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Series on the Safety of Manufactured Nanomaterials

No. 74

EXPOSURE ASSESSMENT OF NANO-SILVER (AgNP): CASE STUDY

IOMC
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This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

The OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (the Joint Meeting) held a Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety (June 2005). This was the first opportunity for OECD member countries, together with observers and invited experts, to begin to identify human health and environmental safety related aspects of manufactured nanomaterials. The scope of this session was intended to address the chemicals sector.

As a follow-up, the Joint Meeting decided to hold a Workshop on the Safety of Manufactured Nanomaterials in December 2005, in Washington, D.C. The main objective was to determine the "state of the art" for the safety assessment of manufactured nanomaterials with a particular focus on identifying future needs for risk assessment within a regulatory context.

Based on the conclusions and recommendations of the Workshop [ENV/JM/MONO(2006)19] it was recognised as essential to ensure the efficient assessment of manufactured nanomaterials so as to avoid adverse effects from the use of these materials in the short, medium and longer term. With this in mind, the OECD Council established the OECD Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the OECD Chemicals Committee in September 2006. This programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. This programme promotes international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

This document presents a case study to assess the exposure to nano-silver (AgNP). The main purpose of this case study was to identify existing data gaps regarding exposure assessment of nanomaterials and to make recommendations on how to address these data gaps. This documents presents information on the materials selected, the approach used, as well as the measurement/modelling methods, and results for each endpoint.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

TABLE OF CONTENTS

BACKGROUND 11
Material Selection 11
AgNP test materials selected by OECD Testing Programme 11
Methods 12
Study design 12
Characterization 12
DATA FOR EXPOSURE ENDPOINTS FOR NANO-SILVER GENERATED IN THIS CASE STUDY. 13
Human occupational exposure 13
Table 1. Data for exposure endpoints for Industry A (Ref. 1).* 13
Table 2. Data for exposure endpoints for Industry A (Ref 7) 14
Table 3. Health Surveillance in nano-silver manufacturing facility (Industry A) (Ref. 2). 15
Table 4. New data for exposure endpoints in printed electronics workplaces (Ref. 10). 16
Human non-occupational exposure 18
Table 5. New data generated in a study to evaluate exposures to nano-silver in children's consumer products conducted by U.S. EPA and U.S. CPSC (Ref. 16) 18
Table 6. Consumer exposure simulation 1 conducted by KIST (Ref. 17). 20
Table 7. Consumer exposure simulation 2 conducted by KIST (Ref. 18). 21
Table 8. Consumer exposure simulation 3 conducted by KIST (Ref. 18). 22
Table 9. Consumer exposure simulation 4 conducted by KIST (Ref. 18). 23
DATA FOR EXPOSURE ENDPOINTS FOR NANO-SILVER FROM OTHER SOURCES 24
Human occupational exposure 24
Table 10. Existing exposure endpoints (Ref. 3). 24
Human non-occupational exposure 25
Table 11. Existing exposure endpoints (Ref. 4) 25
Table 12. Existing exposure endpoints (Ref. 4). 26
Exposure to biota 27
Table 13. Existing exposure endpoints (Ref. 4). 27
Table 14. Existing exposure endpoints (Ref. 5). 28
Table 15. Existing exposure endpoints (GER: UMSICHT project funded by Federal Ministry of Education and Research [BMBF]). 29
CONCLUSIONS 31
REFERENCES 33
ANNEX. TEMPLATE FOR COLLECTING THE DATA AND REPORTING INFORMATION ON EXPOSURE 35

BACKGROUND

1. OECD Working Party on Manufactured Nanomaterials (hereafter WPMN) agreed to work on case studies on exposure assessment for manufactured nanomaterials, with special attention in nanomaterials used in the OECD Testing Programme on Manufactured Nanomaterials (hereafter Testing Programme[1]). This report presents an exposure assessment case-study of nano-silver (AgNP). The main purpose of this case study was to identify existing data gaps regarding exposure assessment of nanomaterials and to make recommendations on how to address these data gaps. This documents presents information on the materials selected, the approach used, as well as the measurement/modelling methods, and results for each endpoint.

2. This case study was led by the United States and the Republic of Korea, with the inputs from the OECD WPMN members. A template for collecting the data and reporting information on exposure was developed (see Annex), which can be use in future exposure assessment case studies for other nanomaterials.

Material Selection

3. The OECD Testing Programme selected four types of nano-silver with two size ranges (10-20 nm and 50-100 nm) and two capping agents (citrate and PVP). These materials were provided by ABC Nanotech and Ras materials GmbH. In addition, NanoComposix was chosen as an alternative material. The group agreed to use, whenever possible, specific sources of study materials which were used in the Testing Programme.

