

Suggested Criteria and Ranking Procedure of Nanoproducts

Volume III „Bioni Hygienic“

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08/2012

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Ranking of Nanoproducts

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Introduction

In order to analyze and evaluate nanoproducts we propose a combination-method consisting of product description according to selected criteria and additional ranking in numbers between 1 and 3
[1 (poor degree of fulfillment), 2 (medium), 3 (high)].

Main topics, index

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0 Classification, basic information

Country	Prod.-No.	Product-Name	Manufacturer / Contact-Person
Germany	3	Bioni Hygienic®	Address Bioni CS GmbH, Lessingstr. 21, 46149 Oberhausen, Mr. Sven Knoll Phone 0049 (0)208 621 7553 Mail info@bioni.de

Short description of product-type and basic features

Dispersion paint for **interior use** with **strong antimicrobial additional functionality based on nano-silver**.

Application areas: hospitals, food-industry, etc..

Excellent moisture regulating properties, water repellent,
Permeable to water vapour.

Superior heat reflection properties „Cool Paint“.

Fire rating: Class A (ASTM E84) 0 (0-25) flame spread, 5 (0-450) smoke development.

Superior adhesion, crack-bridging abilities.

Sustainable, reduces frequency of repaints.

Exceeds requirements indoor air quality (IAQ) regulations (VOC-content < 5 g/l)

Odor-free - can be applied in occupied areas

Free of conventional biocides, solvents, softeners,
Environmental friendly, LEED (USGPC).

Main difference to Bioni Perform® is a nano-suspension content of 6 %.



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1 Is it a real nano-product?

1.1 Criterion: Particle size data of basic material available, diameter below 100 nm

Particle size of basic material was analyzed by X-Ray Diffraction and is around 10 nm. Particle size distribution of nano suspension was analyzed by PCS [Photon Correlation Spectroscopy] (12.1 [nm]). In the product a combination of SEM [Scanning Electron Microscopy] and EDX [Energy Dispersive X-Ray Spectroscopy] was used to obtain simultaneously information about morphology and chemistry.

Evaluation: 3

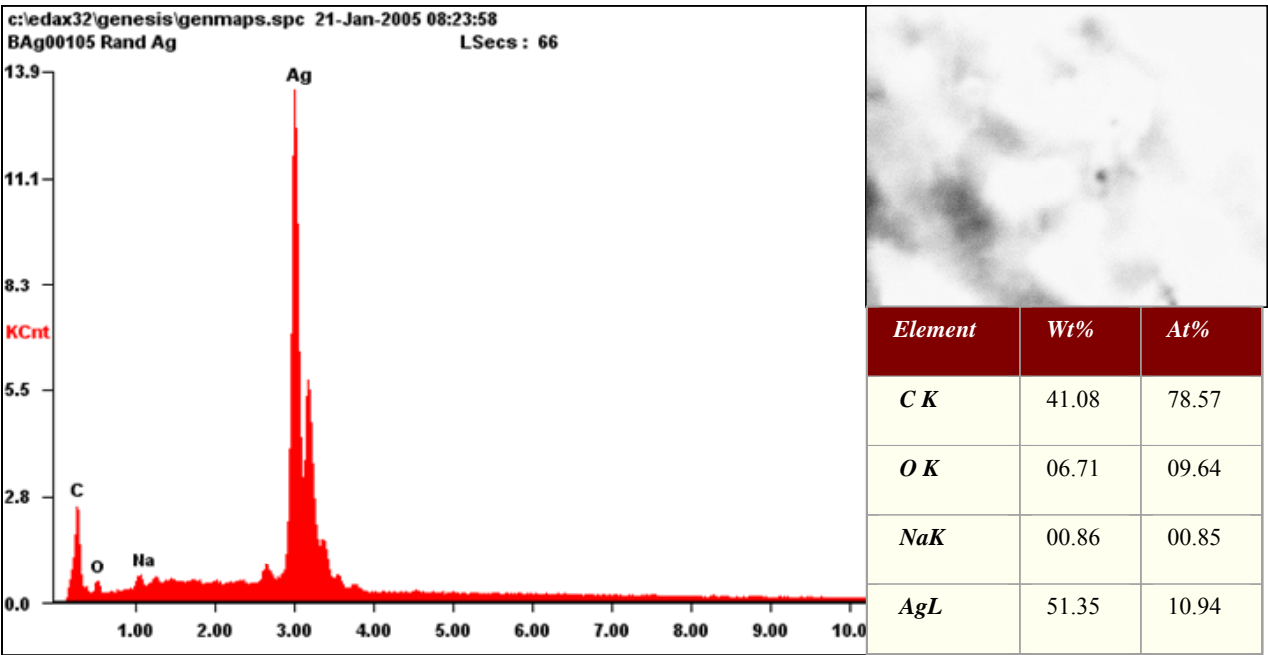


Figure 4.1: Combination of SEM and EDX to check simultaneously morphology and chemistry in the final product. So it could be demonstrated, that there are also nanoparticles on product level.

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1.2 Criterion: Effect dominated by particle size

Particle size domination can be concluded from mass-specific antimicrobial efficiency.

Evaluation: 3

1.3 Criterion: Stabilization concept applied

Calculation of surface potential u according Poisson-Boltzmann-Equation (1) leads to an effective selection of chemical stabilizers.

Evaluation: 3

$$\nabla^2 U(\eta, \theta) = \frac{(\cosh \eta - \cos \theta)^2}{B^2} \cdot \frac{\partial^2 U}{\partial \eta^2} + \frac{(\cosh \eta - \cos \theta)^2}{B^2} \cdot \frac{\partial^2 U}{\partial \theta^2} - \frac{\sinh \eta \cdot (\cos \eta - \cos \theta)}{B^2} \cdot \frac{\partial U}{\partial \eta} + \left(\frac{(\cosh \eta - \cos \theta)^2}{\tan \theta} - (\cosh \eta - \cos \theta) \cdot \sin \theta \right) \cdot \frac{1}{B^2} \cdot \frac{\partial U}{\partial \theta} = \sinh(U(\eta, \theta)) \quad (1)$$

U: Reduced Electrostatic Potential, B: Constant in Bispheric System of Coordinates

1.4 Criterion: Nano system integration solved and analytically proved

Homogeneity and stability obtained and proved by SEM / X-Ray Fluorescence.

Evaluation: 3

1.5 Criterion: Consistency of product philosophy

The recipe is based on non-human-toxic substances. Conventional biocides can be completely replaced.

Evaluation: 3

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2 Product benefits

2.1 Criterion: Invention step compared to state of the art

High invention step compared to conventional biocides related to effectiveness, sustainability and replacement of toxic components.

State of the art is the use of predominantly 6 types of biocides:

- Carbamates
- Isothiazolinones
- Triazines
- Phenylureas
- Metalorganics
- Quartary alkyl-ammonium salts

These components are of organic nature with lower chemical stability. Furthermore human-toxicity is problematic.

Nano-silver as an inorganic element is stable and not human-toxic considering dose and working principle in the sense of a surface interaction.

Evaluation: 3

2.2 Criterion: Patent protection

Patent protection obtained (PCT/EP2006/065581, DE10 2005 041 006.5-43 and PCT/EP for AE, CA, US, RU).

