Unit	Description	Default values
A	m^2	Evaporation surface textile	40 m^2 (20 m^2 for coating)
AddOn	kg CP/kg material	Weight of chemical product (CP) applied per weight of material to be treated	
$AddOn_{Area}$	kg CP/m^2 material	Weight of chemical product applied per area of material to be treated	
Air volume flow	m^3/h	Total air volume flow in exposed area	
C_{liquor}	kg CP/kg liquor	Concentration/addition of a chemical product (CP) to the liquor	
$C_{mole,sub}$	mole/L	Molar concentration of a substance in a liquid system	
$C_{mole,water}$	mole/L	Molar concentration of water (as solvent) in a liquid system	
$C_{sub,CP}$	mg/kg	Concentration of a substance in a chemical product	
$C_{sub,wet,article}$	mg/kg	Concentration of a substance in the wet phase of an article after a wet application step before drying	
$C_{sub,liq}$	mg/L	Concentration of a substance in the liquor	
$C_{sub,air}$	mg/m^3	Concentration of a substance in the atmosphere above a liquid (equilibrium, e.g. in the air phase of a closed barrel).	
$C_{sub,workplace}$	mg/m^3	Concentration of a substance in the workplace atmosphere.	
CP	-	Chemical product	
$D_{air,sub}$	m^2/h	Diffusion coefficient of a substance in air	
Emission mass flow	mol/h	Molar mass flow of a substance evaporating from a wet surface	
f_{dil}	-	Dilution factor. Dilution occurs when the gas phase from a barrel or vessel expands to the working environment; the factor is model specific.	
(1- F2)	-	Factor considering the temporal development of the substance concentration in the workplace atmosphere during the shift with: $F2 = \frac{1-e^{(-\lambda \cdot \Delta t)}}{\lambda \cdot \Delta t}$	
Liquor	-	The liquid/fluid that is used to treat a material (e.g. a fabric). The liquid is usually a solvent such as water in which the active substance (e.g. a dye stuff) and auxiliary substances (e.g. dispersing agent) are dissolved.	
$liquor_{pick-up}$	%	Portion of liquor picked up by a textile in a wet process, in weight percentage of the textile weight.	

Parameter	Unit	Description	Default values
LR	-	Liquor ratio, ratio between substrate and liquor in a batch process. Usually between 1:4 and 1:10 (example: 1 kg textile to 4 liter of dyeing liquor)	
LR_{norm}	-	Depends in practice on process and equipment. To make calculations comparable a value of 1:4 used as realistic worst case	1:4
m_{sub}	g	Mass of substance	
mole fraction	-	Mole fraction of a substances in a substance mixture	
MW	g/mol	Molecular weight of a chemical substance	
n	mol	Number of moles of a substance (m_{sub}/MW)	
OF	-	Location factor, relates the substance concentration at the workplace to the calculated average concentration in the whole area (here: affected workplace directly located at source)	2 (worst case)
p_{sub}	mbar	Vapor pressure of a substance at a specific temperature	
$p_{sub,part}$	mbar	Partial vapor pressure of a substance in a mixture, based on mole fraction	
R	mbar*m³/(mol*K)	Universal gas constant, 8.314 J/(mol*K) or 0.08314 mbar*m³/(mol*K).	0.08314 mbar*m³/(mol*K)
$R_{release,water,}$	wt %	Substance-specific release rate to the water phase in weight percentage during wet processing	
Reference weight textile	kg/m²	Weight of a material per unit area	
T	K	Temperature in Kelvin	
Δt	h	Time period of emission (one shift of 8 h)	8
V	m³	Volume (gas volume in ideal gas equation)	
V_{exp}	m³	Exposed area at stenter inlet area considered for calculation	500 m³
vel_{air}	m/s	Air flow velocity over liquid/wet surface (here wet textile at inlet area of stenter)	0.1 m/s
x_{liq}	m	Length overflowed liquid surface	1 m
β	m/h	Mass transfer coefficient of a substance into the gas phase	
γ	-	Activity coefficient of a chemical substance in a liquid phase	2
λ	1/h	Air exchange rate at workplace	4/h
ν_{air}	m²/h	Kinematic viscosity air	0.055 m²/h

Table 13: Parameters for scenario calculations (OH module)

5.5.3.2 Scenario: Opening barrel

This scenario describes the situation of a worker opening a barrel of a chemical product and being exposed to the substance concentration in the supernatant gas phase (see Figure 11). The model assumptions are:

The barrel is partly empty and when opening, a volume of 50 liters from the gas phase above the liquid disperses into the working area. Outside the barrel the volume of 50 liters is diluted to 2500 liters.

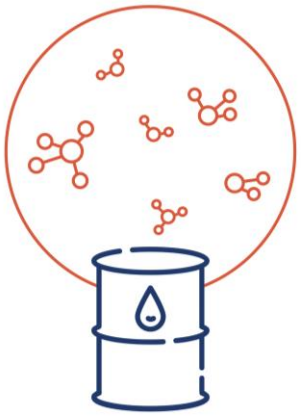


Figure 11: Substance vapor over an open barrel

Based on the molecular weight, vapor pressure (at 25°C) and concentration of the substance in the chemical product, the concentration in the gas phase is calculated using Raoult's law and the ideal gas law.

