CHEMICAL SAFETY REPORT

Substance Name: gold

EC Number: 231-165-9

CAS Number: 7440-57-5

Registrant's Identity: WCA Environment ltd

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Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

This substance does not meet criteria for being classified as a PBT, vPvB, or dangerous chemical, therefore specific risk management measures are not required to be included in Sections 9 and 10 of the CSR.

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

This substance does not meet criteria for being classified as a PBT, vPvB, or dangerous chemical, requiring specific risk management measures; however general principles of safe handling and use are followed.

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

This substance does not meet criteria for being classified as a PBT, vPvB, or dangerous chemical, requiring specific risk management measures; however general principles of safe handling and use are followed.

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

The substance **gold** is an element having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

Table 1. Substance identity

EC number:	231-165-9
EC name:	gold
CAS number (EC inventory):	7440-57-5
CAS name:	Gold
IUPAC name:	gold(1+)
Molecular formula:	Au
Molecular weight range:	196.966

Structural formula:

Au

1.2. Composition of the substance

Name: Gold massive

Description: Mono constituent substance.

Degree of purity: 99.5 — 100.0 % (w/w)

Table 2. Constituents

Constituent	Typical concentration	Concentration range	Remarks
gold EC no.: 231-165-9	99.95 % (w/w)	99.5 — 100.0 % (w/w)	

Table 3. Impurities

Impurity	Typical concentration	Concentration range	Remarks
Impurities	0.05 % (w/w)	0.0 — 0.5 % (w/w)	Several impurities such as Ag, Platinum Group Metals (PGM), Cu, Ni and Pb which do not affect the classification of the substance because of their non-hazardous nature or because they do not exceed the classification cut-off limits in the substance

Name: Gold powder

Description: Mono constituent substance.

Degree of purity: 99.5 — 100.0 % (w/w)

Table 4. Constituents

Constituent	Typical concentration	Concentration range	Remarks
gold EC no.: 231-165-9	99.95 % (w/w)	99.5 — 100.0 % (w/w)	

Table 5. Impurities

Impurity	Typical concentration	Concentration range	Remarks
Impurities	0.05 % (w/w)	0.0 — 0.5 % (w/w)	Several impurities such as Ag, Platinum Group Metals (PGM), Cu, Ni and Pb which do not affect the classification of the substance because of their non-hazardous nature or because they do not exceed the classification cut-off limits in the substance

1.3. Physicochemical properties

Table 6. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	Gold is a soft, yellow metal	**Value used for CSA:** solid at 20°C and 101.3 kPa Statements on appearance are taken from

Property	Description of key information	Value used for CSA / Discussion
		two peer-reviewed handbooks (Lide 2008, O'Neil 2006). These are considered suitable for use as key studies for this endpoint.
Melting / freezing point	The melting point of gold is 1064.18°C - 1064.76°C	Melting point values are taken from two peer-reviewed handbooks (Lide 2008, O'Neil 2006). Although the original references could not be reviewed, the results from two peer-reviewed handbooks are in agreement and therefore these are suitable for use to complete this endpoint.
Boiling point	The boiling point of gold is 2700 - 2856°C	Boiling point values are taken from two peer-reviewed handbooks (Lide 2008, O'Neil 2006). Although the original references could not be reviewed, the results from two peer-reviewed handbooks are in agreement and therefore these are suitable for use to complete this endpoint.
Relative density	The relative density of gold is 19.3	Density values are taken from two peer-reviewed handbooks (Lide 2008, O'Neil 2006). Although the original references could not be reviewed, the results from two peer-reviewed handbooks are in agreement and therefore these are suitable for use to complete this endpoint.
Granulometry	The proportion of gold powder < 100 µm is 4.9%	A GLP-compliant study following OECD guideline 110 is available for this endpoint, for gold powder (Harlan Laboratories 2011). This is considered suitable as a key study for this endpoint.
Water solubility	Gold powder showed no dissolution above the Limit of Detection in either the 24-hour screening transformation dissolution study (LOD: 0.1 µg/L) or in the full 28-day test (LOD: 0.3 µg/L).	GLP-compliant transformation dissolution tests were conducted according to OECD guideline 29 (ECTX 2012a, ECTX 2012b). In the 24-hour screening test a loading rate of 100 mg/L was used and the test was conducted at pH 6 and pH 8. In the full study loading rates of 10 and 100 mg/L (7 days duration) and 1 mg/L (28 days duration) were used. The test was conducted at pH 6, which is taken to represent the worst case as more acidic conditions generally tend to favour metal solubility. Gold powder showed no dissolution above the limit of detection in either test.
Autoflammability / self-ignition temperature	Gold showed no signs of self-ignition or self-heating throughout the test	A GLP-compliant study following a modified UN N4 method is available for this endpoint (Harlan Laboratories 2011). The modified method is considered to produce equally robust results as the standard method but uses less volume of test substance. This is considered as suitable for use as the key study for this endpoint.
Flammability	Gold is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening	A GLP-compliant study following UN method N1 is available for this endpoint (Harlan Laboratories 2011). This is

Property	Description of key information	Value used for CSA / Discussion
	test	considered suitable as the key study.

Data waiving

Information requirement: Vapour pressure

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the vapour pressure study does not need to be conducted as this substance has a melting point above 300°C.

Information requirement: Partition coefficient n-octanol/water (log value)

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the partition coefficient study does not need to be conducted as this substance is inorganic.

Information requirement: Surface tension

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the surface tension study does not need to be conducted as, based on the structure of this substance, surface activity is not expected or predicted and surface tension is not a desired property of the material.

Information requirement: Flash point

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the flash point study does not need to be conducted as this substance is inorganic.

Information requirement: Explosive properties

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the explosive properties study does not need to be conducted as there are no chemical groups associated with explosive properties present in the molecule.

Information requirement: Oxidising properties

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the oxidising properties study does not need to be conducted as the substance is incapable of reacting exothermically with combustible materials on the basis of its chemical structure.