Evaluation: 3

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2.3 Criterion: Efficiency of effect related to mass ratio

High antimicrobial efficiency because of synergetic effects where the nano-silver mass ratio could be reduced to the order of 10 ppm.

Evaluation: 3

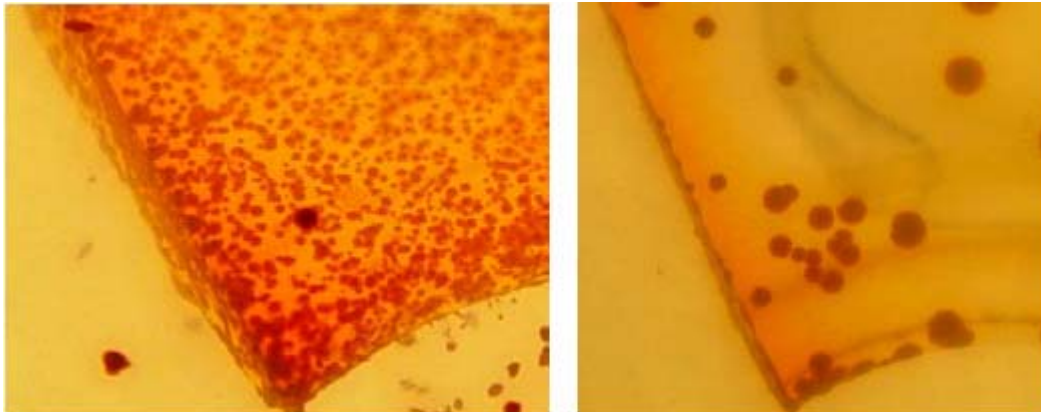


Figure 7.1: Example of the effect of nano silver concept against the dangerous multi-resistant hospital germ Staphylococcus Aureus (MRSA). Left picture: Untreated sample. Right picture: Treated sample where MRSA (red areas) is suppressed.

In Bioni Hygienic a nano silver content was chosen, which guaranties a germ reduction rate of 99,999 % (5-log).

At the same time numerous mechanisms of action reduce the risk of resistancy formation.

2.4 Criterion: Sustainability of effect

Working principle of antimicrobial effect via surface reaction in the sense of catalysis; no drug-release.

Evaluation: 3

2.5 Criterion: Limitations / possible negative side effects

Under adverse conditions surface reactions could be impeded by secondary pollution effects.

Evaluation: 2

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3 Market potential

3.1 Criterion: Cost-benefit ratio

Excellent cost-benefit ratio specifically considering sustainability and reduction of repaint frequency.

Evaluation: 3

3.2 Criterion: Nice to have – or problem- solver

Problem solver.

Evaluation: 3

3.3 Criterion: Range of applications

Interior application in hospitals etc..

Evaluation: 2

3.4 Criterion: Market volume compared to market saturation

Large market volume compared to saturation.

Evaluation: 3

3.5 Criterion: Competitive situation

Indirect competitive situation with paints containing conventional biocides; risk of product piracy. However, this particular market segment is still not targeted by competitors.

Evaluation: 3

3.6 Criterion: Import / export restrictions

No restrictions so far, but to be expected in future in some foreign countries, e.g. US.

Evaluation: 2

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3.7 Criterion: Existence and quality of distribution network

Sophisticated national and international distribution network.

Evaluation: 3

3.8 Criterion:

Information / consulting according product complexity

Product consulting available.

Evaluation: 3

3.9 Criterion: Warranty, service

Mandatory warranty and sophisticated service worldwide.

Evaluation: 3

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4 Product safety

4.1 Definition and risk assessment of nanomaterials in the REACH context (max. 3 products)

(assignment to work package 4.2.1)

4.1.1 Criterion: Specific toxicological analysis of the nanomaterial(s) used in the product according to safety data sheet

No toxicological impacts indicated (and to be indicated) in product data sheet. Nano-silver is a trace constituent in a order of magnitude of 10 ppm. Nano-silver is combined with a polymer binder phase and anchored via dipole interactions.

Evaluation: 3

4.1.2 Criterion: Estimation of REACH compliance

Reach conformity ensured by component suppliers.

Evaluation: 3

4.1.3 Criterion: Estimation of basic health hazards

Provided the ordinary use of the product, health hazards are very unlikely. Potential risks during product life-cycle are indicated in 4.2 ff.

Evaluation: 3

4.1.4 Criterion: Estimation of basic environmental hazards

Provided the ordinary use of the product, environmental hazards are very unlikely.

Potential risks during product life-cycle are indicated in 4.2 ff.

Evaluation: 3

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4 Product safety

4.2 Elaboration of specific exposure scenarios (max. 3 nanomaterials) (assignment to work package 4.2.2)

4.2.1 Criterion: Exposure scenarios related to people according product application

During ordinary product application the release of single nano-silver particles is impossible because of chemisorption (dipole interaction) with polymer binder phase. Furthermore surface energy prohibits ablation.

The theoretical case of the direct interaction of nano-silver powder with skin can be answered by results of EU-project „NANODERM“ (IC: QLK4-CT-2002-02678). Skin penetration is very unlikely for - not only size - but surface charge matters.

Evaluation: 3

4.2.2 Criterion: Exposure scenarios related to the environment

Estimation of basic toxicity of silver and further references are given in: Daunerer, Handbuch der Umweltgifte, 6/2006, 1 ff. Release of nano-silver out of products is matter of several studies (see table in chapter 6.3).

To investigate exposure scenarios product samples were mechanically stressed. As a result of trace analysis with ICP-MS (iCAP 6300 Thermo Electron Cooperation) no emission of single nano-silver particles was detected.

In addition leaching of facades was investigated. The detected concentration is close to the determination limit of the analytical device, where nano particle release by sample preparation (centrifugation) is under discussion. For additional comments see 4.3.

Evaluation: 3

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4 Product safety

4.3 Additional detailed criteria

4.3.1 Criterion: Estimation of human toxicity of the nano drugs under consideration of dose, particle properties (size, surface charge) and chemistry

Estimation of dose-depending basic toxicity of silver with additional numerous references are given in „Report of the Task Group on Reference Man“, Pergamon Press 1974, 407 f. FDA classification of silver is GRAS (generally recognized as safe). Daily intake per person by water and food is 30 µg (Hamilton).

Risk potential of nano-silver powder considering the boundary conditions is limited. Contrary to popular belief alveoli are not reached because of surface affinity. In case of inhalation elimination from the upper part of the lung is possible (BASF).

This is not valid for nano fiber structures.

Evaluation: 2

4.3.2 Criterion: Safety concept of nano system, to avoid uncontrolled release of single nano particles; integration by physisorption / chemisorption

As mentioned in 4.1.1 nano-silver is combined with a polymer binder phase and anchored via dipole interactions.

Evaluation: 3

4.3.3 Criterion: As a consequence of 4.1, 4.2: Product safety for the user

As already discussed in 4.2.1 the product is safe for the user, provided the ordinary use.

