ID Card
Silver

Version 19 June 2017

Notes:

- *This ID card is used to support the substance sameness discussions in SIEFs and to describe the substance to the best of the SIEF members' knowledge.*
- *It also aims at grouping communications relevant to the request of available data or information, the approval of the proposed Lead Registrant and the registration strategy with the SIEF.*
- *It is the responsibility of each individual registrant to identify their substance and to report company-specific identity in their Registration Dossier (section 1 of IUCLID).*

1. Identification of the substance

Table 1. Identification of the substance

	Original (in EC inventory)
Name	Silver
EC number	231-131-3
CAS number	7440-22-4
Description	Not available
Composition type	Mono-constituent substance

2. Synonyms and other identifiers of the substance

None

3. Substances (with core identifiers) also falling under this substance (with justification)

None

4. Information related to molecular and structural formula of the substance

Table 2. Information related to molecular and structural formula of the substance

Molecular formula	Ag
Structural formula	Ag
Smiles notation	[Ag]
Optical activity	
Typical ratio of (stereo) isomers	Not applicable
Molecular Weight / Molecular Weight range	107,87 g/mol

5. Typical composition of the substance

Silver can be placed on the market in nanoforms, fine and coarse powders, and massive forms (e.g.: rods, wire, bars, etc.). Varying particle sizes may influence the classification. All forms of silver will be addressed in the same Registration Dossier but are reported individually in IUCLID section 1.2 and linked to the appropriate classification.

5.1. Silver ≥ 99,9 % Ag in massive form (> 1 mm) – not classified

Table 3. Typical composition

	Name	Symbol / Formula	Typical concentration (range) (%)
Main constituent(s)*	Silver	Ag	≥ 99,9

***** ≥ 80 % (w/w) for mono-constituent substances; ≥ 10 % (w/w) and < 80 % (w/w) for multi-constituent substances.

The composition given above is typical and should therefore represent the majority of Silver ≥ 99,9 % Ag in massive form (> 1 mm) as placed on the EEA market.

5.2. Silver < 99,9 % Ag in massive form (> 1 mm) with no classified impurities – not classified

Table 4. Typical composition

	Name	Symbol / Formula	Typical concentration (range) (%)
Main constituent(s)*	Silver	Ag	≥ 80 - < 99,9
Impurity(ies)#	Several impurities which do not affect the classification of the substance	Au, PGM, Cu, Ni, Pb	> 0,1 - < 20

***** ≥ 80 % (w/w) for mono-constituent substances; ≥ 10 % (w/w) and < 80 % (w/w) for multi-constituent substances.

An impurity is an unintended constituent present in a substance, as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While impurities are present in the final substance, they were not intentionally added.

The composition given above is typical and should therefore represent the majority of Silver < 99,9 % Ag in massive form (> 1 mm) as placed on the EEA market.

5.3. Silver ≥ 99,9 % Ag in powder form (> 100 nm and < 1 mm) – classified for environment

Table 5. Typical composition

	Name	Symbol / Formula	Typical concentration (range) (%)
Main constituent(s)*	Silver	Ag	≥ 99,9

***** ≥ 80 % (w/w) for mono-constituent substances; ≥ 10 % (w/w) and < 80 % (w/w) for multi-constituent substances.

The composition given above is typical and should therefore represent the majority of Silver ≥ 99,9 % Ag in powder form (< 1 mm) as placed on the EEA market.

5.4. Silver < 99,9 % Ag in powder form (> 100 nm and < 1 mm) with no classified impurities – classified for environment

Table 6. Typical composition

	Name	Symbol / Formula	Typical concentration (range) (%)
Main constituent(s)*	Silver	Ag	≥ 80 - < 99,9
Impurity(ies)#	Several impurities which do not affect the classification of the substance	Au, PGM, Cu, Ni, Pb	> 0,1 - < 20

***** ≥ 80 % (w/w) for mono-constituent substances; ≥ 10 % (w/w) and < 80 % (w/w) for multi-constituent substances.

An impurity is an unintended constituent present in a substance, as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While impurities are present in the final substance, they were not intentionally added.