Model assumptions:

- For the calculation of each substance, the system is regarded as a two-component system (substance and water; C_{water} = 1 kg/L - C_{sub}), independent of whether further substances are contained in the product.
- The density of the chemical product is set by default to 1 kg/L.
- Dilution factor f_{dil} = 50
- Temperature: 25°C (298 K)

Calculation:

1. Calculation of the partial pressure of the substance $p_{sub,part}$

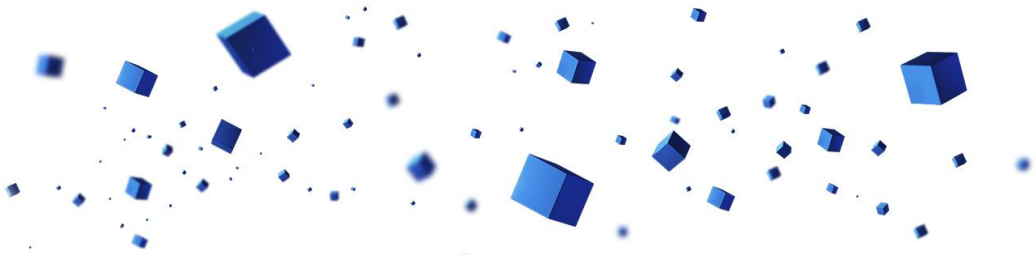
$$p_{sub,part} = p_{sub} \cdot \text{mol fraction} = p_{sub} \cdot \frac{C_{mol,sub}}{C_{mol,sub} + C_{mol,water}}$$ Equation 7

with:

$$C_{mol,sub} = \frac{C_{sub,CP}}{MW \cdot 1000}$$ Equation 8

$$C_{mol,water} = \frac{(1000000 - C_{sub,CP})}{MW \cdot 1000}$$ Equation 9

(1000 and 1000000 are factors for unit correction g/kg and mg/kg)



2. Calculation of the substance concentration in the surrounding using ideal gas equation

$$p \cdot V = \text{constant} = n \cdot R \cdot T \quad \text{with } n = \frac{m_{sub}}{MW}$$ Equation 10

$$\frac{m_{sub}}{V} = \frac{p \cdot MW}{R \cdot T} = c_{sub,air}$$ Equation 11

With factors for unit correction this becomes:

$$C_{sub,workplace} = \frac{p_{sub,part} \cdot MW \cdot 1000}{R \cdot T \cdot f_{dil}}$$ Equation 12

5.5.3.3 Scenario: Opening dyeing machine

This scenario describes the situation of a worker opening a dyeing machine after the dyeing process and being exposed to the substance in the supernatant gas phase expanding to the surroundings. The amount of gas escaping from the dyeing machine is defined to be 2000 liters, the dilution in the workplace area is defined to be 5000 liters.

The calculation is performed in the same way as for the opening barrel scenario, but considering the substance concentration in the liquor, the vapor pressure at a temperature of 60°C and the different dilution factor in the working area.

The liquor concentration is important for this calculation but varies in practice depending on the equipment/machine used. Therefore, the concentration is normalized to a worst-case liquor ratio of 1:4

Model assumptions:

- For the calculation of each substance, the system is regarded as a two-component system (substance and water; c_{water} = 1 kg/L – c_{sub}), independent of whether further substances are contained in the product
- The density of the chemical product is set by default to 1 kg/L
- Temperature: 60°C (333 K)
- Dilution factor f_{dil} = 2.5
- Liquor ratio for normalization LR_{norm} = 1:4

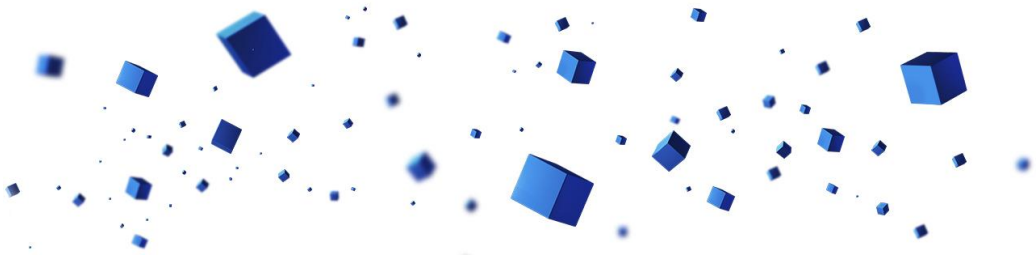
Calculation:

1. Calculation of the substance in the liquor with standardized liquor ratio, depending on the input data

$$C_{sub,liq} = AddOn \cdot C_{sub,CP} \cdot LR_{norm} = AddOn \cdot \frac{C_{sub,CP}}{4}$$ Equation 13

$$C_{sub,liq} = C_{liquor} \cdot C_{sub,CP} \cdot \frac{LR_{norm}}{LR} = C_{liquor} \cdot C_{sub,CP} \cdot \frac{1}{LR \cdot 4}$$ Equation 14

2. Calculation of the partial pressure of the substance $p_{sub,part}$: see Equation 7, with $c_{sub,CP}$ replaced by $c_{sub,liq}$
3. Calculation of the substance concentration in the surroundings using the ideal gas equation: similar to Equation 12, using the model-specific parameter



5.5.3.4 Scenario: Batch application with drying process at stenter

This scenario describes the situation of the wet textile after a batch process at the inlet area of a stenter for a drying process. Diffusion of chemical substances from the wet textile surface occurs and is used to calculate the substance concentration in the surrounding workplace atmosphere. For the calculation this scenario requires as additional substance parameter the diffusion coefficient in air.

