

# bluesign® criteria for chemical assessment

## Annex: Biocidal products and antimicrobial active substances

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## 1 Preliminary remarks

Biocidal products used for manufacturing of bluesign® approved articles must be manufactured by a bluesign® system partner. However, when possible the use of antimicrobial active substances and biocidal products should be avoided or at least minimized. If a customer or a consumer requires an antimicrobial or a biocidal function of the fabric the appropriate product shall be used in a responsible and sustainable manner.

The provisions on biocidal products and antimicrobial active substances shall be regularly reviewed in the light of the scientific and regulatory progress.

## 2 Definitions

### 2.1 Biocidal product

Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by chemical or biological means (see *Biocidal Products Regulation, BPR, Regulation EU 528/2012*). In textile manufacturing biocidal products are mostly used to protect against ticks, carpet beetles, moths, bed bugs, house dust mites, mosquitoes, etc.

### 2.2 Antimicrobial active substance

Any substance used to destroy or suppress the growth of micro-organisms (bacteria, viruses or fungi) on inanimate objects and surfaces. In textile manufacturing, antimicrobial active substances are mostly used to control growth of odor causing bacteria.

## 3 Reporting

It is a duty of a manufacturer of a product intended for the bluesign® registration to report the required data in a compact risk assessment to bluesign technologies. The required data have to be made available as the additional information to the Product Screening Form or to the online homologation form. The data shall be submitted to bluesign technologies in a printed or electronic format (PDF).

It is strongly recommended to attach original test reports wherever possible.

The risk assessment is peer-reviewed by bluesign technologies. If the evaluation of the data leads to the conclusion that the product is compliant with the bluesign® criteria, the product can be registered in the bluesign® bluefinder. The peer-review is submitted to the manufacturer of the product.

## 4 Risk assessment

The manufacturer of a biocidal product or an antimicrobial active substance that is intended for registration as “bluesign® approved” shall submit to bluesign technologies a compact risk assessment with the following information:

- Description of the substance/mixture and its application
- Life-cycle hazard profile
- Life-cycle exposure profile (human, environment)
- Risk evaluation (workplace, consumer, environment)
- Risk management (workplace, consumer, environment)

Unless stated otherwise, the risk assessment must include at least the data described in Chapter 5.

**Note 1:** Due to nondisclosure aspects, bluesign technologies may accept (on a case by case basis) that some of the required data are not reported or are reported only in an indirect way.

**Note 2:** If not stated otherwise, information shall be given for the complete mixture or the active substance(s). In each case the information shall be consistent and it must be clear whether a mixture or an active substance(s) is/are addressed.

**Note 3:** Only those biocidal products that show compliance with the BPR and associated documents are allowed under the bluesign® system.

## 5 Required data

### 5.1 Product information

- Trade name
- Manufacturer
- Regulatory compliance (notification and registration of the product)
- Claims (biological effect(s), type of substrate(s), type of final article(s))
- Material Safety Data Sheet (GHS Standard)
- Technical Data Sheet

### 5.2 EHS-data

#### 5.2.1 Composition

- Active substance(s)
  - Common name(s)
  - IUPAC name
  - CAS number
  - % w/w
- Other substance(s)
  - Common name(s)
  - IUPAC name
  - CAS number
  - % w/w

Information on active substance(s) and substances, that are restricted and banned under the bluesign® system, is mandatory. Information on other substances in the product is strongly recommended. In cases where the active substance is incorporated in a special matrix (for example zeolithes, gels, capsules, cyclodextrines etc.), a description of the matrix shall be given with special attention to consumer safety issues.

#### 5.2.2 Chemical and physical data

- Appearance
- Melting point
- Boiling point
- Solubility in water
- Density
- pH-value
- Flashpoint
- Ionogenicity
- Potentially dangerous chemical reactivity
- Stability (chemical and physical)

#### 5.2.3 Toxicological data

Note: Bold letters mean mandatory data.

- Toxicity
  - Acute oral LD50 (OECD 423)**
  - Acute dermal LD50 (OECD 402)**
  - Mutagenicity (OECD 471), Ames test (can be replaced by other mutagenicity test methods)**
  - Chromosome aberration (OECD 473)
  - Cancerogenicity (strongly recommended for the active substances)
- Skin tolerance
  - Sensitization (OECD 406) or Local Lymph Node Assay (OECD 429)**
  - Irritation (OECD 404)**
  - Acute eye irritation (OECD 405); mandatory if OECD 404 negative**
  - Cytotox (EN ISO 10993-5)
  - Human repeated patch test or closed single patch test (strongly recommended)
  - Other scientifically proven test methods
- Ecotoxicity
  - Daphnia (OECD 202)**
  - Fish (OECD 203)**
  - Bacteria (OECD 209)**

- Algae (OECD 201)**
- Biodegradability**
- Preferably OECD 302 B; also possible OECD 301 A–F, 303A, 310**
- AOX content**
- BOD5 (Biological Oxygen Demand)**
- COD (Chemical Oxygen Demand) or TOC (Total Organic Carbon)**
- Air Emission Parameters
- Water Hazard Classification

- Exposure to consumer

Information on measured or calculated exposure of the consumer to a product or an active substance (e.g. release rate from textile, penetration rate to human skin) shall be delivered. If possible a comparison with a scientifically acknowledged ADI-value (Acceptable Daily Intake) should be performed.