Evaluation: 3

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4.3.4 Criterion: As a consequence of 4.1, 4.2: Safety and analytical check during component production, system integration and whole life cycle of the product

As already discussed in 4.2.2 a safety concept is implemented and analytically checked.

Transportation incidents with nano-silver suspension have the highest risk regarding the life cycle of the product (more explanations in 4.3.8).

Evaluation: 2

4.3.5 Criterion: Assessment of the principal environmental toxicity of the drugs under consideration of dose, particle properties (size, surface charge) and chemistry

Considering the boundary conditions, the principal environmental toxicity is limited.

Mobility of nano-silver powder in dynamic fluids is limited because of surface affinity.

This is the reason for a low accumulation risk.

Environmental conditions can lead to following reactions (oxidation and sulfate-formation (insoluble in water)).

Evaluation: 2

4.3.6: Criterion: Assessment of the overall system - related to the working principle

Regarding the desired additional antimicrobial functionality in the sense of catalysis the product is sustainable and safe on product level.

This can be underlined by 7 years of field experience.

The more mechanisms of antimicrobial activity, the lower the risk of resistancy formation.

Evaluation: 3

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4.3.7: Criterion: Risk assessment and emission propability

Risk = toxicity * exposition

Summarizing the discussed issues on toxicity and exposition propability the risk is very limited. Furthermore an excellent benefit/risk-ratio could be obtained.

By trace analysis (AES) it has been proven that an uncontrolled release of single nano silver particles will not happen. The working principle is not drug release but surface catalysis.

A risk assesment of other nano products – depending on application – could need the full set of procedures listed in 7.4.

Evaluation: 3

4.3.8 Criterion: Consequences in case of emission, chemical background concentration, mobility and accumulation

Low risk in case of product emission, for nano-particles are present in very low concentration and integrated in a secondary phase.

Transportation incidents with nano-silver suspension have a higher risk. In this case a local and transient contamination of environment will occur, killing microorganisms on surface of existing biofilms. Since the suspension is delivered in a diluted form, aquatic toxicity can be avoided.

Nano-silver powder on the one hand follows flow dynamics in air and water quite good. Since the surface affinity is high on the other hand the mobility is poor. Therefore accumulation is not to be expected. In the environment - depending on reaction conditions - oxidation and sulfate-formation (insoluble in water) can occur.

Chemical background concentration in soil is 0,1 ppm.

Evaluation: 2

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4.3.9 Criterion: GHS (Globally Harmonized System) classification of components

GHS classification ensured by component suppliers.

Evaluation: 3

4.3.10 Criterion: CLP (Regulation on Classification, Labeling and Packaging of substances and mixtures) compliance

CLP compliance ensured by component suppliers.

Evaluation: 3

4.3.11 Criterion: If applicable:

BPD (Biocide Product Directive) compliance

Not applicable, product is not subject to BPD
(Evaluation to be adapted in excel-sheet).

Evaluation: -

4.3.12 Criterion: Potential to replace a harmful existing technology

The product replaces competitor's products containing human-toxic conventional biocides.

Evaluation: 3

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5 Ethical, social and economic consequences and perspectives

5.1 Criterion: Ethical issues of paradigm shift

Paradigm shift and switching to non-human-toxic sustainable components improves the ethical act.

Evaluation: 3

5.2 Criterion: Availability of components and resource conservation

High efficacy at low concentration in combination with a sustainable quasi catalytic effect protects resources

Evaluation: 3

5.3 Criterion: Social consequences of technology change

Positive social consequences are to be expected depending on degree of technology change.

Evaluation: 2

5.4 Criterion: Economic consequences related to production company and national / international economy

Since product introduction in 2005 up to now the economic success for the manufacturer is evident (international reference objects, „Technology Fast 50 Award 2009“).

Yet the influence on national and international economy is small.

Evaluation: 2

5.5 Criterion:

The product development is embedded in a general nano suspension technology for a variety of different applications.

Evaluation: 3

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5.6 Criterion: Connectivity to further developments

Similar product developments (e.g. nano-silver wall-paper) are carried out.

Evaluation: 3

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6 Summary, conclusion, embedding, recommendations and outlook

Bioni Hygienic is a real nano-product with effective and sustainable antimicrobial additional functionalization. Using nanosilver, conventional human-toxic and environmental hazardous biocides can be replaced. The core of the risk assessment is the analytical proof that during life cycle no uncontrolled release of individual nanoparticles occurs. Costly toxicological tests, which are presented in the appendix as a systematic review, therefore are dispensable. The degree of compliance with product safety was evaluated according to the criteria specified in section 4. The overall result is supported by seven years of practical field experience.

It is known that the results presented in the reports (volume I-III) will be integrated in the „Nanoforce“ project, where – inter alia – the question is discussed whether additional legal regulatory measures are necessary to ensure nano safety.

Since the products are rated to special cases, the results have only limited relevance. Therefore it may be allowed to contribute with independent additional background information related to systems with nano-release.

Based on the chemical nature, nanoparticles and products are already subject to numerous regulations (see figure 22.1) in Germany. At international level, there are additional requirements in the context of REACH.

Risk assessment usually is performed according to a procedure suggested in figure 23.1. As a result additional toxicity tests are necessary as listed in 7.4.

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For reasons of product liability, each company is interested to carry out basic tests to determine the toxicological endpoints (concentration limits), because these data are needed anyway for the safety data sheets.

Depending on applications, where homologations are necessary, additional tests must be performed. This is the case e.g. for food additives, biocides and pharmaceuticals. Pharmaceuticals need the full set of test procedures listed in 7.4.

Finally the question related to additional regulations should be addressed.

In order to answer this question with transparency, the following considerations, statements and hard facts are listed below:

Contrary to public opinion and a nanoproduct database of Bund für Umwelt und Naturschutz Deutschland e.V.

(http://www.bund.net/nc/themen_und_projekte/nanotechnologie/nanoprodukt_datenbank/produktsuche/), only very few products meet the nano-criteria set out in section 1.

-From the ratio between research projects including toxicity studies and the number of new nanoproducts introduced in the market it can be concluded that the safety issue is taken seriously.

-So far no adverse health effects or environmental hazards have been reported to the author.

-The scenarios of free-flying nanoparticles penetrating into cells are unrealistic, since beside size – surface charge, polarity, hydrophilicity etc. are relevant (figures 24.1, 24.2).

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-The alveoli penetration of nanoparticles is usually estimated inadequate. It is true that nanoparticles can be carried away in the gas flow very well. But it is also a matter of fact that a high surface affinity exists so that the deposition takes place in the upper region of respiratory tract. Furthermore, we should be aware that ejection mechanisms are active as long as it does not concern fibers.

-Nature seems to have an intrinsic nano safety mechanism: Minimizing of surface energy is a driving force for voluntary and spontaneous re-agglomeration.

-Nevertheless the residual risks should be estimated appropriate and managed with respect.

-Therefore nanosafety research should be continued - according the priorities and conditions listed in report I.

-Since regulatory work is already in progress, the question is no longer whether – but to which extend additional regulations make sense.

-Knowing the four main groups of stakeholders, the international trail over CEN and OECD as well as the existing and planned working groups, own conclusions can be drawn related to time frame and scope of expected regulations.