Model assumptions:

- 1 kg textile takes 1 kg of liquor after batch application
- Textile area considered for diffusion: 20 m^2 textile, in total 40 m^2 (due to diffusion from both sides of the textile)
- Exposed area (V_{exp}): 500 m^3
- Air exchange rate (λ): 4 times per hour

This model is only valid for water-based systems (solvent-based processes need exhaust ventilation in place).

Calculation:

1. Calculation of the substance concentration in the wet phase on the article (after batch application). The concentration of substances in the wet phase on an article is not the same as the starting concentration in the liquor. Substances show different behavior regarding their tendency to remain on the textile or in the water. To consider this in the calculation, release rates are used, the same as used in the consumer safety module. The model assumption has two steps:

   - All chemical substances from the liquor are taken up by the wet phase on the textile
   - This concentration is reduced by using the release rate as an indicator of how much of a substance (in percent) goes into the wastewater path

   In a first step the initial substance concentration in the liquor is calculated and corrected with the release rate.

$$C_{sub,wet,article} = C_{liquor} \cdot \frac{1}{LR} \cdot C_{sub,CP} \cdot \left(1 - \frac{R_{release,water}}{100}\right) \quad \text{Equation 15}$$

   or:

$$C_{sub,wet,article} = AddOn \times C_{sub,CP} \cdot \left(1 - \frac{R_{release,water}}{100}\right) \quad \text{Equation 16}$$

   If no release rate can be determined for a substance or group, a worst-case calculation with release rate 0 takes place.

2. Calculation of substance in the workplace atmosphere. A diffusion model is used to calculate the substance concentration in the workplace atmosphere.[4]

$$C_{sub,workplace} = \frac{\text{Emission mass flow} \cdot MW \cdot (1 - F2) \cdot OF \cdot 1000}{\text{Air volume flow}}$$ Equation 17

with:

The factor 1000 (g/mg) is used for unit correction

OF = Location factor = 2 (affected workplace directly located at source)

$$F2 = \frac{1 - e^{(-\lambda \cdot \Delta t)}}{\lambda \cdot \Delta t}$$ Equation 18

$$\text{Air volume flow} = V_{exp} \cdot \lambda$$ Equation 19

$$\text{Emission mass flow} = \frac{\text{mole fraction} \cdot \gamma \cdot p_{sup} \cdot \beta \cdot A}{R \cdot T}$$ Equation 20

$$\beta = 0.0111 \cdot \frac{\left(vel_{air} \cdot 3600 \frac{s}{h}\right)^{0.96} \cdot D_{air,sub}{}^{0.19}}{\nu_{air}{}^{0.14} \cdot x_{liq}{}^{0.04}}$$ Equation 21

5.5.3.5 Scenario: Pad application with drying process at stenter

This scenario is similar to the scenario 'Batch application with drying process at stenter' and describes evaporation from a wet textile at the stenter before it comes to the drying compartments. It differs from the former module in the different calculation of the substance concentration in the wet textile. In contrast to the former model, no release rate is considered. It is assumed that the concentration of substances in the wet phase on the textile is the same as the concentration in the liquor. The liquor pick-up is a relevant parameter in this model, but can vary depending on the process, equipment, kind of textile and adjustments. In the model calculations the pick-up is standardized to a value of 50% (worst-case).

The textile has passed the foulard for pick-up of liquor and afterwards a rolling system and the inlet area. In these areas evaporation driven by diffusion from wet surfaces takes place. The calculation model is based on the release amount of a substance to the surrounding in relation to a defined surrounding area of 500 m³ combined with an air exchange rate of 4 times per hour. The ambient conditions are set to 30/25/20°C depending on the availability of vapor pressure data. The evaporation surface is set to 40 m².

[4] BIA Report 3/2001, *Berechnungsverfahren und Modellbildung in der Arbeitsbereichsanalyse*, HVBG, 2001

Model assumptions:

- 1 kg textile takes up 0.5 kg of liquor after pad application (relates to a pick-up normalization of 50%)
- Textile area considered for diffusion: 20 m^2 textile, in total 40 m^2 (due to diffusion from both sides of the textile)
- Exposed area: 500 m^3
- Air exchange rate (λ): 4 times per hour

Calculation:

1. Calculation of the substance in the wet phase on the article (after pad application)

$$C_{sub,wet,article} = C_{liquor} \cdot C_{sub,CP} \cdot \frac{liquor_{pick-up}}{50}$$ Equation 22

$$C_{sub,wet,article} = AddOn \cdot C_{sub,CP} \cdot 2$$ Equation 23

Factor 2 in Equation 23 relates to a liquor pick-up of 50% (textile:liquor ratio = 2:1).

2. Calculation of the substance concentration in the workplace atmosphere. This part of the calculation is exactly the same as in the scenario 'Batch application with drying process at stenter' (Equation 17 onwards).

5.5.3.6 Scenario: Coating application with drying process

This scenario is similar to the scenario 'Pad application with drying process at stenter' and describes evaporation from a wet textile at the stenter before it comes to the drying compartments. It differs from the former module in that diffusion/evaporation takes place only from one side (coated side) of the textile

Chemical products that are applied undiluted (ready to use) form a special case. In that scenario, the calculation step for the concentration of the substance in the liquor is no longer relevant.