AgNP test materials selected by OECD Testing Programme

Test Material #	Mean Core Diameter (nm)	Capping Agent	Company	Observations
1	between 10 nm and 15 nm	citrate	ABCNanotech	
2 (NM 300)	between 10 nm and 20 nm	PEG 25 trioleate	Ras materials GmbH (Rent a scientist GmbH)	NanoComposix can also be used, preferably as an alternate material.
3 (NM 301)	between 50 nm and 100 nm	citrate	RAS GmbH (Rent a scientist GmbH)	NanoComposix can also be used, preferably as an alternate material
4 (NM 302)	between 50 nm and 100 nm	PVP	RAS GmbH (Rent a scientist GmbH)	NanoComposix can also be used, preferably as an alternate material

[1] More information can be found at: http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm

Methods

Study design

4. The format for reporting exposures in exposure assessment case-studies including exposure endpoints was developed by OECD WMPN participants through iterative consensus-building process. This format is shown in the Annex. Data reported in this case-study were collected from OECD WPMN participants through data calls utilizing the tables in the Annex.

Characterization

5. Specific characterization methods are described in published research papers. Personal and area sampling, real-time aerosol monitoring, and silver analysis are described in Ref. 1, 2 and 7.

DATA FOR EXPOSURE ENDPOINTS FOR NANO-SILVER GENERATED IN THIS CASE STUDY

Human occupational exposure

Table 1. Data for exposure endpoints for Industry A (Ref. 1). *

Endpoint	Value/characteristics	Method
Exposure situation (process, facility, operation…)	Silver nanoparticles <100 nm in size using a large-scale pilot reactor	dry ICP method manufacturing
Materials used	Silver nanoparticles ranging from 20 to 30 nm were manufactured from precursors (silver wire, powder, and liquid) which were introduced to the reactor using a ICP torch and reacted with acetylene and oxygen gases.	
Emission sites	Silver nanomaterials manufacturing workplace	
Emission levels	Mass (3.7-4 h): 0.00002-0.00102 mg/m^3 (Ag) (LOD = 0.15 ppb; LOQ = 0.51 ppb) Number(6 h): Indoor: 534.6-6,657 particle/cm^3 (average diameter: ~100 nm, range 15-710 nm) In side of the collector: 25,022-2,373,309 particle/cm^3 (average diameter: ~30nm, range 15-710 nm)	Mass concentration with NIOSH 7300, Number concentration using DMAS (SMPS) in real time
Emission material	Silver nanoparticles, daily production amount; 5 kg/day	
Exposure material	Silver nanoparticles	

Inhalation Exposure		
Personal exposure – 8h TWA	0.00102 mg/m^3 (159 min, 315.8L) 0.00012 mg/m^3 (160 min, 315.2L)	NIOSH 7300-ICP method
Total Dose/Biomarkers		
Blood	0.034 µg/dL (Person 1: Male/42 age, 7yr; Exposed at 0.00035 mg Ag per m^3)	Digestion with nitric acid using microwave digestion system, digested fluid analyzed with a flameless method (graphite furnace) using atomic absorption spectrophotometer based on NIOSH 8005 (blood), and 8310 (urine).
	0.030 µg/dL (Person 2: Male/37 age, 7 yr; Exposed at 0.00135 mg Ag per m^3)	
Urine	0.043 µg/dL (Person 1)	
	ND (Person 2)	

*Rows without data in this and following tables were deleted. Instead data gaps are briefly described after the tables.

LOD, limit of detection; LOQ, limit of quantification; DMAS, differential mobility analysing system; SMPs, scanning mobility particle sizer; ICP, inductive coupled plasma;

6. **Data gaps**: personal peak exposures, dermal/ocular and GI exposures were not characterized in this study and therefore these endpoints are missing from the table.

Table 2. Data for exposure endpoints for Industry A (Ref 7).

Endpoint	Value/characteristics	Method
Exposure situation (process, facility, operation…) for continuous 3 days monitoring	Silver nanoparticles <100 nm in size using a large-scale pilot reactor	dry ICP method manufacturing