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This leads to the following final conclusions:

-Only lean regulations will improve nano safety in practice.

-Provided that safety in general is already covered by other legislation (e.g. REACH, work protection rules, etc.), we only see a limited need for additional regulation, which is explained below by topics and application areas:

Physical Nanotechnology: No major action identified.

Chemical Nanotechnology

Particle level: Action necessary for pyrophoric particles and fibers.

Product level: Action needed for products following the principle of drug release and products containing nanofibers.

Application areas: As e.g. food and pharmaceutical industries are already heavily monitored, the cosmetics industry is identified as the weakest link in the chain.

-Whenever the risk assessment indicates a high risk, or there are new insights beyond the general state of knowledge, the issue of additional regulations should be checked again in the sense of a continuous improvement process.

As immediate measures to improve nano safety the following regulations are proposed:

- Labeling requirement for nano products for customer information
- Experimental evidence of nano functionalization to avoid fake products
- Registration of nano products
- Improving the monitoring of compliance of existing security measures

Finally it should be stated that – completely independent - the Working Party of Manufactured Nanomaterials of OECD comes to similar assessments (document no.: ENV/SMMONO(2009)21).

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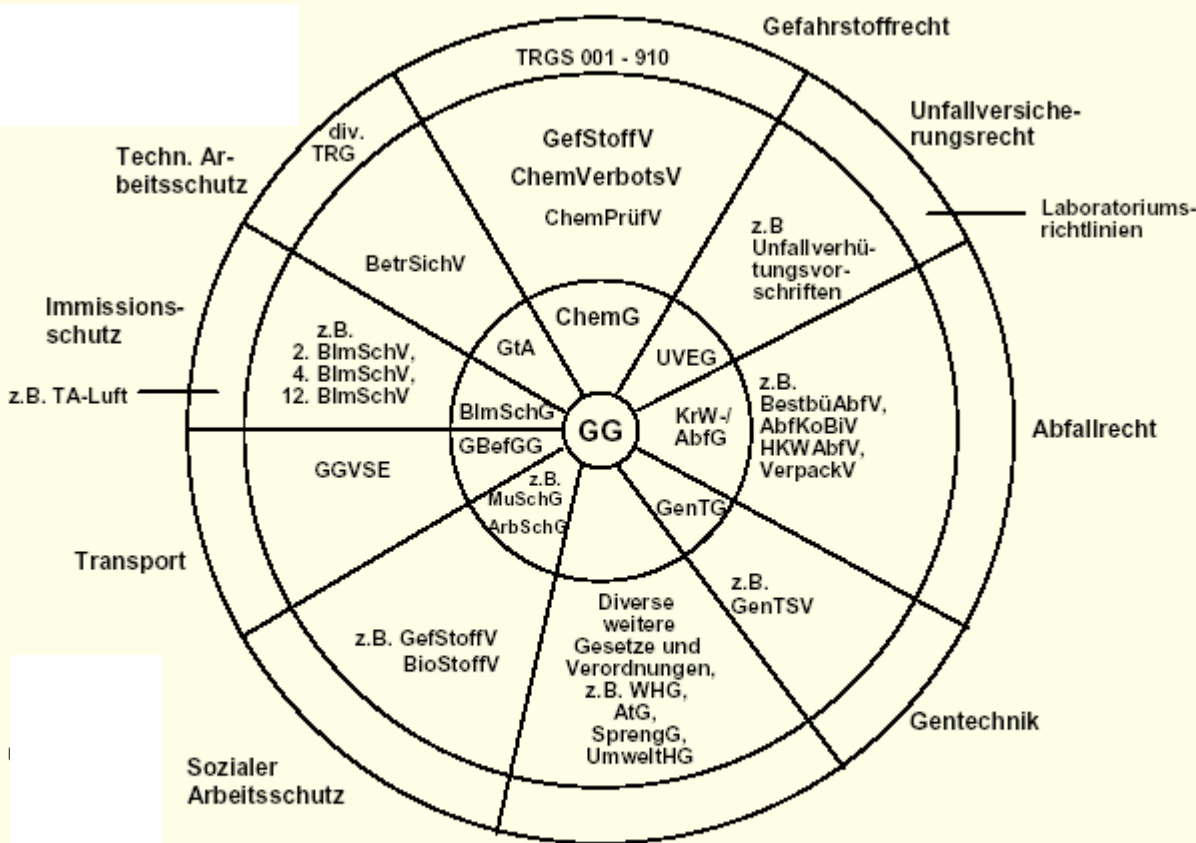


Figure 22.1: Overview of laws and regulations concerning chemical-, product- and work-safety (-> ISO/TR 12885) in Germany.