2. MANUFACTURE AND USES

No information available on quantities

2.1. Manufacture

Table 7. Manufacture

Identifiers	Use descriptors	Other information
M-1: Manufacture of the substance (as such)	**Environmental release category (ERC):** ERC 1: Manufacture of substances **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 25: Other hot work operations with metals PROC 26: Handling of solid inorganic substances at ambient temperature PROC 27a: Production of metal powders (hot processes) PROC 27b: Production of metal powders (wet processes)	

Table 8. Manufacturing process related to the specified manufacture(s)

Related manufacture(s)	Description of manufacturing process
	Manufacturing process of gold Gold is obtained from primary and secondary sources by hydrometallurgical processes. In the first process step the gold containing material is dissolved in aqua regia (hydrochloric acid/nitric acid) or other acidic and oxidative conditions (as hydrochloric acid/chlorine and hydrochloric acid/hydrogen peroxide). After a filtration gold is extracted from the impure solution to produce a semi-pure tetrachloroauric acid/acidic solution. The pure gold is obtained as a coarse powder by the reduction of tetrachloroauric acid in aqueous/acidic solution with a sulfur dioxide or other reducing agents. After a leaching process the gold is 99.95 % pure. When the feed material contains significant quantities of metallic impurities, a solvent extraction step may be introduced alternatively before the gold precipitation stage. Alternatively cast gold anodes or gold grain contained in suitable containers as anodes are electrolysed, dissolving the gold in an electrolyte mainly

Related manufacture(s)	Description of manufacturing process
	composed of gold chloride and hydrochloric acid. The gold ions are then deposited on suitable metal cathodes to produce pure gold metal of 99.95%.

No information available on production of articles covered by the specified use(s)

2.2. Identified uses

Table 9. Formulation

Identifiers	Use descriptors	Other information
F-1: Formulation	**Environmental release category (ERC):** ERC 2: Formulation of preparations **Process category (PROC):** PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 26: Handling of solid inorganic substances at ambient temperature PROC 27a: Production of metal powders (hot processes) **Product Category formulated:** PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Technical function of the substance during formulation:** alloying element	Substance supplied to that use: As such
F-2: Formulation of cosmetic products	**Environmental release category (ERC):** ERC 2: Formulation of preparations **Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent	Substance supplied to that use: As such

Identifiers	Use descriptors	Other information
	Product Category formulated: PC 28: Perfumes, fragrances PC 39: Cosmetics, personal care products **Technical function of the substance during formulation:** cosmetics	

Table 10. Uses at industrial sites

Identifiers	Use descriptors	Other information
IW-1: Use as an intermediate	**Environmental release category (ERC):** ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 19: Intermediate **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals **Technical function of the substance during formulation:** Intermediates	Substance supplied to that use: As such Subsequent service life relevant for that use: no
IW-2: Use as chemical in health services and in laboratories	**Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles **Process category (PROC):** PROC 8b: Transfer of substance or preparation	Substance supplied to that use: In a mixture Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	(charging/discharging) from/to vessels/large containers at dedicated facilities PROC 15: Use as laboratory reagent PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature **Product Category used:** PC 21: Laboratory chemicals **Sector of end use:** SU 20: Health services SU 24: Scientific research and development **Technical function of the substance during formulation:** Laboratory chemicals	
IW-3: Reforming/Reshaping of gold metal	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25: Other hot work operations with metals PROC 26: Handling of solid inorganic substances at	Substance supplied to that use: As such Subsequent service life relevant for that use: yes Link to the subsequent service life: A-8: Service life of articles with low contact potential (gold included as internal part of the article) by consumers A-3: Service life of articles with high contact potential (gold-containing surfaces) in industrial settings A-4: Service life of articles with low contact potential (gold included as internal part of the article) in industrial settings A-5: Service life of articles with high contact potential (gold-containing surfaces) in professional settings A-6: Service life of articles with low contact potential (gold included as internal part of the article) in professional settings A-7: Service life of articles with high contact potential (gold-containing surfaces) by consumers

Identifiers	Use descriptors	Other information
	ambient temperature PROC 27a: Production of metal powders (hot processes) **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Sector of end use:** SU 14: Manufacture of basic metals, including alloys SU 15: Manufacture of fabricated metal products, except machinery and equipment SU 16: Manufacture of computer, electronic and optical products, electrical equipment SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Technical function of the substance during formulation:** used as base metal or alloy	
IW-4: Production of gold alloys	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-8: Service life of articles with low contact potential (gold included as internal part of the article) by consumers A-1: Service life of dental alloys in professional settings A-2: Service life of dental alloys by consumers A-3: Service life of articles with high contact potential (gold-containing surfaces) in industrial settings A-4: Service life of articles with low contact potential (gold included as internal part of the article) in industrial settings A-5: Service life of articles with high contact potential (gold-containing surfaces) in professional settings A-6: Service life of articles with low contact potential (gold included as internal part of the article) in professional

Identifiers	Use descriptors	Other information
	PROC 25: Other hot work operations with metals PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Sector of end use:** SU 14: Manufacture of basic metals, including alloys SU 15: Manufacture of fabricated metal products, except machinery and equipment SU 16: Manufacture of computer, electronic and optical products, electrical equipment **Technical function of the substance during formulation:** component in alloy	settings A-7: Service life of articles with high contact potential (gold-containing surfaces) by consumers
IW-5: Use in surface treatment	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 13: Treatment of articles by dipping and pouring PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 25: Other hot work operations with metals **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Sector of end use:** SU 14: Manufacture of basic metals, including alloys **Technical function of the substance during formulation:**	Substance supplied to that use: As such Subsequent service life relevant for that use: yes Link to the subsequent service life: A-8: Service life of articles with low contact potential (gold included as internal part of the article) by consumers A-3: Service life of articles with high contact potential (gold-containing surfaces) in industrial settings A-4: Service life of articles with low contact potential (gold included as internal part of the article) in industrial settings A-5: Service life of articles with high contact potential (gold-containing surfaces) in professional settings A-6: Service life of articles with low contact potential (gold included as internal part of the article) in professional settings A-7: Service life of articles with high contact potential (gold-containing surfaces) by consumers

Identifiers	Use descriptors	Other information
	Corrosion inhibitors and anti-scaling agents	
IW-6: Production of gold-containing articles	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 15: Use as laboratory reagent PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25: Other hot work operations with metals PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Sector of end use:** SU 14: Manufacture of basic metals, including alloys SU 15: Manufacture of fabricated metal products, except machinery and equipment SU 16: Manufacture of computer, electronic and optical products, electrical equipment SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment SU 20: Health services SU 24: Scientific research and development	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-8: Service life of articles with low contact potential (gold included as internal part of the article) by consumers A-3: Service life of articles with high contact potential (gold-containing surfaces) in industrial settings A-4: Service life of articles with low contact potential (gold included as internal part of the article) in industrial settings A-5: Service life of articles with high contact potential (gold-containing surfaces) in professional settings A-6: Service life of articles with low contact potential (gold included as internal part of the article) in professional settings A-7: Service life of articles with high contact potential (gold-containing surfaces) by consumers

Identifiers	Use descriptors	Other information
	Technical function of the substance during formulation: production of conductive agents for electronics, production of medical devices	
IW-7: Use of gold supported catalysts	**Environmental release category (ERC):** ERC 6b: Industrial use of reactive processing aids **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) **Product Category used:** PC 0: Other: Catalyst **Sector of end use:** SU 4: Manufacture of food products SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) **Technical function of the substance during formulation:** Catalyst	Subsequent service life relevant for that use: no