The composition given above is typical and should therefore represent the majority of Silver < 99,9 % Ag in powder form (< 1 mm) as placed on the EEA market.

5.5. Silver ≥ 99,9 % Ag in nanoform (≤ 100 nm) – classified for environment

Table 7. Typical composition

	Name	Symbol / Formula	Typical concentration (range) (%)
Main constituent(s)*	Silver	Ag	≥ 99,9

***** ≥ 80 % (w/w) for mono-constituent substances; ≥ 10 % (w/w) and < 80 % (w/w) for multi-constituent substances.

The composition given above is typical and should therefore represent the majority of Silver ≥ 99,9 % Ag in nanoform (≤ 100 nm) as placed on the EEA market.

Nanosilver products placed on the market can contain additional chemicals often indistinguishably named surface coatings, solvents or dispersion agents (e.g alcohols, polyvinylpyrrolidone (PVP), citrate, cellulose, and other carbohydrates and fatty acids). Based on the available information on the relative hazard and fate properties of ionic silver and nanosilver (including various size ranges and surface coatings) the silver REACH dossier is also considered to adequately address the properties of nanosilver materials with surface coatings that have been added during the manufacturing process and have the primary function of preventing agglomeration or aggregation of primary particles in suspension and where the coating material can also be demonstrated by the individual registrants to be of no or less toxicity than ionic silver. Nanosilver products/preparations containing co-solvents and/or dispersion agents rather than surface coating should be considered as mixtures/preparations rather than as discrete forms of silver.

Any nanosilver product with a surface coating which is specifically designed to interact with biological receptors and/or which have hazardous properties in their own right (e.g. meet the criteria for SVHC, including PBT or vPvB properties) are explicitly not covered by the silver REACH dossier. In addition, multi-

metal (alloy) nanomaterials containing elemental silver (i.e. particles composed of silver together with one or more additional metals) are outside the scope of this registration. Specific (and sometimes confidential) information on the composition, particle size, surface area, and identity and intended function of any surface coating applied to a nanosilver product included in a REACH registration will be included in the individual registrants' dossiers rather than in the joint dossier.

5.6. Silver < 99,9 % Ag in nanoform (≤ 100 nm) with no classified impurities – classified for environment

Table 8. Typical composition

	Name	Symbol / Formula	Typical concentration (range) (%)
Main constituent(s)*	Silver	Ag	≥ 80 - < 99,9
Impurity(ies)#	Several impurities which do not affect the classification of the substance	Au, PGM, Cu, Ni, Pb	> 0,1 - < 20

***** ≥ 80 % (w/w) for mono-constituent substances; ≥ 10 % (w/w) and < 80 % (w/w) for multi-constituent substances.

An impurity is an unintended constituent present in a substance, as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While impurities are present in the final substance, they were not intentionally added.

The composition given above is typical and should therefore represent the majority of Silver < 99,9 % Ag nanoform (≤ 100 nm) as placed on the EEA market.

Nanosilver products placed on the market can contain additional chemicals often indistinguishably named surface coatings, solvents or dispersion agents (e.g alcohols, polyvinylpyrrolidone (PVP), citrate, cellulose, and other carbohydrates and fatty acids). Based on the available information on the relative hazard and fate properties of ionic silver and nanosilver (including various size ranges and surface coatings) the silver REACH dossier is also considered to adequately address the properties of nanosilver materials with surface coatings that have been added during the manufacturing process and have the primary function of preventing agglomeration or aggregation of primary particles in suspension and where the coating material can also be demonstrated by the individual registrants to be of no or less toxicity than ionic silver. Nanosilver products/preparations containing co-solvents and/or dispersion agents rather than surface coating should be considered as mixtures/preparations rather than as discrete forms of silver.

Any nanosilver product with a surface coating which is specifically designed to interact with biological receptors and/or which have hazardous properties in their own right (e.g. meet the criteria for SVHC, including PBT or vPvB properties) are explicitly not covered by the silver REACH dossier. In addition, multi-metal (alloy) nanomaterials containing elemental silver (i.e. particles composed of silver together with one or more additional metals) are outside the scope of this registration. Specific (and sometimes confidential) information on the composition, particle size, surface area, and identity and intended function of any surface coating applied to a nanosilver product included in a REACH registration will be included in the individual registrants' dossiers rather than in the joint dossier.