Model assumptions:

- 1 kg textile takes up 1 kg of liquor after coating application
- Textile area considered for diffusion: 20 m^2 textile (diffusion only from coated side)
- Exposed area: 500 m^3
- Air exchange rate (λ): 4 times per hour

1. Calculation of the substance on the article (after coating application):

$$C_{sub,wet,article} = AddOn \cdot C_{sub,CP}$$ Equation 24

$$C_{sub,wet,article} = \frac{AddOn_{area}}{\text{Reference weight textile}} \cdot C_{sub,CP}$$ Equation 25

2. Calculation of the substance concentration in the workplace atmosphere. This part of the calculation is exactly the same as in the scenario 'Batch application with drying process at stenter' (Equation 17 onwards).

5.5.4 Result and rating

The described models provide data for a predicted concentration of substances in the workplace atmosphere. Depending on the process, one or more models can be relevant. The results are compared to legal OEL limits as described in section 5.5.1.

Different limit types exist, depending on the time a worker is exposed to substances (see Table 14). For the scenarios 'Opening barrel' and 'Opening dyeing machine' the result is compared against short-term exposure limits (STEL), and the results of the three scenarios with drying process are compared with time weighted average limits (TWA, considering an eight-hour workday). The chemical product is rated 'black' if any of the calculated concentrations is above the corresponding STEL or TWA limit. If more than one STEL or TWA limit exist, the calculated results are compared against the lowest limit.

Scenario	Exposure	Limit type
Opening barrel	Short	STEL (TRGS 900/910, OSHA, GB/Z)
Opening dyeing machine	Short	STEL (TRGS 900/910, OSHA, GB/Z)
Batch application with drying process at stenter	Long	TWA (TRGS 900/910, OSHA, GB/Z)
Pad application with drying process at stenter	Long	TWA (TRGS 900/910, OSHA, GB/Z)
Coating application with drying process at stenter	Long	TWA (TRGS 900/910, OSHA, GB/Z)

Table 14: Relevant limit types according to the exposure scenario in the occupational health module

A 'grey' rating results when the calculated value reaches 50% of the 'black' limit. A comment in the bluesign® FINDER points out that occupational exposure limits need to be controlled. For substances that are classified as carcinogenic, the 'grey' rating area is extended down to 25% as shown in the scheme below.

Substance type	Calculated workplace concentration in % of strictest limit	Rating
Non-carcinogenic substances	≤ 50	blue
	> 50 ≤ 100	grey
	> 100	black
Carcinogenic substances	≤ 25	blue
	> 25 ≤ 100	grey
	> 100	black

Table 15: Rating rules for the occupational health module

5.6 Air emission module

5.6.1 Purpose and description

Certain processes in the textile industry come with the risk of air emission. The air emission module conducts an assessment to determine whether release of volatile organic compounds (VOC) might be a concern when using a chemical product. Air emission relevant processes covered by the methodology are:

- Coating
- Finishing

The amount of organic carbon likely to be released from a chemical product is compared to an organic carbon threshold value. Exceeding the threshold value should trigger additional measures to reduce organic carbon emission at facility level.

5.6.2 Required data

The data required to perform the assessment in the air emission module consists of:

- Full categorization (Sector of use, product category and sub-category, process category and sub-category)
- TOC (total organic carbon) content that is likely to be released from the chemical product

The part of the TOC that is released from the chemical product during heat treatment steps can be determined as an emission factor that is either measured by an accredited laboratory or calculated using the TEGEWA emission factor model[5]. Another way is to estimate the volatile fraction of the TOC by applying a worst-case approximation as described in the bluesign guidance sheet 'Generation of Data for the bluesign® TOOL'.

5.6.3 Rating

The TOC values of the product are compared with the limit values listed in the table below. If the corresponding limits are exceeded, the product is rated 'grey'. A 'black' rating is not possible because the final emission situation depends on many local parameters (volumes, equipment, emission control measures) that can only be evaluated on site. Two different limits exist, depending on how the TOC is determined.

- If the TOC value is estimated/calculated (TOC_{est}) based on composition information and the carbon content of the relevant substances (according to the method described in the guidance sheet 'Generation of Data for the bluesign® TOOL'), a 'blue'/'grey' limit of 50 g C per kg chemical product is applicable.
- If the emission factor is determined by testing or calculated from test results of components (TOC_{EF}), a limit of 20 g C per kg chemical product is applicable. The difference relates to the specific conditions of the test method, in particular the calibration of the detecting FID unit. This results in a lower value in testing compared to the real TOC content.

Parameter	Abbreviation	Reported TOC release in g C per kg chemical product	Rating
Total organic carbon (as emission factor f_C)	TOC_{EF}	≤ 20	blue
		> 20	grey
Total (volatile) organic carbon (estimated)	TOC_{est}	≤ 50	blue
		> 50	grey

Table 16: Rating rules for the air emission module

[5] https://echa.europa.eu/documents/10162/983773/pt9_oecd_esd_no_7_textile_finishing_industry_en.pdf/2d6bb902-83cc-4ff1-94ef-6e8fb2aab978

5.7 Environment module

5.7.1 Purpose and description

In the environment module common environmental data is collected that characterizes a chemical product and influences the chemical product's impact at facility level, especially when looking at wastewater emission. Most of the parameters do not directly lead to a rating (see Table 17) but are necessary to calculate the environmental performance indicators (eKPIs) of a manufacturing facility (e.g. a textile manufacturer), which are regularly determined by bluesign® COMPANY ASSESSMENTs.