Table 11. Uses by professional workers

Identifiers	Use descriptors	Other information
PW-1: Use as chemical in health services and in laboratories	**Environmental release category (ERC):** ERC 8b: Wide dispersive indoor use of reactive substances in open systems **Process category (PROC):** PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent **Product Category used:**	Substance supplied to that use: In a mixture Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	PC 21: Laboratory chemicals **Sector of end use:** SU 20: Health services SU 24: Scientific research and development **Technical function of the substance during formulation:** Laboratory chemicals	
PW-2: Reforming/Reshaping of gold metal	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25: Other hot work operations with metals **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Sector of end use:** SU 14: Manufacture of basic metals, including alloys SU 15: Manufacture of fabricated metal products, except machinery and equipment SU 16: Manufacture of computer, electronic and optical products, electrical equipment SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	Substance supplied to that use: As such Subsequent service life relevant for that use: yes Link to the subsequent service life: A-8: Service life of articles with low contact potential (gold included as internal part of the article) by consumers A-5: Service life of articles with high contact potential (gold-containing surfaces) in professional settings A-6: Service life of articles with low contact potential (gold included as internal part of the article) in professional settings A-7: Service life of articles with high contact potential (gold-containing surfaces) by consumers

Identifiers	Use descriptors	Other information
	Technical function of the substance during formulation: production of jewellery and production of conductive agents for electronics	
PW-3: Use of dental alloys	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25: Other hot work operations with metals **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Sector of end use:** SU 14: Manufacture of basic metals, including alloys **Technical function of the substance during formulation:** dental alloy	Substance supplied to that use: In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-1: Service life of dental alloys in professional settings A-2: Service life of dental alloys by consumers
PW-4: Production of gold-containing articles	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis)	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service

Identifiers	Use descriptors	Other information
	where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25: Other hot work operations with metals **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Sector of end use:** SU 14: Manufacture of basic metals, including alloys SU 15: Manufacture of fabricated metal products, except machinery and equipment SU 16: Manufacture of computer, electronic and optical products, electrical equipment SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment **Technical function of the substance during formulation:** production of jewellery, watches, investment products, production of technical products	life: A-8: Service life of articles with low contact potential (gold included as internal part of the article) by consumers A-5: Service life of articles with high contact potential (gold-containing surfaces) in professional settings A-6: Service life of articles with low contact potential (gold included as internal part of the article) in professional settings A-7: Service life of articles with high contact potential (gold-containing surfaces) by consumers

Table 12. Consumer uses

Identifiers	Use descriptors	Other information
C-1: Production of gold-containing articles	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix **Product Category used:** PC 7: Base metals and alloys PC 14: Metal surface treatment products, including	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes

Identifiers	Use descriptors	Other information
	galvanic and electroplating products PC 14: Metal surface treatment products, including galvanic and electroplating products PC 33: Semiconductors PC 7: Base metals and alloys **Technical function of the substance during formulation:** production of jewellery, watches, investment products, production of technical products	Link to the subsequent service life: A-8: Service life of articles with low contact potential (gold included as internal part of the article) by consumers A-7: Service life of articles with high contact potential (gold-containing surfaces) by consumers
C-2: Consumer cosmetic use	**Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems **Product Category used:** PC 28: Perfumes, fragrances PC 39: Cosmetics, personal care products PC 28: Perfumes, fragrances PC 39: Cosmetics, personal care products **Technical function of the substance during formulation:** cosmetic	Substance supplied to that use: In a mixture Subsequent service life relevant for that use: no

Table 13. Article service life

Identifiers	Use descriptors	Other information
SL-1: Service life of dental alloys in professional settings	**Article category related to subsequent service life (AC):** AC 7: Metal articles **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles	Article used by: workers
SL-2: Service life of dental alloys by consumers	**Article category related to subsequent service life (AC):** AC 7: Metal articles **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life	Article used by: consumers

Identifiers	Use descriptors	Other information
	articles and materials with low release	
SL-3: Service life of articles with high contact potential (gold-containing surfaces) in industrial settings	**Article category related to subsequent service life (AC):** AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 7: Metal articles **Environmental release category (ERC):** ERC 12b: Industrial processing of articles with abrasive techniques (high release) ERC 12a: Industrial processing of articles with abrasive techniques (low release) **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25: Other hot work operations with metals	Article used by: workers
SL-4: Service life of articles with low contact potential (gold included as internal part of the article) in industrial settings	**Article category related to subsequent service life (AC):** AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 7: Metal articles **Environmental release category (ERC):** ERC 12b: Industrial processing of articles with abrasive techniques (high release) ERC 12a: Industrial processing of articles with abrasive techniques (low release) **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles	Article used by: workers
SL-5: Service life of articles with high contact potential (gold-containing surfaces) in professional settings	**Article category related to subsequent service life (AC):** AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 7: Metal articles **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations	Article used by: workers

Identifiers	Use descriptors	Other information
	with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25: Other hot work operations with metals	
SL-6: Service life of articles with low contact potential (gold included as internal part of the article) in professional settings	**Article category related to subsequent service life (AC):** AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 7: Metal articles **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles	Article used by: workers
SL-7: Service life of articles with high contact potential (gold-containing surfaces) by consumers	**Article category related to subsequent service life (AC):** AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 7: Metal articles **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release	Article used by: consumers
SL-8: Service life of articles with low contact potential (gold included as internal part of the article) by consumers	**Article category related to subsequent service life (AC):** AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 7: Metal articles **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release	Article used by: consumers

2.3. Uses advised against

No information available

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Name: Gold Powder

Implementation: EU

State/form of the substance: powder

Related composition:
Name: Gold powder

Classification

The substance is not classified.