### 5.3 Confirmation of the antimicrobial/biocidal effect

The claimed biological effect has to be determined and demonstrated on all relevant substrates and on their claimed properties (e.g. after a certain number of wash cycles) by the appropriate test methods.

The examples of the relevant test methods are listed below. Please note that many standards have equivalents that are normally also accepted.

#### 5.3.1 Antibacterial efficacy

- Count test JIS L 1902:2002 or its equivalent ISO EN DIN 20743
- Count test ASTM E 21-49 (shake flask test)
- AATCC 147 (Antibacterial Activity Assessment of Textile Materials), Parallel Streak Method
- SN 195 920 (agar diffusion test)

Tests have to be carried out against the relevant test bacteria (mostly given in the method). The bacteria's spectra in the compound should be known. Examples of relevant bacteria are:

- Staphylococcus aureus ATCC 6538
- Klebsiella pneumoniae ATCC 4352
- Escherichia coli ATCC 11229
- Pseudomonas aeruginosa ATCC 15442

#### 5.3.2 Antimycotic efficacy (fungi, mould and mildew)

- SN 195 921 (agar diffusion plate test)
- AATCC 30 (agar diffusion plate test)
- ASTM G 21-96 (resistance to mould - fungi)
- EN ISO 11721-1 (Determination of resistance of cellulose-containing textiles to micro-organism)
- BS 6085, Section 5 (saturated atmosphere test)

Tests have to be carried out against the relevant test fungi (mostly given in the method). The fungi's spectra in the compound should be known. Examples of relevant fungi are:

- Aspergillus niger ATCC 6275 (mould causing black marks)
- Penicillium funiculosum EMPA 112 (mould)
- Trichophyton mentagrophytes EMPA 334 (athlete's foot)
- Candida albicans ATCC 10231 (yeast)

#### 5.3.3 House dust mites

- AFNOR NF G 39-011

#### 5.3.4 Other organisms

Ticks, carpet beetles, moths, bed bugs, mosquitoes and other organism have to be tested under an internationally accepted quality control standard.

#### 5.3.5 Fastness properties

To avoid release of an active substance during use, fastness properties must be at a high level. Values for wash and light fastness as well as values for the release resistance to dry cleaning must be reported to bluesign technologies.

Claimed release resistance has to be tested and, if possible, analyzed on all relevant substrates separately under defined standardized conditions. Substrate, recipe and application process, load test methods and efficacy test methods and results have to be disclosed to bluesign technologies.

Examples of resistance tests:

- Shrinkage and appearance test EN ISO 6330 (Textiles - Domestic Washing and Drying Procedures for Textile Testing)
- Leaching tests e.g. with synthetically made sweat (or urine)
- Light or UV-stability
- Dry cleaning resistance
- Foam cleaning resistance

#### 5.3.6 Application

The manufacturer of an antimicrobial active substance or a biocidal product is obliged to inform the textile finisher in a detailed document on the appropriate application technique (pick-up, liquor ratio, temperature, drying/fixation conditions, textile substrates, etc.) and on the appropriate risk management.

#### 5.3.7 Disposal of residual liquors and/or exhausted baths

The manufacturer of an antimicrobial active substance or a biocidal product is obliged to inform the textile finisher in a detailed document on the appropriate method to dispose the residual liquors and/or exhausted baths.

## 6 Downstream user

The downstream user (as for example a textile finishing plant) must use an antimicrobial active substance or a biocidal product in a responsible way. Emissions to the wastewater and off-gas have to be avoided or at least minimized. Regarding the emissions to the water path, PEC/PNEC calculations have to be performed prior use.

Occupational health aspects are of importance. All employees that are in contact with the antimicrobial active substances or biocidal products have to be periodically educated concerning the handling of these chemicals; an appropriate personal protective equipment must be available (safety gloves, safety glasses etc.).

## 7 Labeling

Those textiles that are labeled with the bluesign® trademark and that are finished with an antimicrobial active substance or a biocidal product, must include the information confirming that the textile is finished with an antimicrobial substance or a biocidal product.

## 8 Standards for the involved laboratories

The tests that are necessary to verify compliance with the bluesign® system have to be carried out by third party-certified laboratories (DIN EN ISO 17025 or a comparable certification). If a certificate from a third party is not given, the manufacturer of the substance has to report to bluesign technologies that an adequate quality assurance system is established (round robin test, quality management documentation etc.).

## 9 Validity

This document comes into effect from April 01, 2014. It replaces the *bluesign® criteria for biocidal products and antimicrobial active compounds*, edition 1.3 from March 2010.

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

## 10 Other applicable documents

- bluesign® system (effective version)
- bluesign® system substances list (effective version)
- bluesign® criteria for chemical assessment (homologation) (effective version)
- bluesign® criteria for bluesign® approved chemical products and articles for industrial use (effective version)