6. Information on appearance, physical state and properties of the substance

Table 9. Appearance / physical state / properties of the solid substance

Physical state	Solid
Physical form*	Crystalline
Appearance	Grey-metallic powder or massive
Particle size**	Nanoform / Fine powder / Coarse powder / Massive object
Does the substance contain 'bound water'?#	No
Does the substance contain 'crystallisation water'?#	No
Does the solid hydrolyse?##	No
Is the solid hygroscopic?§	No

***** Crystalline form: solid material whose constituent atoms, molecules, or ions are arranged in an ordered pattern extending in all three spatial dimensions. Amorphous form: solid material whose constituent atoms, molecules, or ions are randomly arranged.

** Nanoform: particles in the size range 1 - 100 nm (for full definition of a nanomaterial, see http://ec.europa.eu/environment/chemicals/nanotech/index.htm#definition). Fine powder: particles in the size range 100 – 2.500 nm. Coarse powder: particles in the size range 2.500 nm – 1 mm. Massive object: particles in the size range > 1 mm.

'Bound water': water molecules that are coordinated as bound ligands. 'Crystallisation water' or hydration water: water that occurs in crystals (necessary for the maintenance of crystalline properties) but which is not directly bound to the metal ion (a hydrate contains a definite % of crystallisation water e.g. CuSO4 x 5 H2O, an anhydride does not contain any water)

Hydrolysis: decomposition (cleavage of chemical bonds) by the addition of water.

§ Hygroscopic substance: readily attracts moisture from its surroundings in open air, through either absorption or adsorption. Cf. also water/moisture content in tables under section 5.

7. Analytical data

Annex VI of REACH requires the registrant to describe the analytical methods and/or to provide the bibliographical references for the methods used for identification of the substance and, where appropriate, for the identification of impurities and additives. This information should be sufficient to allow the methods to be reproduced.

Table 10. Analytical methods for identification of the substance

Parameter / Method	Recommended for substance identification and sameness check	Applicable	Not applicable or not recommended
Elemental analysis			
ICP (ICP-MS or ICP-OES)	X		
Atomic absorption spectroscopy (AAS)		X	
Glow discharge mass spectrometry (GDMS)			X
Molecular analysis			
Infrared (IR) spectroscopy			X
Raman spectroscopy			X
Mineralogical analysis			
X-Ray Fluorescence (XRF)			X
X-Ray Diffraction (XRD)			X

Morphology and particle sizing			
Electron microscopy (SEM, TEM, REM)* #	X		
Laser diffraction* #	X		
Particle size by other means (e.g. sieve analysis)#			X
Surface area by N-BET* #	X		
Other			
Gravimetric weight loss analysis for determination of residual solvent and organics on the surface of the metal Thermal Gravimetric Analysis (TGA) will determine the same as above.	X		
KSCN titration for assay determination	X		
Field emission SEM for PSD and morphology determination of nano Ag	X		
Screen analyses for PSD determination of coarse powders	X		

* Analytical techniques particularly (but not exclusively) relevant for nanomaterials.
# The choice of the technique for particle size depends on the size of the material as manufactured/imported/placed on the market/used.

EPMF Recommendation:
Based on guidance and knowledge available to EPMF and EBRC Consulting GmbH by July 2013, below recommended characterisation steps should be performed by each legal entity for each type of nanomaterial in order to satisfy the requirements/expectations of ECHA and other authorities:

1. **Select and prepare adequate sample**: Cf. e.g. ISO 14887:2000 and OECD's "Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials" (2012).
2. **Determine substance composition**: The recommended technique will depend on the nature of the substance and on the type of information which needs to be provided (elemental, oxidation state, compounds, species, etc.). The information provided needs to be sufficient to demonstrate the identity of the substance, confirm sameness across joint registrants of the substance, and demonstrate suitability of the risk assessment (i.e. that the substance registered is properly covered by the (worst case/conservative) working assumptions and scope of the assessment). The technique shall be able to identify:
   - Main and minor constituent(s);
   - Impurities (normally resulting from the process used to manufacture the substance); and
   - Additives necessary to preserve the stability of the substance and which cannot be separated without affecting the stability of the substance or changing its composition (e.g. coating preventing a nanomaterial from agglomerating).
3. **Determine particle size distribution**: Determine the volume based distribution (by DLS / laser diffraction) + number based distribution (can theoretically be calculated from the volume based distribution but with some uncertainty). At this point in time, it appears most feasible to use image analysis of REM/TEM images, i.e. counting of particles of different sizes on the images. This can be done (semi-)automatically by some laboratories. (NOTE: DLS only is not appropriate or sufficient as it is heavily weighted towards detection of larger agglomerates; the intensity of the DLS signal varies in proportion to the sixth power of the diameter of the particle (Domingoes et al. 2009)).
4. **Determine surface area**: BET for dry powders. For suspensions, estimate surface area on the basis of particle size distribution (if shape of particles is more or less spherical);
5. **Report detailed morphology**: Digital light microscopic images + either TEM or REM to qualitatively describe the shape and the agglomeration behaviour of the particles.

The results of this characterisation work will need to be attached to the registrants' individual IUCLID 5 files and reported to the entity preparing the joint registration dossier so the individual registrants' information can be reported in an aggregated manner in the joint dossier and provide an indication of the boundaries of applicability/coverage of the scope of the dossier.
Note: Discussion between industry, authorities and researchers on the definition and characterisation of nanomaterials are still on-going (July 2013). Therefore, neither EBRC nor EPMF can be made liable for any follow up efforts or costs, in case the experimental work suggested above is not accepted or is deemed insufficient by authorities.

8. Lead Registrant

Aurubis AG (Germany) volunteers to be the Lead Registrant for Silver. The EPMF will provide support to the Lead Registrant as laid down in the EPMF Agreement.

9. REACH Strategy

The table below presents the overall Registration Strategy for Silver based on the information available to the EPMF by the date given above on the document.
The Registration Dossier will be prepared for the highest substance status (information requirements associated to a substance or Article 10 Registration being higher than an intermediate handled under strictly controlled conditions or Article 17 or 18 one) and associated tonnage band.
The recap below therefore reflects the scope of work of the EPMF for Silver and sets the minimum and maximum set of information that will be gathered and/or produced when preparing the Registration Dossier for Silver as described in this ID Card.
If higher information requirements are necessary, these can be included in the Registration dossier (if EPMF is made aware of these additional requirements in-time) as an update to the already submitted dossier.

Table 11. REACH strategy for the substance (basis for REACH Registration preparation)

Item	Description	
REACH category	Mono-constituent substance	
Highest status	Substance	
Highest tonnage band	> 1000 t/a	
Information requirements	Available / Existing + Annex VII – VIII – IX - X	
Existing classification*	Silver ≥ 99,9 % Ag in massive form (> 1 mm) – not classified	None
	Silver < 99,9 % Ag in massive form (> 1 mm) with no classified impurities – not classified	None
	Silver ≥ 99,9 % Ag in powder form (< 1 mm) – classified for environment	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Acute M-factor 10 Chronic M-factor 10
	Silver < 99,9 % Ag in powder form (< 1 mm) with no classified impurities – classified for environment	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Acute M-factor 10 Chronic M-factor 10
	Silver ≥ 99,9 % Ag in nanoform (≤ 100 nm) – classified for environment	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Acute M-factor 1000 Chronic M-factor 100
	Silver < 99,9 % Ag in nanoform (≤ 100 nm) with no classified impurities – classified for environment	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Acute M-factor 1000 Chronic M-factor 100
Registration deadline	2010	
Other REACH titles	Silver is on the CoRAP list for Substance Evaluation by The Netherlands REACH Competent Authorities (RIVM) in 2014	

***** Classification notified (February 2012)

10. Scope of the Registration Dossier

The uses included in this Registration Dossier are listed on the EPMF website.