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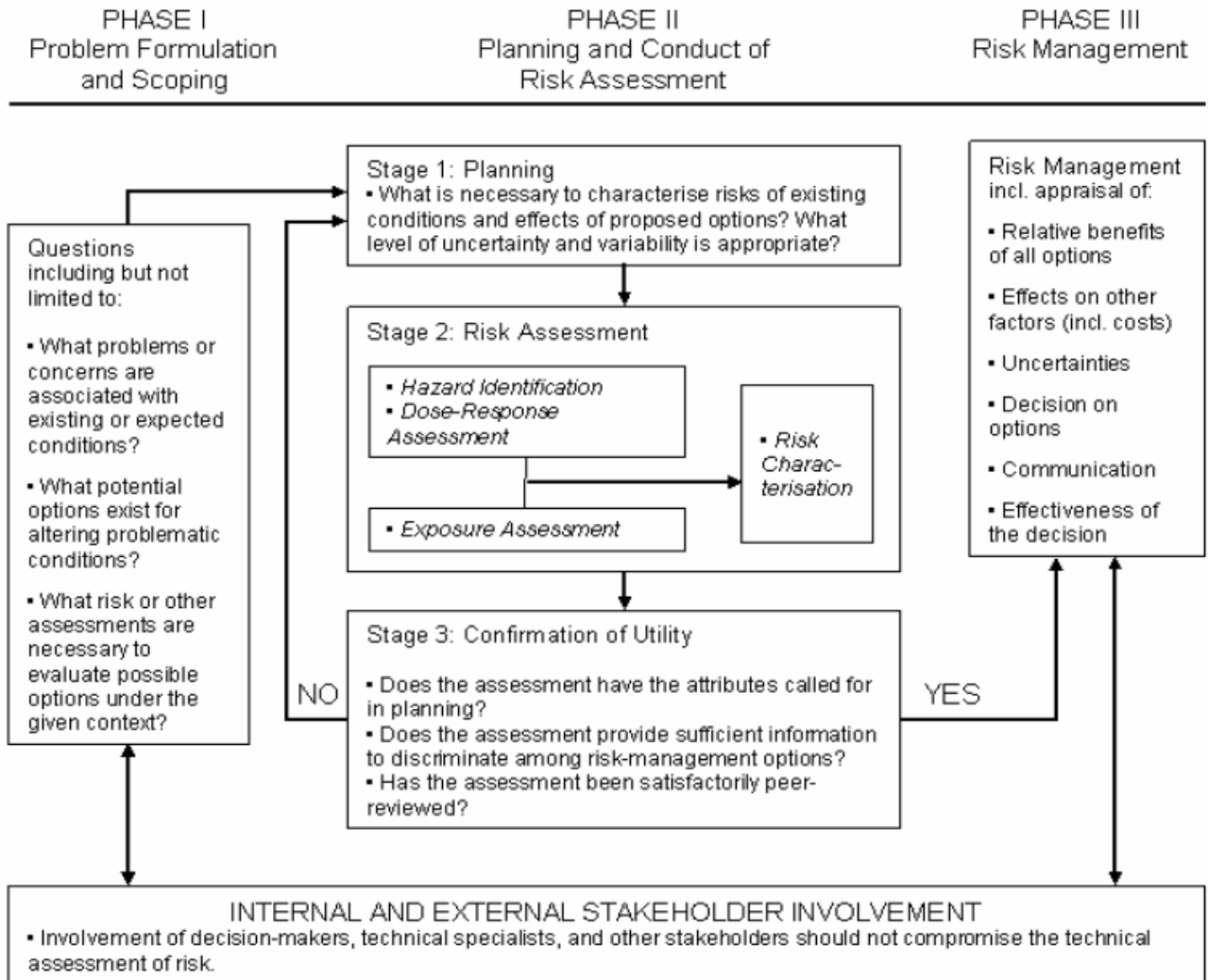
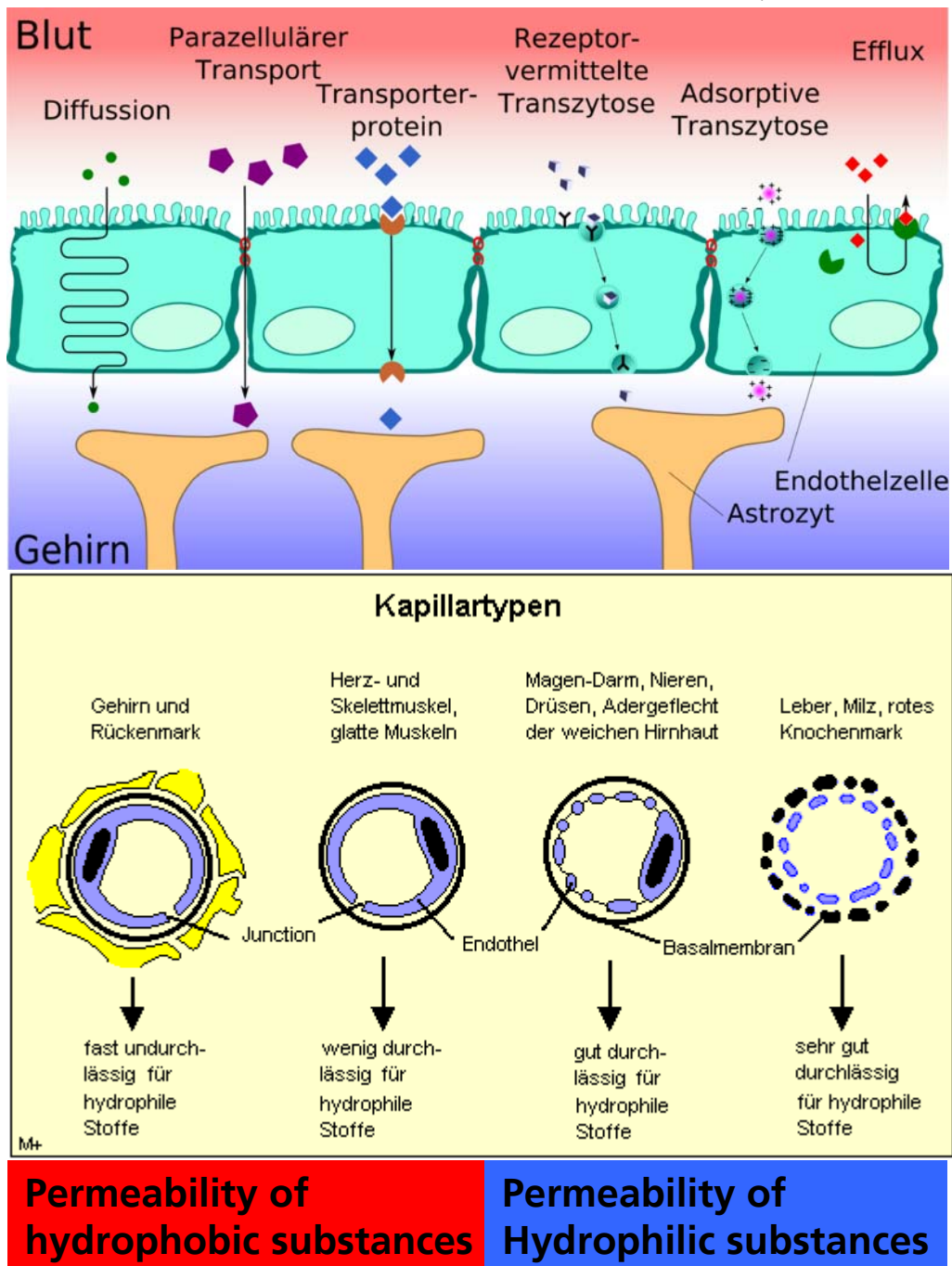


Figure 23.1: Proposal from National Research Council (NRC), USA, for a general method of risk assessment and management.

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Sources: Wikipedia, Medizininfo



Figures 24.1, 24.2: Possible permeation mechanisms of blood-brain barrier and capillaries: The particle size is only one criterion!

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7.0 Appendix

7.1 Product data sheet (TDS)

Bioni Hygienic^{MEDICAL}

Multi-functional interior paint based on green nano-technology with unmatched performance