Materials used	Silver nanoparticles ranging from 20 to 30 nm were manufactured from precursors (silver wire, powder, and liquid) which were introduced to the reactor using an ICP torch and reacted with acetylene and oxygen gases.	
Emission sites	Silver nanomaterials manufacturing workplace	
Emission levels	Mass (159-350 min): 0.00501 to 0.2887 mg/m^3 (Ag) for injection room; all other locations were lower than 0.0013 mg/m^3 (Ag) Number (3 day): Indoor: 911,170 (1st day), 1,631,230 (2nd day), and 1,265,024 (3rd day) particles/cm^3 with a size range of 15–710.5 nm during the operation of the reactor, 877,364.9 (1st day), 492,732 (2nd day), and 344,343 (3rd day) particles/cm^3 when the reactor was stopped.	Mass concentration with NIOSH 7300, Number concentration using DMAS (SMPS) in real time
Emission material	Silver nanoparticles, daily production amount; 5 kg/day	
Exposure material	Silver nanoparticles	
Inhalation Exposure		
Personal exposure – 8h TWA	0.00004 to 0.00243 mg/m^3 (Ag) during 3 days; GM* concentrations of TWA and GSD# for the personal sampling were 0.00054 mg/m^3 and 4.358, respectively.	NIOSH 7300-ICP method

*GM, geometric mean
#GSD, geometric standard deviation

7. **Data gaps**: personal peak exposures, dermal/ocular and GI exposures were not characterized in this study and therefore these endpoints are missing from the table.

Table 3. Health Surveillance in nano-silver manufacturing facility (Industry A) (Ref. 2).

Human data				
	TSP*(mg/m^3)	Air Ag (mg/m^3)	Blood(µg/dL)	Urine(µg/dL)
Personal -1 (Male/42age ,7yr)	0.15755	0.00035	0.034 (LOD† 0.18 ppb)	0.043

Personal -2 (Male/37age ,7yr)	0.10869	0.00135	0.030 (LOD† 0.18 ppb)	#ND

*TSP – Total suspended particulate
ND, not detected
† LOD, limit of detection

Table 4. New data for exposure endpoints in printed electronics workplaces (Ref. 10).

Endpoint	Value/characteristics	Method and comments
Exposure situation (process, facility, operation…)	Two workplaces (A and B) inside cleanrooms.	Workplace A: Contact/contactless roll-based printing and coating (roll-to roll, roll-to-plate). Workplace B: Nano thin solar cells/supercapacitors continuous printing production system (spray).
Materials used	Printing used inks containing nano-silver in organic solvents.	
Emission sites	Workplace A: printing press Workplace B: spray printing	

Emission levels	Mass (93-158 min). Workplace A: 0.00002 to 0.00004 mg/m^3 (Ag) Workplace B: not measured. Number. Workplace A: the particle size range was 14.3-697.8 nm. Number concentration was from 0 to 2,091,456.5 particles/cm^3, background was up to 182.1 particles/cm^3. Workplace B: the particle size range was 14.3 to 697.8 nm. Number concentration was from 322,175.1 to 506,146.1 particles/cm^3, background was from 0 to 182.1 particles/cm^3.	The air samples were taken by drawing air through mixed cellulose ester filters in sampling cassettes (25 mm diameter, 0.45 mm pore-size). Area samples were collected by placing the samplers 1–4 m away from the printed electronics equipment, suspected particle or organic solvent emission sources, and at several representative locations throughout the workplace. Mass concentration was measured using NIOSH 7300. Number concentration was measured using DMAS (SMPS) in real time. Ag nanoparticles were morphologically identified using scanning transmission electron microscope.
Emission material	Silver nanoparticles	
Exposure material	Silver nanoparticles	
Inhalation Exposure		
Personal exposure – 8h TWA	0.00024 mg/m^3 (Ag)	Personal samples were collected in the breathing zone using MSA (Escort Elf pump)-operated sampling pumps at a flow rate of 0.901–1.033 L/min for suspended particles. The personal samplers were attached to workers in close contact with the printed electronics activities. Silver was measured using NIOSH 7300-ICP method.

8. **Data gaps**: personal peak exposures, dermal/ocular and GI exposures and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Human non-occupational exposure

Table 5. New data generated in a study to evaluate exposures to nano-silver in children's consumer products conducted by U.S. EPA and U.S. CPSC (Ref. 16)