Table 14. Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:			conclusive but not sufficient for classification	6.1
Flammable gases and chemically unstable gases:			conclusive but not sufficient for classification	6.2
Aerosols:			conclusive but not sufficient for classification	6.2
Oxidising gases:			conclusive but not sufficient for classification	6.3
Gases under pressure:			conclusive but not sufficient for classification	
Flammable liquids:			conclusive but not sufficient for classification	6.2
Flammable solids:			conclusive but not sufficient for classification	6.2
Self-reactive substances and mixtures:			conclusive but not sufficient for classification	
Pyrophoric liquids:			conclusive but not sufficient for classification	6.2
Pyrophoric solids:			conclusive but not sufficient for classification	6.2
Self-heating substances and mixtures:			conclusive but not sufficient for classification	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification	6.2

Oxidising liquids:			conclusive but not sufficient for classification	6.3
Oxidising solids:			conclusive but not sufficient for classification	6.3
Organic peroxides:			conclusive but not sufficient for classification	
Corrosive to metals:			conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

Table 15. Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Acute toxicity - oral:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - inhalation:			conclusive but not sufficient for classification	5.2.3
Skin corrosion / irritation:			conclusive but not sufficient for classification	5.3.4 and 5.4.3
Serious damage / eye irritation:			conclusive but not sufficient for classification	5.3.4
Respiratory sensitisation:			conclusive but not sufficient for classification	5.5.3
Skin sensitisation:			conclusive but not sufficient for classification	5.5.3
Aspiration hazard:			data lacking	5.2.3
Reproductive Toxicity:			conclusive but not sufficient for classification	5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			data lacking	5.7.3
Carcinogenicity:			conclusive but not sufficient for classification	5.8.3
Specific target			conclusive but	5.2.3 and

organ toxicity - single exposure:			not sufficient for classification	5.3.4
Specific target organ toxicity - repeated exposure:			conclusive but not sufficient for classification	5.6.3

*) Justification for (non) classification can be found in the CSR section indicated

Table 16. Classification and labelling according to CLP / GHS for environmental hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification	7.6
Hazards to the aquatic environment (chronic/long-term):			conclusive but not sufficient for classification	7.6
Hazardous to the ozone layer:			data lacking	7.6

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Signal word: No signal word

Name: Gold Massive

Implementation: EU

State/form of the substance: solid

Related composition:
Name: Gold massive

Classification

The substance is not classified.

Table 17. Classification and labelling according to CLP / GHS for physicochemical properties

Hazard class	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:			conclusive but not sufficient for classification	6.1
Flammable gases and chemically unstable gases:			conclusive but not sufficient for classification	6.2
Aerosols:			conclusive but not sufficient for	6.2

			classification	
Oxidising gases:			conclusive but not sufficient for classification	6.3
Gases under pressure:			conclusive but not sufficient for classification	
Flammable liquids:			conclusive but not sufficient for classification	6.2
Flammable solids:			conclusive but not sufficient for classification	6.2
Self-reactive substances and mixtures:			conclusive but not sufficient for classification	
Pyrophoric liquids:			conclusive but not sufficient for classification	6.2
Pyrophoric solids:			conclusive but not sufficient for classification	6.2
Self-heating substances and mixtures:			conclusive but not sufficient for classification	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification	6.2
Oxidising liquids:			conclusive but not sufficient for classification	6.3
Oxidising solids:			conclusive but not sufficient for classification	6.3
Organic peroxides:			conclusive but not sufficient for classification	
Corrosive to metals:			conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

Table 18. Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Acute toxicity - oral:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for	5.2.3

			classification	
Acute toxicity - inhalation:			conclusive but not sufficient for classification	5.2.3
Skin corrosion / irritation:			conclusive but not sufficient for classification	5.3.4 and 5.4.3
Serious damage / eye irritation:			conclusive but not sufficient for classification	5.3.4
Respiratory sensitisation:			conclusive but not sufficient for classification	5.5.3
Skin sensitisation:			conclusive but not sufficient for classification	5.5.3
Aspiration hazard:			data lacking	5.2.3
Reproductive Toxicity:			conclusive but not sufficient for classification	5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			data lacking	5.7.3
Carcinogenicity:			conclusive but not sufficient for classification	5.8.3
Specific target organ toxicity - single exposure:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated exposure:			conclusive but not sufficient for classification	5.6.3

*) Justification for (non) classification can be found in the CSR section indicated

Table 19. Classification and labelling according to CLP / GHS for environmental hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification	7.6
Hazards to the aquatic environment (chronic/long-term):			conclusive but not sufficient for classification	7.6
Hazardous to the			data lacking	7.6

ozone layer:				

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Signal word: No signal word

3.2. Classification and labelling according to DSD / DPD

3.2.1. Classification and labelling according to the criteria in Directive 67/548/EEC (DSD) and Directive 1999/45/EC (DPD)

No relevant information available

3.2.2. Self classification(s)

No relevant information available

3.2.3. Other classification(s)

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

No experimental studies on the fate and partitioning of gold in environmental media have been performed. The hydrolysis study was not considered scientifically necessary and therefore it was waived as gold is not expected to undergo hydrolysis in the environment due to a lack of hydrolysable functional groups. The biodegradation study has been waived as the substance is an inorganic.

A GLP complaint OECD 106 guideline test is available with tetrachloroauric acid (Klawonn 2016) and a read across of the data to gold has been considered appropriate. A limited partitioning study with three soils was performed to determine the Kd values. The approach was considered adequate for the information requirements. The Kd values of 16185.05, 1878.31 and 595.32 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. The Koc values of 2415679.1, 94864.0 and 34411.7 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

Data waiving

Information requirement: Hydrolysis

Reason: study scientifically unjustified

Justification: In accordance with section 1 of REACH Annex XI, the hydrolysis study does not need to be conducted as this substance is not expected to undergo hydrolysis in the environment due to a lack of hydrolysable functional groups and therefore testing does not appear scientifically necessary.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available

4.1.1.2.2. Phototransformation in water

No relevant information available

4.1.1.2.3. Phototransformation in soil

No relevant information available

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: study scientifically unjustified

Justification: In accordance with column 2 of REACH Annex VII, the ready biodegradability study does not need to be conducted as the substance is inorganic.

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

4.1.2.2. Biodegradation in soil

No relevant information available

4.1.3. Summary and discussion of degradation

4.2. Environmental distribution

4.2.1. Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 20. Studies on adsorption/desorption

Method	Results	Remarks	Reference
Study type: adsorption/desorption (soil) batch equilibrium method OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method)	Adsorption coefficient: Koc (Soil 2.3): 2415679.1 (% Org. C: 0.67) (room temperature, sampling time 48 h) Kd (Soil 2.3): 16185.05 (% Org. C: 0.67) (room temperature, sampling time 48 h) Koc (Soil 2.4): 94864 (% Org. C: 1.98) (room temperature, sampling time 48 h) Kd (Soil 2.4): 1878.31 (% Org. C: 1.98) (room temperature, sampling time 48 h) Koc (Soil 6S): 34411.7 (% Org. C: 1.73) (room temperature, sampling time 48 h) Kd (Soil 6S): 595.32 (% Org. C: 1.73) (room temperature, sampling time 48 h) Mass balance (in %) at end of adsorption phase: 99.8 after 48 h (#1) 98.5 after 48 h (#2) 95.8 after 48 h (#3)	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material (CAS name): Hydrogen tetrachloro aurate (III) (See endpoint summary for justification of read-across)** Form: solid	Klawonn T. (2016)

Discussion

A study with tetrachloro auric acid, was conducted according to OECD 106 guideline to determine the Adsorption – Desorption.
A limited partitioning study with three soils was performed to determine the Kd values (Klawonn 2016). The approach was considered adequate for the information requirements and a read across of the data to gold has been considered appropriate.