5.7.2 Required data

The minimum required data to assess a chemical product in the environment module is listed in Table 17 below[6].

Parameter	Abbreviation	Unit	Source
Chemical oxygen demand	COD	mg O_2/g chemical product	Measured, calculated or literature - not rating relevant
Biochemical oxygen demand (after 5 days)	BOD_5	mg O_2/g chemical product	Measured, calculated or literature - not rating relevant
Total phosphorus content	P, total	wt %	Measured or calculated - not rating relevant
Total nitrogen content	N, total	wt %	Measured or calculated - not rating relevant
Adsorbable organic halogen content	AOX	wt %	Measured or calculated[7]
Fluorine content (organically bound)	F	wt %	Measured or calculated

Table 17: Required minimum parameters for the environment module

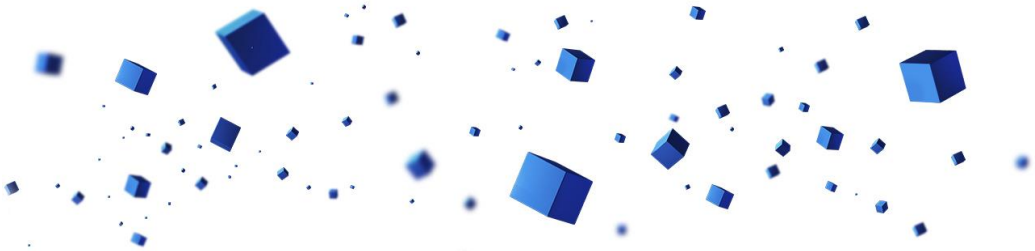
5.7.3 Rating

Only two of the parameters listed in Table 17 are rating relevant: 'Adsorbable organic halogen' and 'Fluorine content'. Both parameters can lead to a grey rating if the defined threshold limits are exceeded (see Table 18).

Parameter	Abbreviation	Reported concentration in wt %	Rating
Adsorbable organic halogen content	AOX	≤ 0.1	blue
		> 0.1	grey
Fluorine content (organically bound)	F	≤ 0.1	blue
		> 0.1	grey

Table 18: Rating rules in the environment module

[6] Data not needed for processes without water release
[7] See Guidance Sheet 'Generation of Data for the bluesign® TOOL'



6 Background on Limit Determination (BSSL, BSBL)

Substances listed in the BSBL and the BSSL have been identified as being relevant for the industries covered by the bluesign® SYSTEM (mainly textile, leather, footwear, accessories) and as posing a potential risk for workers, consumers and the environment. Substance hazards/properties (also called endpoints) that may lead to a BSBL and/or BSSL listing are:

- Carcinogenicity
- Mutagenicity
- Reproductive toxicity
- Endocrine disruption
- Neurotoxicity
- Developmental toxicity
- Acute toxicity
- Specific target organ toxicity
- Skin corrosion or sensitization
- Respiratory sensitization
- Persistency, bioaccumulation
- Aquatic toxicity
- Ozone depletion

6.1 Consumer safety limits (BSSL)

BSSL (consumer safety) limits are determined by considering various factors such as specific substance hazards, detection limits of currently available analytical methods, and legal restrictions. Safe substance concentrations ($C_{textile,safe}$) on a textile are estimated by exposure scenario calculations (for oral, dermal and inhalative exposure), taking into account toxicological data for each substance. These calculations are the science-driven basis to arrive at BSSL limits with usage ranges A, B, C.

6.1.1 Dermal exposure

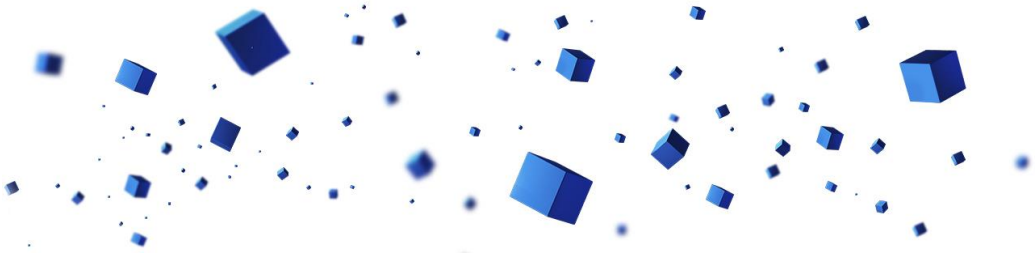
All parameters used to calculate the scenario for dermal exposure are listed and explained in section 6.1.1.3. The factors 100 (percent -> fraction) and 1000 (g/mg) are used for unit correction.