Endpoint	Value/characteristics	Method
Exposure situation (process, facility, operation…)	exposure during intended use of products	
Materials used	Children's consumer products	
Emission sites	Children's consumer products: 13 products including one plush toy (teddy bear), three fabric products (baby blanket, sleepsuit, pair of baby scratch mitts), one set of breast milk storage bags, two sippy cups, three cleaning products (disinfecting spray, surface wipe, kitchen scrubber), two humidifiers claiming to contain silver to prevent biofilm formation in the water tank, and one humidifier accessory (a cube that can be placed in a humidifier's reservoir).	
Emission levels	Amount of silver leached into relevant liquid media 1) plush toy: interior foam (48.2 ± 5.0 mg Ag/kg product) tap water 0.24 ± 0.02 mg Ag/kg product saliva 1.77 ± 0.03 mg Ag/kg product sweat 18.5 ± 1.1 mg Ag/kg product urine 17.4 ± 0.8 mg Ag/kg product 2) plush toy: exterior fur (0.6 ± 0.1 mg Ag/kg product) tap water Not Detected saliva 0.03 ± 0.001 mg Ag/kg product sweat 0.14 ± 0.002 mg Ag/kg product urine Not Detected 3) baby blanket (109.8 ± 4.1 mg Ag/kg product)	The leaching assays consisted of soaking product samples in relevant liquid media under various conditions related to normal use. The leaching media included tap water; synthetic sweat, saliva, and urine; milk formula; and orange juice. Pieces of products of 0.5 g were placed in a 100-mL beaker and enough liquid media was added to achieve a 1:50 mass ratio between the product mass and leaching media. The soaking time depended on each product's intended use and type of liquid media (see Ref. 16 for details). When soaking was completed, 10-mL aliquots were removed from the leachate, 10% nitric was added to dissolve any silver particles present, and the

	tap water 1.6 ± 0.3 mg Ag/kg product saliva 1.2 ± 0.1 mg Ag/kg product sweat 4.8 ± 0.3 mg Ag/kg product urine 3.7 ± 0.3 mg Ag/kg product HCl 4.7 ± 0.0 mg Ag/kg product saline 4.0 ± 0.0 mg Ag/kg product 4) sippy cup 1: rubber ring (24.3 ± 2.9 mg Ag/kg product) milk formula Not Detected orange juice 0.41 ± 0.01 mg Ag/kg product 5) sippy cup 1: transparent cap (9.4 ± 1.0 mg Ag/kg product) milk formula Not Detected orange juice 0.07 ± 0.01 mg Ag/kg product 6) sippy cup 2: spout cover (2.1 ± 1.5 mg Ag/kg product) milk formula 0.93 ± 0.02 mg Ag/kg product orange juice Not Detected 7) breast milk storage bags (0.9 ± 0.6 mg Ag/kg product) milk formula Not Detected. Amount of silver transferred from surfaces onto dermal wipes: 1) baby blanket 23.0 ± 1.4 μg/m^2 2) plush toy: exterior 13.8 ± 8.4 μg/ m^2 3) disinfecting spray 9.0 ± 2.8 μg/ m^2 4) surface wipes 2.3 ± 0.2 μg/ m^2 5) kitchen scrubber 0.3 ± 0.1 μg/ m^2 The tabletop humidifier emitted 2.3 ± 0.7 ppb of silver in the condensed vapor, while the manual humidifier did not emit detectable levels of total silver. Ambient aerosol concentrations were not significantly elevated above background levels (∼3−6 × 103 cm−3 for aerosols 14−750 nm and <150 cm−3 for aerosols 0.3−10 μm in diameter) during product use. If these products emit any form of silver-containing aerosols, the emission rates are very low.	leachate was analyzed for silver content using inductively coupled plasma mass spectrometry (ICP-MS) with detection limit of 0.5 ppb. NIOSH Method 9102: Elements on Wipes that specifies the use of ASTM E 1792-01 benzalkonium chloride moist towelettes was used to evaluate skin exposures. In this swipe method, the sampled surface is swiped three times using overlapping “S” patterns with horizontal and vertical strokes. Towelettes were digested in HNO^3 and H^2O^2 and analyzed for silver content by ICP-MS. To evaluate release from humidifiers, The water reservoir of each humidifier was completely filled with tap water and left at room temperature for 5−6 days. Water samples from each basin were collected, acidified with 10% HNO^3, and analyzed by ICP-MS. To assess the total silver concentration in the vapor produced by each humidifier, the humidifier reservoirs were filled with tap water and left for 3 days. Using PVC reducing pipe and tubing, the outlet of each humidifier was routed through a sealed beaker submerged in ice, to promote condensation inside the beaker (∼20 mL). The condensate was then acidified with 10% HNO^3 and analyzed by ICP-MS. Concentrations and size distributions of aerosols 14−750 nm in diameter were measured using a scanning mobility particle sizer (SMPS 3936, TSI). Larger aerosols (300 nm−10 μm in diameter) were measured using an optical particle counter (Aerotrak, TSI).

Emission material	Almost all of the silver released is thought to be in ionic rather than particulate form.	
Total Dose/Biomarkers		
Total exposure	Ranking of product categories according to their potential for silver bioavailability, from most likely to least likely to be a source of bioavailable silver: plush toy and fabric products (e.g., teddy bear, clothing, blanket), cleaning products (e.g., disinfecting spray and surface wipes), sippy cups, humidifiers, breast milk storage bag, and kitchen scrubber.	