The Kd values of 16185.05, 1878.31 and 595.32 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. The Koc values of 2415679.1, 94864.0 and 34411.7 were determined for Soil 2.3, 2.4 and 6S, respectively,

after 48 h.

The following information is taken into account for any environmental exposure assessment:

The Kd values of 16185.05, 1878.31 and 595.32 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h. The Koc values of 2415679.1, 94864.0 and 34411.7 were determined for Soil 2.3, 2.4 and 6S, respectively, after 48 h.

4.2.2. Volatilisation

No relevant information available

4.2.3. Distribution modelling

No relevant information available

4.2.4. Summary and discussion of environmental distribution

A study with tetrachloroauric acid was conducted according to OECD 106 guideline to determine the Kd values. Read across of the data to gold has been considered appropriate.

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

No relevant information available

4.3.2. Terrestrial bioaccumulation

No relevant information available

4.3.3. Summary and discussion of bioaccumulation

4.4. Secondary poisoning

Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (see CSR chapter 7.6 "PNEC derivation and other hazard conclusions").

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

Data waiving

Reason: study scientifically unjustified

Justification: Zero valent gold is considered inert and hence there will be a lack of transformation and dissolution into soluble forms within the mammalian body. This is supported by results from a bio-elution test in artificial gastric mimetic fluid which showed no metal release above the limit of detection (1µg/L) (Rodriguez, 2012). Consequently, the conduct of any toxicity testing by the oral route of administration is waived. In addition, gold powder was subject to particle size screening by Harlan Laboratories (Tremain and Atwal, 2011). Less than 10 % of the substance passed through a 100 µm sieve, and hence a full particle size distribution assessment was not required since the powder was unlikely to be significantly inhalable (as defined by criteria contained in EUR 20268 EN 2002). However, these data were supported by a particle size distribution assessment (Rodriquez, 2012) in which the 50th and 90th percentiles of the particle size cumulative distribution for gold metal powder were 83.88 and 308.06 µm respectively. Consequently, with 50% of particles actually measured at 83.88 µm the substance was confirmed as unlikely to be significantly inhalable and studies by the inhalation route of administration were also waived. With regards to dermal exposure, there is a long history of the use of gold metal in jewellery, etc., with extensive skin contact. It is not therefore considered relevant to subject metallic gold to acute dermal toxicity testing. This decision is supported by the lack of dissolution observed in artificial sweat (Liden C et al. 1998). The Transformation/Dissolution testing of gold (Brouwers, 2012) showed that the level of dissolution was below the level of detection. Liden et al. (1998) investigated the release of gold metal from 13 different gold-containing jewellery materials stored for several weeks in artificial sweat. No release of gold was detected using ICP and atomic absorption.

There were no tests conducted by either oral, inhalation or dermal routes of administration from which toxicokinetic data could be extracted. There is significant evidence from the cited references to confirm that there would be no systemic exposure in the mammalian system from exposure to gold via these routes.

Reason: study scientifically unjustified

Justification: There is a long history of the use of gold metal in jewellery, etc., with extensive skin contact. It is not therefore considered relevant to subject metallic gold to dermal toxicity testing. This decision is supported by the lack of dissolution observed in artificial sweat (Liden C et al. 1998). The T/D testing of gold (Brouwers, 2012) showed that the level of dissolution was below the level of detection. Liden et al. (1998) investigated the release of gold metal from 13 different gold-containing jewellery materials stored for several weeks in artificial sweat. No release of gold was detected using ICP and atomic absorption. This published data supports the lack of gold dermal bioaccessibility and no further tests were proposed.

5.1.2. Human information

No relevant information available

5.1.3. Summary and discussion of toxicokinetics

Zero valent gold is considered inert and hence there will be a lack of transformation and dissolution into soluble forms within the mammalian body. This is supported by results from a bio-elution test in artificial gastric mimetic fluid which showed no metal release above the limit of detection (1 µg/L). Consequently, the conduct of any toxicity testing by the oral route of administration is waived. In addition, assessment of gold powder for particle size showed less than 10 % of the substance would pass through a 100 µm sieve and particle size cumulative distribution range for gold metal powder was measured at 83.88 to 308.06 µm hence the powder was unlikely to be significantly inhalable (as defined by criteria contained in EUR 20268 EN 2002). Consequently, studies by the inhalation route of administration were also waived. With regards to dermal exposure, there is a long history of the use of gold metal in jewellery, etc., with extensive skin contact. It is not therefore considered

relevant to subject metallic gold to acute dermal toxicity testing. This decision is supported by the lack of dissolution observed in artificial sweat and the T/D testing of gold showed that the level of dissolution was below the level of detection. There were no tests conducted by either oral, inhalation or dermal routes of administration from which toxicokinetic data could be extracted. There is significant evidence from the cited references to confirm that there would be no systemic exposure in the mammalian system from exposure to gold via these routes.

The following information is taken into account for any hazard / risk assessment:

Generation of data for this endpoint was waived since the conduct of appropriate studies from which data would normally be extracted were waived.

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

Data waiving

Information requirement: Acute toxicity after oral administration

Reason: study scientifically unjustified

Justification: Although no proprietary data are available for gold for this endpoint, the HSDB database (Klimisch 2 peer-reviewed database) cites the lack of acute oral toxicity to gold metal dust (Luckey and Venugopal, 1977). In addition, metallic gold powder is considered inert and not bioavailable, which is supported by results from a bio-elution test in artificial gastric mimetic fluid which showed no metal release above the limit of detection (1 µg/L) (Rodriquez, 2012). On this basis it is considered scientifically unjustified to repeat the acute toxicity study by the oral route and the study is waived.

5.2.1.2. Acute toxicity: inhalation

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: study scientifically unjustified

Justification: The gold powder was subject to particle size screening by Harlan (Tremain and Atwal, 2011). Less than 10 % of the substance passed through a 100 µm sieve, and hence a full particle size distribution assessment was not required since the powder was unlikely to be significantly inhalable (as defined by criteria contained in EUR 20268 EN 2002). However, these data were supported by a particle size distribution assessment (Rodriguez, 2012) in which the 50th and 90th percentiles of the particle size cumulative distribution for gold metal powder were 83.88 and 308.06 µm respectively. Consequently, with 50% of particles actually measured at 83.88 µm, the substance was confirmed as being unlikely to be significantly inhalable.