6.1.1.1 Acute dermal exposure

$$C_{textile,safe} = \frac{I_{dermal,acute} \cdot BW \cdot 100 \cdot 100 \cdot 1000}{A_{dermal} \cdot SW_{textile} \cdot MOS \cdot F_M \cdot F_A}$$ Equation 26

6.1.1.2 Chronic dermal exposure

$$C_{textile,safe} = \frac{I_{dermal,chronic} \cdot BW \cdot 100 \cdot 100 \cdot 1000}{A_{dermal} \cdot SW_{textile} \cdot MOS \cdot F_M \cdot F_A \cdot N_{event}}$$ Equation 27



6.1.1.3 Parameters

Parameter	Unit	Description
$I_{dermal,acute}$	mg/(kg bw)	Acute toxic value (LD50 value)
$I_{dermal,chronic}$	mg/(kg BW·day)	Chronic daily value (NOAEL or results from acknowledged risk assessment studies*)
$C_{textile,safe}$	mg/kg	Safe concentration of substance on textile
$SW_{textile}$	g/m²	Specific textile weight
MOS	-	Margin of safety
A_{dermal}	m²	Exposed skin area
F_M	%	Migration portion out of textile
F_A	%	Fraction absorbed, dermal
BW	kg	Body weight
N_{event}	1/day	Number of events per day

Table 19: Parameters for dermal exposure calculation

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

6.1.2 Oral exposure

All parameters used to calculate the scenario for dermal exposure are listed and explained in section 6.1.2.3. The factors 100 (percent -> fraction) and 1000 (g/mg) are used for unit correction.

6.1.2.1 Oral exposure, swallowing

$$C_{textile,safe} = \frac{I_{oral\ (swallowing)} \cdot BW \cdot 100 \cdot 1000}{F_{oral} \cdot Q_{oral} \cdot MOS \cdot N_{event}}$$ Equation 28

with

$$Q_{oral} = A_{textile} \cdot SW_{textile}$$ Equation 29

6.1.2.2 Oral exposure, mouthing

$$C_{textile,safe} = \frac{I_{oral\ (mouthing)} \cdot BW \cdot 100 \cdot 100 \cdot 1000}{F_{oral} \cdot Q_{oral} \cdot F_M \cdot MOS \cdot N_{event}}$$ Equation 30

6.1.2.3 Parameters

Parameter	Unit	Description
$I_{oral(swallowing)}$	mg/(kg bw·day)	Recommended daily intake (swallowing) from acknowledged risk assessment studies or NOAEL*
$I_{oral(mouthing)}$	mg/(kg bw·day)	Recommended daily intake (mouthing) from acknowledged risk assessment studies or NOAEL*
$C_{textile,safe}$	mg/kg	Safe concentration of substance on textile
MOS	-	Margin of safety
F_{oral}	%	Fraction absorbed
F_M	%	Migration portion
Q_{oral}	g	Weight of exposed textile
BW	kg	Body weight
N_{event}	1/day	Number of events per day

Table 20: Parameters for oral exposure calculation

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

6.1.3 Inhalative exposure

All parameters used to calculate the scenario for inhalative exposure are listed and explained in section 6.1.3.3. The factor 100 (percent -> fraction) is used for unit correction.

6.1.3.1 Acute inhalative exposure

$$C_{textile,safe} = \frac{C_{inh} \cdot V_{room} \cdot E_{air} \cdot t_{contact} \cdot \frac{100}{F_{inh}} \cdot \frac{100}{E_{eff}}}{(1 - (e^{(-1 \cdot (0.69312 \cdot HLT^{-1}) \cdot T_{contact})})) \cdot Q_{textile}}$$

Equation 31

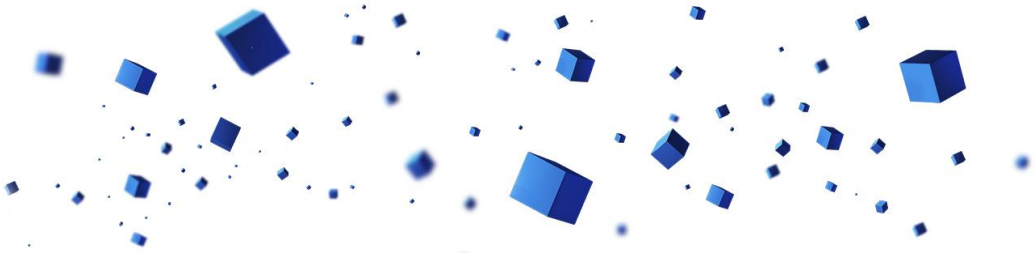
6.1.3.2 Chronic inhalative exposure

$$C_{inh} = \frac{I_{inh}}{MOS} \cdot \frac{BW}{Q_{inh} \cdot t_{contact}} \cdot \frac{100}{F_{inh}}$$

Equation 32

$$C_{textile,safe} = \frac{C_{inh} \cdot V_{room} \cdot E_{air} \cdot t_{exposure}}{Q_{textile}} \cdot \frac{100}{E_{eff}} \cdot \frac{24h}{t_{daily\ exposure}}$$

Equation 33



6.1.3.3 Parameters

Parameter	Unit	Description
C_{inh}	mg/m³	Concentration of substance in air
$Q_{textile}$	kg	Amount of textile
$C_{textile,safe}$	mg/kg	Safe concentration of substance on textile
MOS	-	Margin of safety
V_{room}	m³	Volume of room
E_{air}	1/h	Air exchange rate
$t_{contact}$	h	Contact time
BW	kg	Body weight
F_{inh}	%	Absorption of the inhaled air
E_{eff}	%	Emission efficiency
HLT	h	Half-life time
I_{inh}	mg/(kg BW·day)	Daily intake value (NOAEL or results from acknowledged risk assessment studies)
Q_{inh}	m³/h	Inhalation rate
$t_{exposure}$	h	Chronic time exposure
$t_{daily\ exposure}$	h	Daily time exposure