9. **Data gaps**: exposures and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Table 6. Consumer exposure simulation 1 conducted by KIST (Ref. 17).

Endpoint	**Value/characteristics**	**Method**
Exposure situation (process, facility, operation…)	Nanoaerosol release pattern of an electronic nanoproduct was investigated. The commercial hand dryer having a filter coated with silver nanoparticles was selected as a test nanoproduct and the experiment was carried out in a test chamber.	Test chamber having volume of the 93 L (41 × 35 × 65 cm) large enough to install a full-scale test product such as a hand dryer.
Materials used	Commercial hand dryer having a filter coated with silver nanoparticles	
Emission sites	Commercial hand dryer having a filter coated with silver nanoparticles in a test chamber	
Emission levels	Ranged 10-20 and 150-200 particles/cm^3 for the 1-min and 10-min operation, which are significantly lower than background aerosol level in indoor	The total particle number concentration inside the chamber was monitored every second by using a condensation particle counter (CPC, TSI model 3010) with a detection limit of 10 nm.

	environment (~5,000 to 10,000 particles/cm^3).	
Emission material	Nanoparticles, but chemical composition was not determined due to small amount	
Exposure material	Nanoparticles, but chemical composition was not determined due to small amount	

10. **Data gaps**: exposures and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Table 7. Consumer exposure simulation 2 conducted by KIST (Ref. 18).

Endpoint	**Value/characteristics**	**Method**
Exposure situation (process, facility, operation…)	Nanoaerosol release pattern of an electronic nanoproduct was investigated. The commercial hair irons coated with silver nanoparticles was selected as a test nanoproduct and the experiment was carried out in a test chamber.	Test chamber having volume of the 93 L (41 × 35 × 65 cm) large enough to install a full-scale test product such as a hair irons.
Materials used	Commercial hair irons coated with or without silver nanoparticles	
Emission sites	Commercial hair irons coated with or without silver nanoparticles in a test chamber	
Emission levels	Approximately 40,000 particles/cm^3 when hair iron was operated both products coated with and without silver nanoparticles.	The total particle number concentration inside the chamber was monitored every second by using a condensation particle counter (CPC, TSI model 3010) with a detection limit of 10 nm.
Emission material	Probably evaporation of organic materials	
Exposure material	Probably evaporation of organic materials	

11. **Data gaps**: exposures and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Table 8. Consumer exposure simulation 3 conducted by KIST (Ref. 18).

Endpoint	**Value/characteristics**	**Method**
Exposure situation (process, facility, operation…)	Nanoaerosol release pattern of a face mask was investigated. The commercial face mask coated with silver nanoparticles was selected as a test nanoproduct and the experiment was carried out in a test chamber.	Test chamber having volume of the 27 L (30 × 30 × 30 cm) and it was designed to install a small-scale test product such as a face mask.
Materials used	Commercial face mask coated with silver nanoparticles	
Emission sites	Ccommercial face mask coated with silver nanoparticles in a test chamber	
Emission levels	Approximately 5 particles/cm^3 when continuous air jet was impinged	The total particle number concentration inside the chamber was monitored every second by using a condensation particle counter (CPC, TSI model 3010) with a detection limit of 10 nm.
Emission material	Nanoparticles but not determined	
Exposure material	Nanoparticles but not determined	

12. Data gaps: exposures and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Table 9. Consumer exposure simulation 4 conducted by KIST (Ref. 18).

Endpoint	**Value/characteristics**	**Method**
Exposure situation (process, facility, operation…)	Nanoaerosol release pattern of unused inner pants was investigated. The commercial inner pants coated with silver nanoparticles was selected as a test nanoproduct and the experiment was carried out in a test chamber due to possible release of silver nanoparticles during drying	Test chamber having volume of the 27 L (30 × 30 × 30 cm) and it was designed to install a small-scale test product such as inner pants.
Materials used	Commercial inner pants coated with silver nanoparticles	
Emission sites	Ccommercial inner pants coated with silver nanoparticles in a test chamber	
Emission levels	Approximately 13 particles/cm^3 when pulsed air jet was impinged and measured by particle counter in the test chamber.	The total particle number concentration inside the chamber was monitored every second by using a condensation particle counter (CPC, TSI model 3010) with a detection limit of 10 nm.
Emission material	Nanoparticles but not determined	
Exposure material	Nanoparticles but not determined	

13. **Data gaps**: exposures and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

DATA FOR EXPOSURE ENDPOINTS FOR NANO-SILVER FROM OTHER SOURCES

Human occupational exposure

Table 10. Existing exposure endpoints (Ref. 3).