Product	Application	Conditions during Application:
<p>Product Description:</p> <p>Pure acrylic multi-functional interior paint based on green nano-technology that has been specially developed for tough service environments and high-traffic areas. It provides an extremely durable, disinfectant-resistant and washable finish, is low-VOC and odor-free, permanently prevents the growth of microbes on the paint film and cuts maintenance costs.</p> <p>Features:</p> <ul style="list-style-type: none">- Is specially formulated based on green nano-technology to prevent growth of microbes on the paint film- Highly resistant to cleaners and disinfectants- vapor-permeable- Exceeds indoor air quality regulations measured in VOC (Volatile Organic Compounds)- Eco-friendly formula for environmental protection. Can earn LEED credits.- Odor-free - can be applied in occupied areas- Fire rating: Class A (ASTM E84). No drip-off.- Water-based, free of solvents and safe to use- Has superior flow, hiding and adhesion qualities- Comes in white and 1750 colors- Tested by independent laboratories <p>Technical Information:</p> <p>Form: liquid</p> <p>Color: white and 1750 colors</p> <p>Finish: matte</p> <p>Solids (% by Volume): approx. 56%</p> <p>Thinner: water</p> <p>Vehicle Type: 100% Acrylic resin</p> <p>pH: approx. 9</p> <p>Weight per Gallon: 9.6 lbs (1.15 kg)</p> <p>VOC (ISO 11890-2): 4 g/L 0.03 lbs/gal (=0.35%)</p> <p>Packaging:</p> <p>1 and 3 Gallon pail.</p>	<p>Area of Application:</p> <p>For internal use on old and new plastered walls, ceilings, previously-painted walls and ceilings, concrete, sand-lime bricks, various wall panels.</p> <p>Application Methods:</p> <p>To be applied by brush, roller (use a high-quality lambskin roller) or sprayed using suitable equipment. Stir thoroughly before use.</p> <p>Surface Preparation:</p> <p>The surface must be fully cured, clean, dry and free of dirt, contaminants and release agents. For preparing cementitious substrates refer to ASTM D-4256 and ASTM D-4261. Apply 1 coat Bioni Grip as a primer on new surfaces.</p> <p>MILDEW: Remove mildew before painting by scrubbing and washing. Apply Bioni Clean or Bioni IsoZem. WARNING! If you scrape, sand, or remove old paint, you may release lead dust. LEAD IS TOXIC. EXPOSURE TO LEAD DUST CAN CAUSE SERIOUS ILLNESS, SUCH AS BRAIN DAMAGE, ESPECIALLY IN CHILDREN. PREGNANT WOMEN SHOULD ALSO AVOID EXPOSURE. Wear a NIOSH-approved respirator to control lead exposure. Clean up carefully with a HEPA vacuum and a wet mop. Before you start, find out how to protect yourself and your family by contacting the National Lead Information Center at 1-800-424-LEAD or log on to www.epa.gov/lead.</p> <p>Typical Recommended Paint System:</p> <ul style="list-style-type: none">- 1 coat Bioni Clean if area lightly mildewed or- 1 coat Bioni IsoZem if area badly mildewed or- 1 coat Bioni Grip (if area is not mildewed but needs to be prepared before painting)- 2 coats <i>Bioni Hygienic</i>^{MEDICAL}. <p>Spreading Rate:</p> <p>200-300 sq. ft. per Gallon per coat, applied at 6.5 mils wet, 3.75 mils dry depending on the substrate and texture.</p> <p>Thinning / Mixing:</p> <p>Single pack. Ready to use. If necessary (i.e. if RH <50%, direct sunlight, windy conditions), thin sparingly with clean water up to 1/2 pint per Gallon. The characteristics of the product can be affected if mixed with other substances.</p>	<p>The temperature of the substrate and ambient should be > 41°F during application and drying.</p> <p>Curing / Drying (at 68°F, 50% RH):</p> <p>1 hour (to touch) / 12 hours (to recoat).</p> <p>Storage:</p> <p>Can be stored for approximately 24 months in a cool but frost-free area (unopened).</p> <p>Clean-up:</p> <p>Clean spills and spatters immediately with soap and warm water. Clean hands and tools immediately after use with soap and warm water.</p>
		Disposal
		<p>Handle disposal of waste material in manner which complies to local, state, province and federal laws and regulations.</p> <p>Check www.eearth911.org for recycling and disposal information in your area.</p>
		Health and Safety
		<p>DO NOT TAKE INTERNALLY. KEEP OUT OF REACH OF CHILDREN. Use only with adequate ventilation. Do not breathe spray mist or sanding dust. Ensure fresh air entry during application and drying. Avoid contact with eyes and prolonged or repeated contact with skin. Avoid exposure to dust and spray mist by wearing a NIOSH approved respirator during application, sanding and clean up. Follow respirator manufacturer's directions for respirator use. Close container after each use. FIRST AID: SKIN CONTACT: Wash thoroughly with soap and water. EYE CONTACT: Flush immediately with water for 10-15 minutes and contact a physician. RESPIRATORY PROBLEMS: Remove affected person to fresh air immediately and contact a physician. Read the current Material Safety Data Sheet (MSDS) for additional health and safety information.</p> <p>LIMITATION OF LIABILITY</p> <p>The information herein is given in the best of our knowledge based on practical experience and laboratory testing. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. FOR THE SAID OTHER REASONS, WE DO NOT ASSUME RESPONSIBILITY AND EXPRESSLY DISCLAIM LIABILITY FOR LOSS, DAMAGE OR EXPENSE ARISING OUT OF OR IN ANYWAY CONNECTED WITH THE HANDLING, STORAGE, USE OR DISPOSAL OF THE PRODUCT.</p>

Recommended Use

For indoor use. Ideal for tough service environments such as hospitals, clinics, surgical centers, day care centers and rehabilitation centers. For areas that require better air quality, extreme durability and where a superior protection of the paint film against unwanted micro-organisms is needed.

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7.2 Product safety data sheet (MSDS)

Product: *Bioni Hygienic*

Date of Publication: October 1st 2006

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MSDS-No.: BH-US-2006-1-3

1. Product and Company Identification

Product Name:

Bioni Hygienic

Manufacturer:

Bioni CS GmbH
Lessingstr. 21
D-46149 Oberhausen
Germany

Telephone: +49 208 6217553

Fax: +49 208 6217555

Emergency Telephone Number:

Giftnotruf Berlin (24 hours)

Telephone Number: +49 (0)30/19 240

2. Composition / Information on Ingredients

Chemical Nature of the preparation:

Acrylic copolymer emulsion with Nano-Silver

Hazardous Components:

Ingredient	CAS Number	Weight %	Occupational Exposure Limits		
			OSHA PEL	NIOSH REL	ACGIH TLV
Silver	7440-22-4	< 1%	0.01 mg/m ³	0.01 mg/m ³	0.1 mg/m ³
Titanium Dioxide	13463-67-7	< 20%	15 mg/m ³ **		10 mg/m ³ *

*: as Dust **: Total Dust

OSHA: Occupational Safety and Health Administration (US Dept. of Labour)

NIOSH: National Institute for Occupational Safety and Health

ACGIH: American Conference of Governmental Industrial Hygienists

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

TLV: Threshold Limit Value

3. Hazards Identification

Routes of Exposure

INHALATION: of vapor or spray mist.

EYE and Skin contact with the products, vapor or spray mist.

Effects of Exposure

EYES: Irritation

SKIN: Prolonged or repeated exposure may cause skin irritation.

INHALATION: Inhalation of vapors may cause respiratory tract irritation.

INGESTION: Although ingestion is not considered a significant route of exposure, this material may cause gastrointestinal irritation if ingested.

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Product: *Bioni Hygienic*

Date of Publication: October 1st 2006

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MSDS-No.: BH-US-2006-1-3

4. First Aid Measures

General Information

In all cases of doubt, or when symptoms persist, seek medical advice and show this Safety Data Sheet.

Inhalation

If affected, remove from exposure and seek medical advice.

Skin

Wash skin with soap and plenty of water. Get medical attention if symptoms occur.

Eyes

Flush eyes with large amounts of water for 15 minutes. Get medical attention.

Ingestion

If swallowed, seek medical advice immediately. Do not induce vomiting.

5. Fire Fighting Measures

Flash Point

No Data

Suitable extinguishing media

Use Water fog (or if unavailable fine water spray), alcohol foam, dry agent (carbon dioxide, dry chemical powder).

Protection of Firefighters

Wear positive-pressure self-contained breathing apparatus and protective fire fighting clothing.