5.2.1.3. Acute toxicity: dermal

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: study scientifically unjustified

Justification: There is a long history of the use of gold metal in jewellery, etc., with extensive skin contact. It is not therefore considered relevant to subject metallic gold to acute dermal toxicity testing. This decision is supported by the lack of dissolution observed in artificial sweat (Liden C et al. 1998). The Transformation/Dissolution testing of gold (Brouwers, 2012) showed that the level of dissolution was below the level of detection. Liden et al. (1998) investigated the release of gold metal from 13 different gold-containing jewellery materials stored for several weeks in artificial sweat. No release of gold was detected using ICP and atomic absorption. This published data supports the lack of gold dermal bioaccessibility and no further tests were proposed.

5.2.1.4. Acute toxicity: other routes

No relevant information available

5.2.2. Human information

No relevant information available

5.2.3. Summary and discussion of acute toxicity

The conduct of acute toxicity studies by either the oral, inhalation or dermal routes of administration was waived based on the unlikely exposure to gold metal via these routes. Bio-elution tests using artificial gastric fluid and artificial sweat showed no metal release above the limit of detection (1 µg/L). In addition, the granulometry of gold powder showed that less than 10 % of the substance passed through a 100 µm sieve hence it was considered unlikely to be significantly inhalable.

Value used for CSA:

Acute oral toxicity: No study available

Acute dermal toxicity: No study available

Acute inhalation toxicity: No study available

Justification for classification or non-classification

Through the conduct of bio-elution tests in artificial gastric fluid and sweat and the assessment of particle size, it was concluded that no meaningful studies could be conducted and that gold metal was not classifiable for this endpoint.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

Data waiving

Information requirement: Skin irritation

Reason: study scientifically unjustified

Justification: No proprietary studies have been identified on gold metal itself. The guinea pig Buehler study (Arcelin, 1995) for sensitisation referred to in Section 7.4 showed no evidence of dermal irritation when the Galvanogold was placed on the skin for 24h, three times per week during the induction period (or during the challenge procedure).

There is also clear evidence from the history of use in jewellery articles and in dental restoration that gold metal does not cause skin irritation that would require classification under EU legislation and previous testing of gold (Brouwers, 2012) has shown that any dissolution of the metal is below the limit of detection. Therefore, no further testing was recommended for this endpoint and a Weight of Evidence argument is used.

5.3.1.2. Human information

No relevant information available

5.3.2. Eye

5.3.2.1. Non-human information

Data waiving

Information requirement: Eye irritation

Reason: study scientifically unjustified

Justification: For gold metal, the HSDB database cites Morton GW, Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974, p. 530. Metallic gold dust has been tested in rabbit eyes. The metal persisted for many months and caused invasion by leucocytes, vascularisation, and accumulation of giant cells. Particles too big to be ingested by leucocytes become encapsulated, whereas fine dust is removed.

No additional testing is recommended for this endpoint. Gold (massive or dust) would not be considered a specific eye irritant, although traumatic damage by fine dust particles could be expected.

5.3.2.2. Human information

No relevant information available

5.3.3. Respiratory tract

5.3.3.1. Non-human information

5.3.3.2. Human information

No relevant information available

5.3.4. Summary and discussion of irritation

The conduct of skin and eye irritation studies were waived based on the unlikely exposure to gold metal via these routes. A bio-elution test using artificial sweat showed no metal release above the limit of detection (1 µg/L). In addition, there is a long history of the use of gold metal in jewellery with extensive skin contact without adverse effects.

Value used for CSA:

Skin irritation / corrosion: No study available

Eye irritation / corrosion: No study available

Respiratory irritation / corrosion: No study available

Justification for classification or non-classification

Through the conduct of a bio-elution test in artificial sweat and the lack of adverse skin reactions reported following historical use of gold metal in jewellery with extensive skin contact, it was concluded that gold metal was not classifiable for this endpoint.

5.4. Corrosivity

5.4.1. Non-human information

No relevant information available

5.4.2. Human information

5.4.3. Summary and discussion of corrosion

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

The results of studies on skin sensitisation are summarised in the following table:

Table 21. Studies on skin sensitisation

Method	Results	Remarks	Reference
guinea pig (Dunkin-Hartley) female Guinea pig maximisation test Induction: intradermal and epicutaneous Challenge: epicutaneous, occlusive Vehicle: physiol. saline EU Method B.6 (Skin Sensitisation) OECD Guideline 406 (Skin Sensitisation)	not sensitising No. with positive reactions: 1st reading: 0 out of 10 (test group); 24 h after chall. 2nd reading: 0 out of 10 (test group); 48 h after chall. 3rd reading: 0 out of 10 (test group); 72 h after chall. 1st reading: 0 out of 5 (negative control); 24 h after chall. 2nd reading: 0 out of 5 (negative control); 48 h after chall. 3rd reading: 0 out of 5 (negative control); 72 h after chall.	1 (reliable without restriction) key study experimental result **Test material (common name): Gold**	Albrect A (1999)
guinea pig (Himalayan) female Buehler test Induction: epicutaneous, semiocclusive Challenge: epicutaneous, semiocclusive Vehicle: unchanged (no vehicle) EU Method B.6 (Skin Sensitisation) OECD Guideline 406 (Skin Sensitisation) ISO 10993: 1992 "Biological evaluation of medical devices"	not sensitising No. with positive reactions: 1st reading: 0 out of 10 (negative control); 24 h after chall. 2nd reading: 0 out of 10 (negative control); 48 h after chall. 1st reading: 0 out of 20 (test group); 24 h after chall. 2nd reading: 0 out of 20 (test group); 48 h after chall.	1 (reliable without restriction) supporting study experimental result **Test material (common name): Gold**	Arcelin G (1995)

5.5.1.2. Human information

No relevant information available

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available

5.5.2.2. Human information

No relevant information available

5.5.3. Summary and discussion of sensitisation

Skin sensitisation

The key study showed no evidence of skin sensitisation under the conditions of the test and this result was

supported by a second study to a similar design with a 99.9 % pure electroformed material, AGC Galvanogold, also for dental restorations. In addition, previous testing of gold (Brouwers, 2012) has shown that any dissolution of the metal is below the limit of detection.

The following information is taken into account for any hazard / risk assessment:

A regulatory guideline guinea pig maximisation test (OECD 406) performed with a gold dental alloy with a purity of 98.2 %. This key study showed no evidence of skin sensitisation under the conditions of the test and was supported by negative results in a second study of similar design.