Endpoint	Value/characteristics	Method
Exposure situation (process, facility, operation…)	commercial nano-silver production facility; 3000 kg/month; liquid-phase reduction of $AgNO_3$ by a dispersing agent resulting in a colloidal suspension of 50-60 nm particles.	
Materials used	silver nanoparticles capped with a dispersing agent	
Emission sites	reaction room; drying room; grinding room	
Emission levels	emission at reactor hatch opening is $11x10^6$ cm^{-3} of particle with median diameter of 76 nm; emission at dryer door opening is $1.3x10^6$ cm^{-3} of particle with median diameter of 64 nm; emission at grinder hatch opening is $2.5x10^6$ cm^{-3} of particle with median diameter of 35 nm.	Scanning Mobility Particle Sizer (EPS 4410, CPC 4312, Soft X-ray charger 4530, HCT Co., Korea) equipped with a long differential mobility analyzer (LDMA; DMA 4620, HCT Co., Korea) was used for the real-time measurement of temporal changes in particle size distribution. Electrostatic precipitator (ESP; Nano Particle Collector 4650, HCT Co., Korea) was used to deposit particles onto a TEM grid. TEM was used to confirm the surface area, components, and morphology of the particles.

* CPC, Condensation particle counter; LDMA, long differential mobility analyzer; TEM, transmission electron microscopy

14. **Data gaps**: exposures and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Human non-occupational exposure

Table 11. Existing exposure endpoints (Ref. 4)

Endpoint	Value/characteristics	Method
Exposure situation (process, facility, operation…)	skin and inhalation exposure of consumers to nano-silver via the use of a bathroom cleaning product	
Materials used	1% suspension of nano-silver in a bathroom cleaning product	
Inhalation Exposure		
Personal exposure - peak	ECETOC TRA: 0.0175 mg/m^3, corresponding to 0.0016 mg/kg bw/event ConsExpo: 0.000356 mg/m^3, corresponding to 3.3 x 10-6 mg/kg bw/event	modelling using the European Centre for Ecotoxicology and Toxicology of Chemicals, Targeted Risk Assessment (ECETOC TRA) model (revised first tier version for REACH) and ConsExpo (version 4.1). The ECETOC TRA is a first tier model, based on default algorithms and default assumptions for input parameters. These default assumptions are fixed for most input parameters; only those for weight fraction and body weight (adult or child) can be replaced by product-specific values. The resulting exposure estimate is a worst-case estimate, because for inhalation this model assumes instantaneous release of the substance and no removal by *e.g.* ventilation, and for dermal exposure that 100 % of the substance is in contact with the skin. ConsExpo is a higher tier model, with more complex algorithms and more specific descriptions of exposure processes, with consideration of time-dependent processes (such as migrations/release from a matrix) and disappearance from a medium (such as via ventilation). The

		resulting exposure estimate is therefore more realistic, also because most default input parameters can be replaced by more specific values. Both models are generally used for human exposure assessment of normal, non-nano substances and have not been validated for nanoparticles.
Dermal/Ocular exposure		
Personal exposure - peak	ECETOC TRA: 1.43 mg/kg bw/event Cons Expo: 0.0106 mg/kg bw/event	The same as above
GI exposure		
Personal exposure - peak	Cons Expo: 0.000317 mg/kg bw/event	The same as above
Total Dose/Biomarkers		
Total exposure	ECETOC TRA: 1.43 mg/kg bw/event Cons Expo: 0.011 mg/kg bw/event	The same as above

15. **Data gaps**: exposure materials were not characterized in this study and therefore these endpoints are missing from the table.

Table 12. Existing exposure endpoints (Ref. 4).

Endpoint	**Value/characteristics**	**Method**
Exposure situation (process, facility, operation…)	indirect exposure via drinking water	
GI exposure		

Personal exposure – (day)	0.086 µg/kg bw/day	Exposure modeling: humans are exposed to 2 L/d of untreated river water as drinking water; Predicted Environmental Concentration (PEC_{local}) in the river water is 0.0030 mg/L obtained in environmental emission calculations.

16. **Data gaps**: exposure materials, inhalation and dermal/ocular exposures and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Exposure to biota

Table 13. Existing exposure endpoints (Ref. 4).

Endpoint	**Value/characteristics**	**Method**
Exposure situation (process, facility, operation…)	100 tons/year of bathroom cleaner with 1% silver is released into the environment via the sewer system and a municipal waste water treatment plant as a result of private use.	
Water		
Emission levels	local emission to surface water of 0.00274 mg/L	Modeling using EUSES with default assumptions.