6. Accidental Release Measures

Personal Precautions

Wear adequate personal protective equipment (see section 8).

Environmental Precautions

Do not allow to enter drains or watercourses.

If the product contaminates lakes, rivers or sewages, inform appropriate authorities in accordance with local regulations.

Methods of Cleaning Up

Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

7. Handling and Storage

Handling

Keep area ventilated. Avoid contact with eyes, skin and clothing.

For personal protection see Section 8.

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7. Handling and Storage (cont'd)

Storage

Keep container tightly closed when not in use. Store in cool, frost-free, dry and well-ventilated place away from sources of heat and combustible materials. Keep out of reach of children.

Hygiene Practices

Wash thoroughly after handling. Avoid contact with eyes and skin.

8. Exposure Controls / Personal Protection

Occupational Exposure Limits

This product may contain materials classified as nuisance particulates which may be present at hazardous levels only during sanding or abrading of the dried coating film. The applicable limits for nuisance dusts are:

Ingredient	CAS Number	Weight %	Occupational Exposure Limits		
			OSHA PEL 8-hour TWA	NIOSH REL 10-hour TWA	ACGIH TLV 8-hour TWA
Silver	7440-22-4	< 1%	0.01 mg/m ³	0.01 mg/m ³	0.1 mg/m ³
Titanium Dioxide	13463-67-7	< 20%	15 mg/m ³		10 mg/m ³

Engineering controls and hygienic practices

Ensure adequate ventilation and avoid breathing vapor and spray mist.

Avoid contact with skin and eyes.

Remove contaminated clothing.

When using do not eat, drink and smoke.

Wash hands after using.

Handle in accordance with good industrial hygiene and safety practice.

Personal protective Equipment:

Respiratory System

Not required in case of sufficient ventilation. When sanding or abrading the dried paint film, wear a dust/mist respirator approved by NIOSH/MSHA for dust which may be generated from this product, underlying coatings, or the abrasive.

Hand Protection

Use chemical resistant gloves.

Eye Protection

If there is a risk of eye contact wear safety spectacles with unperforated sideshields.

Skin and Body Protection

Use protective clothing.

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9. Physical and Chemical Properties

Form:	liquid
Colour:	white
Odour:	almost odourless
Flash Point:	no data
Specific Gravity at 20°C:	1.15 g/cm ³
Water Solubility:	Miscible with water
pH:	8.5 - 9.5

10. Stability and Reactivity

Chemical Stability

Stable under normal conditions of use.

Conditions to Avoid

Heat, flames, incompatible materials and freezing temperatures below 0°C (32 °F).

Materials to avoid

Stable under recommended storage and handling conditions (see section 7).

Hazardous Decomposition Products

None known under normal conditions of storage and use.

11. Toxicological Information

Silver is not listed as a human carcinogen by IARC, NTP, OSHA or ACGIH. Inhalation of high amounts of metallic silver vapours may cause lung damage with pulmonary oedema. Repeated long-term exposure to silver dust may cause a grey-blue discoloration of the eyes, nose, throat and skin (argyria/argyrosis).

Rats exposed to Titanium Dioxide dust at 250 mg/m³ developed lung cancer. Such exposure levels are not attainable in the workplace. If the product is handled in accordance with this Safety Data Sheet and the product label no adverse health effects are expected. Symptoms or effects that may arise if the product is mishandled and overexposure occurs are:

Skin Contact

Contact with skin may result in irritation.

Eye Contact

May be an eye irritant.

Inhalation

No adverse effects expected.

Ingestion

No adverse effects expected.

Toxicological Data

No LD50 data available for the product.

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12. Ecological Information

Do not allow to enter drains or watercourses.

Silver may be hazardous to the environment; special attention should be given to aquatic organisms.

13. Disposal Considerations

Product

Recommendation:

Do not allow to enter drains or watercourses.

Handle disposal of waste material in manner which complies to local, state, province and federal laws and regulations.

Packaging

Recommendation:

Dispose according to local regulations.

14. Transport Information

DOT Hazard Classification: No

IMO/IMDG (Sea) and IATA/ICAO (Air): NON-DANGEROUS GOOD

15. Regulatory Information

TSCA (Toxic Substances Control Act) Certification

TSCA Inventory:

All chemicals in this products are listed, or are exempt from listing, on the TSCA INVENTORY.

SARA (Superfund Amendments and Reauthorization Act of 1986)

TITLE III Section 302

Extremely Hazardous Substances (EHSs) / 40 CFR Part 355:

There are no components present in this product at a level which could require reporting under the statute.

CERCLA (Comprehensive Environmental Response Compensation and Liability Act of 1980)

Hazardous Substances / 40 CFR Part 302.4:

Following Chemicals in this product are listed: Silver

Releases in quantities equal or greater than Reportable Quantity (RQ):

There are no components present in this product at a level which could require reporting under the statute.

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15. Regulatory Information (cont'd)

EPCRA (Emergency Planning and Community Right-to-Know Act) Section 313
Toxic Chemical Release / 40 CFR Part 372:

Following Chemicals in this product are listed: Silver (CAS 7740-22-4)
The concentration of Silver in this product is lower than the "De Minimis Concentration" of 1%.

There are no components present in this product at a level which could require reporting under the statute.

EPCRA (Emergency Planning and Community Right-to-Know Act) Section 311/312
Hazardous Chemical Storage Reporting Requirements / 40 CFR Part 370:

Hazard Category Compensation For Reporting Under Sections 311 and 312
(for this product):

Fire Hazard:	No
Sudden Release of Pressure:	No
Reactive:	No
Immediate (Acute) Health Hazards:	No
Delayed (Chronic) Health Hazard:	No

OSHA (Occupational Safety and Health Standard)

Toxic and Hazardous Substances/ 29 CFR Part 1910 Subpart S:

Following Chemicals in this product are listed:

Silver (CAS 7740-22-4): 0.01 mg/m³

Titanium Dioxide (CAS 13463-67-7): (15 mg/m³) Total Dust

CLEAN WATER ACT

Silver (CAS 7740-22-4) is listed as a PRIORITY POLLUTANT and as TOXIC POLLUTANT under the Clean Water Act (CWA).

CLEAN AIR ACT - CAA Section 112(r)

Toxic and Flammable Substances / 40 CFR 68.130

There are no components present in this product listed.

STATE-RIGHT-TO-KNOW:

California Proposition 65

This product contains no "CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY".

Massachusetts Right to Know Substance List (MSL) (105 CMR Section 670.000)

There are no components present in this product at a level which could require reporting under the statute.

Pennsylvania Right to Know Hazardous Substance List

Following Chemicals in this product are listed: Silver (CAS 7740-22-4)

Silver is part of the ENVIRONMENTAL Hazard list.

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15. Regulatory Information (cont'd)

California SCAQMD (South Coast Air Quality Management District)

Rule 443.1: VOC's (Volatile Organic Compounds)

This product contains < 1% by weight VOC.

CANADA

DSL (Domestic Substances List)

All chemicals in this products are listed on the DSL.

WHMIS (Workplace Hazardous Materials Information System)

Ingredient Disclosure List

Following Chemicals in this product are listed: Silver (CAS 7740-22-4)

Disclosure at 1,0% according to the ingredient disclosure list. The concentration of Silver in this product is lower than the 1%.

