bluesign® criteria for chemical assessment

Annex: Nanoscale materials/structures

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Content

1 Preliminary remarks

It is well known, that there can be a general relationship between toxicity and particle size. The smaller a particle, the greater the surface area compared to its volume and the higher its chemical reactivity and biological activity. Nanoparticles can be more readily inhaled and ingested and are more likely than larger particles to penetrate the human skin. Nanoparticles may be able to cross cell membranes or the blood brain barrier.
Therefore, in comparison to conventional textile materials and processes, nanoscale materials may imply a significantly higher risk for humans and the environment.
These potential additional risks require special criteria that are defined by the bluesign® system.

The most important issues concerning nanoscale materials are:

- workplace atmosphere (manufacturing and downstream use)
- off-gas emissions (manufacturing and downstream use)
- wastewater emissions (manufacturing and downstream use)
- consumer safety (release of nanoscale materials during use; inhalative, dermal and oral exposure)
- end of use (release of nanoscale materials during incineration, landfill, recycling, etc.)

Nanoscale materials used for manufacturing of bluesign® approved articles must be manufactured by a bluesign® system partner. However, when possible the use of nanoscale materials should be avoided or minimized.
If a customer or a consumer requires a nanoscale material, the appropriate product shall be used in a responsible and sustainable manner. Only products with a scientifically proven effect and minimized adverse reactions shall be used. The provisions on the nanoscale materials shall be regularly reviewed in the light of the scientific and regulatory progress.

2 Definitions

2.1 Nanoscale

A word used to describe materials/structures in the range of 100 nm and lower.

"Nano" in the context of this document is defined as an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

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 nanoscale material that is intended for registration as "bluesign® approved" shall submit to bluesign technologies a compact risk assessment with the following information:

- Description of the nanoscale material 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 the 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.

5 Required data

5.1 Product information

- Trade name
- Manufacturer
- Regulatory compliance (notification and registration of the product)
- Claims (effect(s), type of substrate(s), type of final article(s), what is claimed as 'nanoscale' – particle size, fiber length, nanoscale film thickness, etc.)
- Material Safety Data Sheet (GHS Standard)
- Technical Data Sheet

5.2 EHS-data

5.2.1 Composition

- Nanoscale material
  - ☐ Common name(s)
  - ☐ IUPAC name
  - ☐ CAS number
  - ☐ % w/w
- Other substance(s)
  - ☐ Common name(s)
  - ☐ IUPAC name
  - ☐ CAS number
  - ☐ % w/w

Information on the nanoscale materials and substances, that are restricted and banned according to the bluesign® system, is mandatory. Information on other substances in the product is strongly recommended. In cases where the nanoscale material is incorporated in a special matrix or coated on substrates etc., a description of the material's construction shall be given with special attention to consumer safety issues.

5.2.2 Chemical and physical data

- Appearance (particle size, fibre length etc.)
- Data on nanoscale structure
- Melting point
- Boiling point
- Solubility in water
- Density
- pH-value
- Flashpoint
- Ionogenity
- 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)
  - Cancerogenity (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 is 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 claimed effect

The claimed effect (e.g. soil release or water repellency) 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.

5.3.1 Fastness properties

To avoid release of nanoscale materials 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 separately on all relevant substrates 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

5.3.2 Application

The manufacturer of a nanoscale material 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.

6 Downstream user

The downstream user (as for example a textile finishing plant) must use the nanoscale materials in a responsible way. Emissions to the wastewater and off-gas have to be avoided or minimized. Regarding the emissions to the water path, PEC/PNEC calculations have to be performed before use.
Occupational health aspects are of importance. All employees that are in contact with the nanoscale materials have to be periodically educated concerning the handling of these chemicals; appropriate personal protective equipment must be available (safety gloves, safety glasses etc.).
The risk management determined by the manufacturer of the nanoscale material shall be implemented (to be checked during on-site inspection by bluesign technologies).

6.1 Measured data

If a significant potential risk of the nanoscale material according to the risk assessment of the manufacturer exists or if scientifically proven concerns from third parties arise, the following data have to be reported:

- Measured values for the workplace atmosphere
- Measured values for the off-gas
- Measured values for the wastewater emissions (if relevant)

bluesign technologies reserves the right to perform measurements concerning workplace atmosphere and air emission and to take samples in the wastewater stream(s) at those production sites where nanoscale materials are processed.

7 Labeling

Those textiles that are certified with the bluesign® label and that are finished with nanoscale materials/structures, must include the information confirming that the textile is finished with the nanoscale material/structure.

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 nanoscale materials/structures,* edition 1.2 from March 2010.

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

10 Other applicable documents

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