17. **Data gaps**: emissions and exposures in air and soil and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Table 14. Existing exposure endpoints (Ref. 5).

Endpoint	**Value/characteristics**	**Method**
Exposure situation (process, facility, operation…)	release of nano-silver from categories of products: textiles, cosmetics/supplements, sprays/cleaning agents, metal products, plastics, paint/sealings during use and disposal.	
Air		
Exposure level	Predicted Environmental Concentration Realistic Exposure – 1.7x10-3 µg/m^3 High Exposure – 4.4x10^{-3} µg/m^3.	Modeling using substance flow analysis
Water		
Exposure level	Predicted Environmental Concentration Realistic Exposure – 0.03 µg/L High Exposure – 0.08 µg/L.	Modeling using substance flow analysis
Soil		
Exposure level	Predicted Environmental Concentration Realistic Exposure – 0.02 µg/kg High Exposure – 0.1 µg/kg.	Modeling using substance flow analysis

18. **Data gaps**: total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

Table 15. Existing exposure endpoints (GER: UMSICHT project funded by Federal Ministry of Education and Research [BMBF]).

Endpoint	**Value/characteristics**	**Method**
Exposure situation (process, facility, operation…)	Release of nano-silver from textiles intended for domestic uses: Environmental exposure scenarios for nano-silver consider the washing of textiles in domestic homes and the release of wastewater to WWTPs. Data on ecotoxicological effects and environmental fate of the nano-silver NM300-K (material 2) as well as data on emission data for nano-silver from textiles were derived from a German joint research project called UMSICHT. Emission data consider the concentrations of nano-silver released from three different textile types (cotton, polyester, lyocell cellulose fibre) upon standardized washing processes (DIN EN ISO 105 C12-2S) at differing temperatures. Maximum release rates were used for a conservative scenario. Concentrations of nano-silver for sewage sludge and PECs of nano-silver for the environmental compartments surface water, sediment and soil (after sewage sludge application) were deduced. For the derivation of PECs an exposure approaches have been used considering the emission based on technological process data: Emissions of nano-silver from textiles into WWTP per inhabitant (GER) and day: Scenario A (cotton): 312.5 $\mu g \cdot inh^{-1} \cdot d^{-1}$ Scenario B (polyester): 162.5 $\mu g \cdot inh^{-1} \cdot d^{-1}$ Scenario C (lyocell fibre): 21.9 $\mu g \cdot inh^{-1} \cdot d^{-1}$	Calculations are based on the ECHA Guidances on Information Requirements and Chemical Safety Assessment and technological process data, e.g. weight of laundry, fraction of nano-silver-containing textiles per washing, nano-silver emission from nano-silver containing laundry, assumed washing per day, no. of washing machines per inhabitant.

19. **Data gaps**: emissions and exposures in air and total dose/biomarkers were not characterized in this study and therefore these endpoints are missing from the table.

WWTP		
Exposure level	Effluent: Predicted Concentration Scenario A (cotton): 0.156 µg/L Scenario B (polyester): 0.081 µg/L Scenario C (lyocell fibre): 0.011 µg/L Sludge: Predicted Concentration Scenario A (cotton): 3.96 mg/kg_{dw} Scenario B (polyester): 2.06 mg/kg_{dw} Scenario C (lyocell fibre): 0.28 mg/kg_{dw}	Assuming 10 000 inhabitants per WWTP, a volume of 200 L waste water per day and inhabitant, a fraction of 10 % of nano-silver remaining in the effluent and 90% of nano-silver in the sewage sludge and a sludge rate of 710 kg/d
Surface Water		
Exposure level	Predicted Environmental Concentration Scenario A (cotton): 15.63 ng/L Scenario B (polyester): 8.13 ng/L Scenario C (lyocell fibre): 1.09 ng/L	Assuming a fraction of 10% of nano-silver remaining in the effluent, a volume of 200 L waste water per day and inhabitant and a 10fold dilution of waste water in the receiving water body
Sediment		
Exposure level	Predicted Environmental Concentration Scenario A (cotton): 4.08 $µg/kg_{dw}$ Scenario B (polyester): 2.12 $µg/kg_{dw}$ Scenario C (lyocell fibre): 0.29 $µg/kg_{dw}$	Using the arithmetic mean of retention coefficients for the investigated nano-silver in soils of 257.7 L/kg since adsorption coefficients for nano-silver in sediment were not available and assuming a volume fraction of water in suspended matter of 90%, of suspended matter of 10 %, a density of solid phase of 2500 kg/m^3, a bulk density of suspended matter (wet) of 1150 kg/m^3 and a conversion factor sediment (ww) to sediment (dw) of 4.6
Soil		
Exposure level	Predicted Environmental Concentration Scenario A (cotton): 6.62 $µg/kg_{dw}$ Scenario B (polyester): 3.44 $µg/kg_{dw}$ Scenario C (lyocell fibre): 0.46 $µg/kg_{dw}$	Application via sewage sludge assuming an application rate of sewage $sludge_{dw}$ of 5 tons/hectare in 3 years (according to the sewage sludge regulation (AbfKlärV), a soil density of 1.5 g_{dw}/cm^3 and a soil depth of 0.2 m