There are no components present in this product at a level which could require reporting under the statute.

NPRI (National Pollutant Release Inventory)

Following Chemicals in this product are listed: Silver (CAS 7740-22-4)

16. Other Information

The information in this MSDS was obtained from sources which we believe are reliable. HOWEVER, THE INFORMATION IS PROVIDED WITHOUT ANY WARRANTY, EXPRESSED OR IMPLIED, REGARDING ITS CORRECTNESS.

The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. FOR THIS AND OTHER REASONS, WE DO NOT ASSUME RESPONSIBILITY AND EXPRESSLY DISCLAIM LIABILITY FOR LOSS, DAMAGE OR EXPENSE ARISING OUT OF OR IN ANY WAY CONNECTED WITH THE HANDLING, STORAGE, USE OR DISPOSAL OF THE PRODUCT.

This MSDS was prepared and is to be used only for this product. If the product is used as a component in another product, this MSDS information may not be applicable.

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7.3 Literature

Bemerkungen	Review	Review	Modellstudie – Multikompartiment Modell	Modellstudie – Freisetzung beim Entsorgungsprozess	Größenklassen durch Filtration 20-100nm, 100- 400nm und Trennung nach Partikeln und Ionen nach REM & ToF SIMS	Review – Ökotoxikologie ökotoxikologische Studie	ökotoxikologische Studie, Verwendung sehr hoher Konzentrationen
Analytik	o	o	o	o	+	+	+
Dispergierung	o	o	o	o	o	o	-
Bezugsquelle der Materialien	o	o	o	o	(+)	-	-
Versuchsdurchführung	o	o	+	+	+	+	+
Versuchsaufbau	o	o	+	+	+	+	-
Masse	o	o	+	+	+	-	-
BET-Oberfläche	o	o	o	o	o	-	-
pH-Wert	o	o	o	o	-	-	-
Persistenz - Löslichkeit / Dispergierbarkeit	o	o	o	o	o	-	-
Stabilität von Suspensionen	o	o	o	o	o	-	-
Oberflächenreinheit / Oberflächenverunreinigung	o	o	o	o	-	+	-
Oberflächenladung / Zeta Potential	o	o	o	o	-	-	-
Spezifische Oberfläche	o	o	o	o	-	-	-
chemische Zusammensetzung	o	o	o	o	+	-	-
Aggregation / Agglomeration	o	o	o	o	+	-	-
Partikelmorphologie / Kristallphase und Kristallinität (REM/TEM- Aufnahmen)	o	o	o	o	+	+	-
Partikelanzahlgrößen- verteilung	o	o	o	o	-	-	-
Primärpartikelgröße	o	o	o	-	+	+	-
Literatur							
Wijnhoven et al. 2009							
Luoma 2008							
Blaser et al. 2008							
Müller & Nowak 2008							
Benn & Westerhoff 2008							
Hagenhoff et al. 2009							
Ökotoxikologie							
Ratte 1999							
Lee et al. 2007							
Asharani et al. 2008							

Table 33.1
Review of the literature dealing with the release of nanosilver out of products
 +: information available, -: information missing, o: information not relevant
 (source: UBA-report 52/2010).

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7.4 Overview „Test procedures for risk assessment of nano materials, objects and products“

The following tables provide an overview and systematic presentation of toxicity tests for risk assessment.

Chapter 6 refers to 7.4.

More detailed descriptions can be found in the correlating OECD tests no. 400 – 488.

In vitro Experiments				
	Toxicology	Dermal Absorption	Pig skin, Franz cell	
		Permeation through oral Mucosa	Franz diffusion cell	
		Epiderm Skin Irritation	Human epidermis model	Analysis Cytotoxicity
		Inhalation	Exposure module	Analysis Cytotoxicity

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In vitro Experiments			
Toxicology	Cytocompatibility	Apoptosis	Caspase Activation, ...
		Membrane Damage	PI-Exclusion, ...
		Mitochondrial Damage	TMRM-Uptake
		Oxidative Stress	DCF-Oxidation, ...
		Proliferation	Thymidine-Uptake
		Viability	ATP-Content, ...
	Hemocompatibility	Clotting	Prothrombin Fragments
		Hemolysis	Hemoglobin Release
		Immunogenicity	C3a Protein
		Inflammation	Myeloperoxidase
		Thrombocyte Activation	Serotonin Release

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In vitro Experiments				
Toxicology	Genotoxicity Mutagenicity	Ames Test	Salmonella Typhimurium	
		Chromosomal Changes		
		DNA Changes	8-OHdG	
	Immunotoxicity Cellular Stress	Cytotoxicity / Proliferation		
		Reporter Cell Lines	Proinflammatory chemokine IL-8 in human epithelial cells A549	

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In vitro Experiments			
Toxicology	Tissue Investigations	Cell Morphology	Immunofluorescent Coloration, Optical Imaging
		Proliferation	BrdU-Assay
		Tightness	Trans Epithelial Electric Resistance (TEER) Measurement
		Viability	FDA/ethidium bromide coloration -> live/dead discrimination

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In vitro Experiments			
Toxicology	Human Models	Cellular Response	Viability
			Inflammatory response, Signal Molecules, Interleukins
			Antioxidant (Reduced Glutathione) Measurement
			Oxidative Stress, ROS Generation
			Stress, Genotoxic Response
			Toxicity
		Liver Model	
		Liver Cell Function	Albumin / Urea
			Xenobiotic Metab.

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Ex vivo, In vivo Experiments			
Online Technologies	Skin, Tissue, Muscle	Open Flow Microperfusion (OFM) Catheter	HPLC, GC-MS
	Skin, Tissue, Muscle	Open Flow Microperfusion (OFM) Catheter	HPLC, GC-MS

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In vivo Experiments			
In vivo Imaging, „Molecular Imaging“, targeted, switchable	Optical Imaging Fluorescence, Bioluminescence, NIR-Emission 700-900 nm	NIR-Fluorophores, Cyanines, Cy2, Cy3, ... QD	
	MRI Magnetic Resonance Imaging	Magnetite	
	PET Positron (β+) Emission Tomography, space and time-resolved	Radioisotope-drug-combinations depending on target, ¹⁸ F, ...	
	SPECT Single Photon Emission Computed Tomography, γ-Emission	Radioisotopes, ¹¹¹ In, ...	

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In vivo Experiments			
Toxicology: Blood Count, Clinical Chemistry (serum parameters for Kidney, liver, inflammation, immune response), Histopathology, Immunohisto- Chemistry (proliferation, inflammation, oxidative stress)	Level 1	Carcinogenicity	
		Reproduction Toxicity	According ICH, OECD rules
		Sensitization	Mouse model, (Local Lymph Node Assay [LLNA])
			Guinea pig methods
		Skin and Eye Irritation	
	Level 2	Subacute, Subchronic and Chronic Toxicity	28, 90 days 6, 12 month
			All routes of administration
	Level 3	Acute Toxicity	All routes of administration
		Immunogenicity	
		Mutagenicity	Micronucleus test
		Short Term Toxicity	