Table 21: Parameters for inhalative exposure calculation

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

6.1.4 Default values for consumer safety calculations

Parameter	Unit	Description	Default values
$SW_{textile}$	g/m²	Specific textile weight	Baby: 300 g/m² Class A (next to skin): 300 g/m² Class B (occasional skin contact): 300 g/m² Class C (no skin contact): 500 g/m²
MOS	-	Margin of safety	1 (for risk assessment values) 1000 (when NOAEL value used)
A_{dermal}	m²	Exposed skin area	Baby: 0.5 m² Class A: 1.5 m² Class B: 1.5 m² Class C: 1.0 m²
F_M	%	Migration portion out of textile	Dermal, acute: 100 % Dermal, chronic, sweat management: 5 % Dermal, chronic, hydrophilic agents: 10 % Mouthing: 10 %

Parameter	Unit	Description	Default values
F_A	%	Fraction absorbed, dermal	Dermal: 100 % (worst-case)
F_{oral}	%	Fraction absorbed, oral	Oral: 100 % (worst-case)
F_{inh}	%	Absorption of the inhaled air	Inhalation: 100 % (worst-case)
BW	kg	Body weight	Baby: 3 kg Adult: 60 kg
$A_{textile}$	m^2	Area of textile (swallowing, mouthing)	Baby, swallowing: 0.001 m^2 Baby, mouthing: 0.0025 m^2 Adult, swallowing: 0.01 m^2 Adult, mouthing: 0.04 m^2
Q_{oral}	g	Weight of exposed textile	Baby, swallowing: 0.3 g Baby, mouthing: 0.75 g Adult, swallowing: 3 g Adult, mouthing: 12 g
E_{air}	1/h	Air exchange rate	Normal use: 0.5/h Tent: 1/h Baby buggy: 1.5/h
E_{eff}	%	Emission efficiency	100 % (worst-case) 50 % (outside baby buggy)
N_{event}	1/day	Number of events per day	1
Q_{inh}	m^3/h	Inhalation rate	Adult: 0.83 m3/h Child: 0.42 m3/h Baby: 0.19 m3/h
$t_{exposure}$	h	Chronic time exposure	90 days = 2160 h
$t_{daily\ exposure}$	h	Daily time exposure	24 h

Table 22: Default values for consumer safety calculations

6.2 BSBL limits

Threshold limits for chemical substances in finished chemical products such as auxiliaries or dyes are determined by considering several aspects, including back calculation from consumer safety limits, legal restrictions, available data on toxicological and ecotoxicological endpoints (see also introduction in chapter 6) and GHS classifications.

6.3 Stakeholder involvement

Changes regarding the selection of priority substances and substance limits are discussed during the annual Chemical Expert Group meeting with participation of product stewardship experts from chemical suppliers, associations, authorities, laboratories, brands and manufacturers to clarify feasibility as well as technical and analytical details.

7 Data Sources

Assessment of chemicals is based on the best available data. The following sources (list not exhaustive) are taken into consideration when identifying the substances of concern:

- National/international consumer safety regulation
- National/international regulations on environmental protection and occupational health
- Voluntary agreements within the chemical and textile industry
- Substances of concern listed in the 'Restricted Substances Lists (RSLs)' and 'Manufacturing Restricted Substances Lists (MRSLs)' of various retailers and brands
- Web tools/search engines

The following table summarizes the most important references.

Name	Source/Authors	Web link
International		
SIDS Initial Assessment Report	Organization for Economic Co-operation and Development (OECD)	https://hpvchemicals.oecd.org/ui/Search.aspx
INCHEM database	WHO, International Program on Chemical Safety (IPCS)	https://inchem.org/#/
IARC Monographs (WHO)	International Agency for Research on Cancer (IARC)	https://monographs.iarc.who.int/agents-classified-by-the-iarc/
International Chemical Safety Cards (ICSC)	International Labour Organization (ILO)	www.ilo.org/dyn/icsc/showcard.home
OSPAR Publications	OSPAR Commission	https://www.ospar.org/work-areas/hasec/hazardous-substances
Endocrine Disruptor List	Danish Environmental Protection Agency on behalf of some European Authorities	https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu
State of the Science of Endocrine Disrupting Chemicals – 2012	WHO/UNEP	https://apps.who.int/iris/rest/bitstreams/1104667/retrieve
ECHA - Information on Chemicals	European Chemical Agency (ECHA)	https://echa.europa.eu/en/information-on-chemicals
ECHA – C&L Inventory	European Chemical Agency (ECHA)	https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database
REACH – Registered Substances Factsheets (Dossiers)	European Chemical Agency (ECHA)	https://echa.europa.eu/de/information-on-chemicals/registered-substances
SVHC (substances of very high concern) candidate list	European Chemical Agency (ECHA)	https://echa.europa.eu/en/candidate-list-table
PBT assessment list	European Chemical Agency (ECHA)	https://echa.europa.eu/de/pbt
European Union Risk Assessment Reports	European Chemical Agency (ECHA)	https://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation
Priority Endocrine Disruptors	European Commission	https://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm#priority_list