Value used for CSA: No adverse effect observed (not sensitising)

Respiratory sensitisation

Value used for CSA: No study available

Justification for classification or non-classification

According to the results of the two guinea pig maximisation tests, gold does not meet the current EU-CLP criteria for classification as a skin sensitiser. No risk phrase is required.

The respiratory sensitisation potential of gold was not evaluated. Hence, gold cannot be classified with respect to this endpoint.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

Data waiving

Information requirement: Repeated dose toxicity after oral administration

Reason: study scientifically unjustified

Justification: No proprietary data are available for gold for this endpoint. In addition, metallic gold powder is considered inert and not bioavailable, which is supported by results from a bio-elution test in artificial gastric mimetic fluid which showed no metal release above the limit of detection (1 µg/L) (Rodriguez, 2012). On this basis it is considered scientifically unjustified to conduct a repeat dose study by the oral route and the study is waived.

5.6.1.2. Repeated dose toxicity: inhalation

Data waiving

Information requirement: Repeated dose toxicity after inhalation exposure

Reason: study scientifically unjustified

Justification: The physico-chemical assessment of gold powder showed that less than 10 % of the substance passed through a 100 µm sieve (Tremain and Atwal, 2011) and hence a full particle size distribution assessment was not required since the powder is unlikely to be significantly inhalable (as defined by criteria in EUR 20268 EN 2002). However, these data were supported by a particle size distribution assessment (Rodriguez, 2012) in which the 50th and 90th percentiles of the particle size cumulative distribution were 83.88 and 308.06 µm respectively. Consequently, with 50% of particles actually measured at 83.88 µm, the substance was confirmed as being unlikely to be significantly inhalable.

5.6.1.3. Repeated dose toxicity: dermal

Data waiving

Information requirement: Repeated dose toxicity after dermal administration

Reason: study scientifically unjustified

Justification: There is a long history of the use of gold metal in jewellery with extensive skin contact. It is not, therefore, considered relevant to subject metallic gold to repeat-dose dermal toxicity testing. This decision is supported by the lack of dissolution observed in artificial sweat (Liden C et al. 1998)

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available

5.6.2. Human information

No relevant information available

5.6.3. Summary and discussion of repeated dose toxicity

The conduct of repeat-dose toxicity studies by either the oral, inhalation or dermal routes of administration was waived based on the unlikely exposure to gold metal via these routes. Bio-elution tests using artificial gastric fluid and artificial sweat showed no metal release above the limit of detection (1 µg/L). In addition, the granulometry of gold powder showed that less than 10 % of the substance passed through a 100 µm sieve hence it was considered unlikely to be significantly inhalable.

Value used for CSA (via oral route - systemic effects):

No study available

Value used for CSA (dermal - systemic effects):

No study available

Value used for CSA (dermal - local effects):

No study available

Value used for CSA (inhalation - systemic effects):

No study available

Justification for classification or non-classification

Through the conduct of bio-elution tests in artificial gastric fluid and sweat and the assessment of particle size, it was concluded that no meaningful studies could be conducted and that gold metal was not classifiable for this endpoint.

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

The results of in vitro genotoxicity studies are summarised in the following table:

Table 22. In vitro genotoxicity studies

Method	Results	Remarks	Reference
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) S. typhimurium, other: TA 100, TA 1535, TA 102, TA 98, TA 1537 (met. act.: with and without) Test concentrations: 10, 20, 40,	Evaluation of results: negative Test results: negative for S. typhimurium, other: TA 100, TA 1535, TA 102, TA 98, TA 1537(all strains/cell types tested); met. act.: with and without;	2 (reliable with restrictions) key study experimental result **Test material (EC name): gold**	Donath C, Kraft M (2008)

Method	Results	Remarks	Reference
60, 80, and 100 % concentrations of the test item extract. The 100 % extracts correspond to a surface/volume-ratio of 3 cm2/mL 0.9 % NaCl. Positive control substance(s): Sodium azide, 4-nitro-o-phenylene-diamene, Methyl methane sulfonate, 2-aminoanthracene. OECD Guideline 471 (Bacterial Reverse Mutation Assay) EU Method B.13/14 (Mutagenicity - Reverse Mutation Test Using Bacteria) EPA OPPTS 870.5100 - Bacterial Reverse Mutation Test (August 1998)	cytotoxicity: no; vehicle controls valid: yes; negative controls valid: yes; positive controls valid: yes		

Data waiving

Information requirement: In vitro genotoxicity

Reason: study scientifically unjustified

Justification: No data for gold are available to fulfil the *in vitro* cytogenicity in mammalian cells endpoint. However, possible toxicological relevance for conducting the test was first established by assessing the dissolution of gold in bio-elution studies (Rodriguez, 2012). In this bio-elution test in artificial gastric mimetic fluid, there was no metal release detected above the limit of detection (1 µg/L). On this basis it is considered scientifically unjustified to conduct the *in vitro* cytogenicity in mammalian cells test and the study is waived.

Information requirement: In vitro genotoxicity

Reason: study scientifically unjustified

Justification: No data for gold are available to fulfil the *in vitro* gene mutation in mammalian cells endpoint. However, possible toxicological relevance for the conduct of this test was first established by assessing the dissolution of gold in bio-elution studies (Rodriguez, 2012). In this bio-elution test in artificial gastric mimetic fluid there was no metal release detected above the limit of detection (1 µg/L). On this basis it is considered scientifically unjustified to conduct the *in vitro* gene mutation in mammalian cells test and the study is waived.

5.7.1.2. In vivo data

No relevant information available

5.7.2. Human information

No relevant information available

5.7.3. Summary and discussion of mutagenicity

The key study followed standard guidelines at the time, involving the use of five strains of Salmonella typhimurium (TA98, TA100, TA1535, TA1573 and TA102) exposed to concentrations up to 100 % using a preincubation method in the presence or absence of metabolic activation. The test substance was found to be non-mutagenic to bacterial strains in this test.

The following information is taken into account for any hazard / risk assessment:

A GLP regulatory guideline Ames test (OECD471) performed with the test substance (84.8% gold).

Value used for CSA: Genetic toxicity: No adverse effect observed (negative)

Justification for classification or non-classification

The test substance (84.8 % gold) was found to be non-mutagenic to bacterial strains. However, mutagenicity studies in mammalian cells were waived on the basis of results from a bio-elution test in which showed no gold metal release above the limit of detection (1 µg/L). Consequently, it is not possible to classify the test substance for this endpoint.

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

No relevant information available

5.8.1.2. Carcinogenicity: inhalation

No relevant information available

5.8.1.3. Carcinogenicity: dermal

No relevant information available

5.8.1.4. Carcinogenicity: other routes

No relevant information available

5.8.2. Human information

No relevant information available

5.8.3. Summary and discussion of carcinogenicity

Information on this endpoint not required under Annex VII and VIII of REACh regulations 2007.