CONCLUSIONS

20. Some limited data on nano-silver emissions in the workplace already existed or were developed for this case study. More studies are underway looking at consumer exposures to products treated with nano-silver. However, personal exposure data is still very limited. Specifically for the following exposure groups:

- **human occupational exposure**: Data on personal peak exposures, dermal/ocular and GI exposures and total dose/biomarkers is either unavailable or very limited;

- **human non-occupational exposure**: Data on exposures are limited to modelling for some uses of consumer products containing nano-silver; and

- **exposure to biota**: Data on total dose/biomarkers is not available.

21. The main technical challenge for this case study was the lack of standardized protocols for exposure measurements. The *OECD guidance on Emission Assessment for Identification of Sources and Release of Airborne Manufactured nanomaterials in the Workplace: compilation of existing guidance emission assessment* (reference 6) was used as a reference material. However, this document was recently superseded by the OECD document on *Harmonized tiered approach to measure and assess the potential exposure to airborne emissions of engineered nano-objects and their agglomerates and aggregates at workplaces* (reference 21).

22. Another challenge was the lack of consensus as to which measurement unit is to be preferred in measuring nanomaterials (weight, particle numbers, particle size distribution, surface area), and there may not be one unit that can be applied for each exposure scenario.

23. To make collected exposure data more useful in risk assessment, the following suggestions were made:

- Collect more detailed information, including repeated measures of exposure by job/task, perhaps, in the form of job-exposure matrix, and estimation of individual workers' exposures.

- Apart from data on exposure in production facilities for nanoparticles and use of consumer products, it would be worthwhile to evaluate exposure resulting in manufacture from treatment with nano-silver, e.g. in textile production, and resulting from processing of nano-silver treated goods, e.g. cutting and sewing nano-silver treated textiles. Likewise, the influence of wear and tear on release from consumer products should deserve some attention.

- Collect exposure data, including reliable information on background exposure to silver (e.g. through food and water) and aggregate (cumulative) exposure to silver from multiple sources. Such exposure data can be linked with human health effects data and used to develop a model that predicts the adverse health effects and which is based on a exposure-response relationship and a physiologically based pharmacokinetic model.

- Collect human exposure data to give an indication of whether worker exposures are above or below the critical health effect level for humans which was obtained by extrapolation from the animal data.

- Collect more detailed information on releases of nano-silver from products or applications over the entire life circle into the different environmental compartments. Develop appropriate methods and models to specifically estimate the environmental exposure of nano-silver. Consider aggregated environmental exposure of (nano) silver from different sources.

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ANNEX. TEMPLATE FOR COLLECTING THE DATA AND REPORTING INFORMATION ON EXPOSURE

Reporting exposure endpoints for human occupational and non-occupational exposure

Endpoint	Value/characteristics	Method
Exposure situation (process, facility, operation…)		
Materials used		
Emission sites		
Emission levels		
Emission material		
Exposure material		
Inhalation Exposure		
Personal exposure - peak		
Personal exposure – 8h TWA		
Dermal/Ocular exposure		
Personal exposure - peak		
Personal exposure – 8h TWA		
GI exposure		
Personal exposure - peak		
Personal exposure – 8h TWA		
Total Dose/Biomarkers		
Total exposure		

Reporting human surveillance data

Human data				
	TSP*(mg/m^3)	**Air Ag (mg/m^3)**	**Blood (µg/dL)**	**Urine(µg/dL)**
Person #1				

*TSP – Total suspended particulate

Reporting exposure endpoints for exposures to biota

Endpoint	Value/characteristics	Method
Exposure situation (process, facility, operation…)		
Materials used		
Air		

Emission sites		
Emission levels		
Emission material		
Exposure level		
Exposure material		
Water		
Emission sites		
Emission levels		
Emission material		
Exposure level		
Exposure material		
Soil		
Emission sites		
Emission levels		
Emission material		
Exposure level		
Exposure material		
Total Dose/Biomarkers		
Total exposure		