Name	Source/Authors	Web link
Germany		
Publications of the commission of DFG for the Investigation of Health Hazards of Chemical Compounds in the Work Area	German Research Foundation (DFG)	https://www.dfg.de/en/dfg_profile/statutory_bodies/senate/health_hazards/results/index.html
UBA publications	German Environment Agency (UBA)	https://www.umweltbundesamt.de/en
BfR publications	German Federal Institute for Risk Assessment (BfR)	www.bfr.bund.de/en/publications.html
GESTIS Database on Hazardous Substances	Institute for Work Safety (IFA)	https://gestis.dguv.de/search
TRGS 900 (Occupational Exposure Limits)	Federal Institute for Occupational Safety and Health (BAuA)	https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-900.html
TRGS 910 (Occupational Exposure Limits)	Federal Institute for Occupational Safety and Health (BAuA)	https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/TRGS-910.html
TRGS 905 (list of CMR substances)	Federal Institute for Occupational Safety and Health (BAuA)	https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-905.html
Chemsafe database	Federal Institute for Materials Research and Testing - Society for Chemical Technology and Biotechnology e.V.	https://www.chemsafe.ptb.de/
United States of America		
EPA Laws and Regulations	United States Environmental Protection Agency (US EPA)	https://www.epa.gov/laws-regulations
NIOSH Information on Chemicals	The National Institute for Occupational Safety and Health (NIOSH)	www.cdc.gov/niosh/topics/chemical.html
NIOSH Potential Occupational Carcinogens	The National Institute for Occupational Safety and Health (NIOSH)	https://www.cdc.gov/niosh/topics/cancer/npotocca.html
OSHA Regulations	United States Department of Labor Occupational Safety & Health Administration	www.osha.gov
OSHA - Permissible Exposure Limits	United States Department of Labor Occupational Safety & Health Administration	https://www.osha.gov/annotated-pels
Proposition 65 List	State of California Environmental Protection Agency (EPA)	https://oehha.ca.gov/proposition-65/proposition-65-list
OEHHA Toxicity Criteria Database	California Office of Environmental Health Hazard Assessment (OEHHA)	https://oehha.ca.gov/chemicals
Integrated Risk Information System (IRIS)	United States Environmental Protection Agency (EPA)	www.epa.gov/iris/
IRIS Assessments	United States Environmental Protection Agency (EPA)	https://iris.epa.gov/AtoZ/?list_type=alpha
IRIS Advances Search Database	United States Environmental Protection Agency (EPA)	https://cfpub.epa.gov/ncea/iris/search/index.cfm?keyword=
PubChem	United States National Institutes of Health - National Library of Medicine	https://pubchem.ncbi.nlm.nih.gov/
ChemIDplus	United States National Institutes of Health - National Library of Medicine	https://chem.nlm.nih.gov/chemidplus/

Name	Source/Authors	Web link
NIH Monographs	United States National Institutes of Health	https://ntp.niehs.nih.gov/publications/monographs/index.html
Toxics Release Inventory (TRI) Program	United States Environmental Protection Agency (EPA)	https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri
China		
GBZ 2.1 - Occupational exposure limits for hazardous agents in the workplace	National Health Commission (NHC)	https://www.chinesestandard.net/PDF/English.aspx/GBZ2.1-2019
Japan		
GHS Classification Result by the Japanese Government	National Institute of Technology and Evaluation (NITE)	https://www.nite.go.jp/chem/english/ghs/ghs_download.html
Other sources		
ETAD Regulations and Recommendations	The Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD)	www.etad.com/index.php
CESIO RECOMMENDATIONS for the harmonized classification and labelling of surfactants	CESIO Association (the European Committee of Organic Surfactants and their Intermediates)	https://www.cesio.eu/index.php/policy-legislation/classification-labelling
ZDHC MRSL	ZDHC Foundation	https://mrsl.roadmaptozero.com/
AFIRM Restricted Substances List	Apparel and Footwear International RSL Management (AFIRM) Working Group	https://afirm-group.com/afirm-rsl/

Table 23: Data sources

8 Validity

This document comes into effect 2022-11. It replaces the bluesign® CRITERIA for chemical assessment version 2.0. For all companies that signed an agreement for an assessment or for a bluesign® SYSTEM PARTNERSHIP before 2022-11, the amended and newly introduced requirements are binding with immediate effect for new chemical products. For chemical product that were registered before November 2022 transition periods apply. This document is subject to revisions. Details on the revision procedure for regular and unscheduled revisions are compiled in the bluesign® SYSTEM document.

9 Other Appliable Documents

Direct annexes to this document:

- *ANNEX: Biocidal products and antimicrobial active substances*
- *ANNEX: Nanoscale materials/structures*
- *ANNEX: Flame retardants*
- *ANNEX: GHS rating matrix*
- *ANNEX: Exceptions*

Other important documents:

- *bluesign® SYSTEM*
- *bluesign® glossary*
- *bluesign® SYSTEM BLACK LIMITS (BSBL)*
- *bluesign® SYSTEM SUBSTANCES LIST (BSSL) - Consumer safety limits*
- *bluesign® CRITERIA for production sites*
- *Guideline 'Product Stewardship for Chemical Suppliers'*
- *Guidance Sheet 'Input stream management commodity/basic chemicals in textile production'*
- *Guidance Sheet 'Generation of Data for the bluesign® TOOL*

Current versions are available for download at www.bluesign.com/criteria.

Disclaimer

This document is a publication of bluesign technologies ag. It compiles requirements and guidelines for bluesign® SYSTEM PARTNERS on a particular subject or subjects and may not be an exhaustive treatment of such subject(s). Contents are not intended as a statement of legal requirements or as legal advice. This document is provided 'as is'. bluesign technologies ag expressly disclaims all implied warranties including, without limitation, warranties of merchantability, title, fitness for a particular purpose, non-infringement, security and accuracy.