Value used for CSA (route: oral):

No study available

Value used for CSA (route: dermal):

No study available

Value used for CSA (route: inhalation):

No study available

Justification for classification or non-classification

Since no data was required for this endpoint under Annex VII and VIII of REACh regulations 2007, gold metal cannot be classified for this endpoint.

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

Data waiving

Information requirement: Toxicity for reproduction / fertility

Reason: study scientifically unjustified

Justification: There are no studies published or available on this endpoint for gold. However, metallic gold powder is considered inert and not bioavailable, which is supported by results from a bioelution test in artificial gastric mimetic fluid which showed no metal release above the limit of detection (1 µg/L) (Rodriguez, 2012). In addition, other potential routes of administration for such a study, inhalation and dermal are also ruled out. The physico chemical assessment of gold powder showed that less than 10 % of the substance passed through a 100 µm sieve (Tremain and Atwal, 2011), and hence a full particle size distribution assessment was not required since the powder was unlikely to be significantly inhalable (as defined by criteria contained in EUR 20268 EN 2002). However, these data were supported by a particle size distribution assessment (Rodriguez, 2012) in which the 50th and 90th percentiles of the particle size cumulative distribution for gold metal powder were 83.88 and 308.06 µm respectively. Consequently, with 50% of particles actually measured at 83.88 µm, the substance was confirmed as being unlikely to be significantly inhalable. There is also a long history of extensive dermal contact with gold metal in jewellery coupled with a lack of dissolution observed in artificial sweat (Liden C et al. 1998). On this basis it is considered scientifically unjustified to conduct a reproductive toxicity screening study by any of these administration routes and it is, therefore, waived.

Toxicity to reproduction: other studies

No relevant information available

5.9.1.2. Human information

No relevant information available

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

Data waiving

Information requirement: Developmental toxicity / teratogenicity

Reason: study scientifically unjustified

Justification: There are no studies published or available on this endpoint for gold. However, metallic gold powder is considered inert and not bioavailable, which is supported by results from a bioelution test in artificial gastric mimetic fluid which showed no metal release above the limit of detection (1 µg/L) (Rodriguez, 2012). In addition, other potential routes of administration for such a study, inhalation and dermal are also ruled out. The physico chemical assessment of gold powder showed that less than 10 % of the substance passed through a 100 µm sieve (Tremain and Atwal, 2011), and hence a full particle size distribution assessment was not required since the powder was unlikely to be significantly inhalable (as defined by criteria contained in EUR 20268 EN 2002). However, these data were supported by a particle size distribution assessment (Rodriguez, 2012) in which the 50th and 90th percentiles of the particle size cumulative distribution for gold metal powder were 83.88 and 308.06 µm respectively. Consequently, with 50% of particles actually measured at 83.88 µm, the substance was confirmed as being unlikely to be significantly inhalable. There is also a long history of extensive dermal contact with gold metal in jewellery coupled with a lack of dissolution observed in artificial sweat (Liden C et al. 1998). On this basis it is considered scientifically unjustified to conduct a reproductive toxicity screening study by any of these administration routes and it is, therefore, waived.

5.9.2.2. Human information

No relevant information available

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

The conduct of repeat-dose toxicity studies by either the oral, inhalation or dermal routes of administration was waived based on the unlikely exposure to gold metal via these routes. Bio-elution tests using artificial gastric fluid and artificial sweat showed no metal release above the limit of detection (1 µg/L). In addition, the granulometry of gold powder showed that less than 10 % of the substance passed through a 100 µm sieve hence it was considered unlikely to be significantly inhalable.

Value used for CSA (route: oral):

No study available

Value used for CSA (route: dermal):

No study available

Value used for CSA (route: inhalation):

No study available

Developmental toxicity

The conduct of repeat-dose toxicity studies by either the oral, inhalation or dermal routes of administration was waived based on the unlikely exposure to gold metal via these routes. Bio-elution tests using artificial gastric fluid and artificial sweat showed no metal release above the limit of detection (1 µg/L). In addition, the granulometry of gold powder showed that less than 10 % of the substance passed through a 100 µm sieve hence it was considered unlikely to be significantly inhalable.

Value used for CSA (route: oral)

No study available

Value used for CSA (route: dermal):

No study available

Value used for CSA (route: inhalation):

No study available

Justification for classification or non-classification

Since there are no specific studies conducted for this endpoint, gold metal cannot be classified for the endpoint.

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available

5.10.1.2. Immunotoxicity

No relevant information available

5.10.1.3. Specific investigations: other studies

No relevant information available

5.10.2. Human information

No relevant information available

5.10.3. Summary and discussion of other effects

5.11. Derivation of DNEL(s) and other hazard conclusions

5.11.1. Overview of typical dose descriptors for all endpoints

Table 23. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
Acute toxicity	oral	No study available	
Acute toxicity	dermal	No study available	
Acute toxicity	inhalation	No study available	
Irritation / Corrosivity	skin	No study available	
Irritation / Corrosivity	eye	No study available	
Irritation / Corrosivity	respiratory tract	No study available	
Sensitisation	skin	No adverse effect observed (not sensitising)	
Sensitisation	respiratory tract	No study available	
Repeated dose toxicity	oral	No study available	
Repeated dose toxicity	dermal (systemic effects)	No study available	
Repeated dose toxicity	dermal (local effects)	No study available	
Repeated dose toxicity	inhalation (systemic effects)	No study available	
Mutagenicity	in vitro / in vivo	No adverse effect observed (negative)	see section 5.7.1 / 5.7.2
Carcinogenicity	oral	No study available	
Carcinogenicity	dermal	No study available	
Carcinogenicity	inhalation	No study available	
Reproductive toxicity: effects on fertility	oral	No study available	
Reproductive toxicity: effects on fertility	dermal	No study available	
Reproductive toxicity: effects on fertility	inhalation	No study available	
Reproductive toxicity: developmental toxicity	oral	No study available	
Reproductive toxicity: developmental toxicity	dermal	No study available	
Reproductive toxicity:	inhalation	No study available	

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
developmental toxicity			

Justification for endpoint selection:

- Sensitisation (skin): This study is a Klimisch 1 (Reliable without restrictions) Guinea pig maximisation study which, although not recognised as the most sensitive study design for this endpoint, was conducted according to GLP.

- Mutagenicity: A Klimisch 2 (Reliable with restrictions), GLP compliant, guideline study, available as an unpublished report. Test substance is 84.8 % gold.

5.11.2. Selection of the DNEL(s) or other hazard conclusion for critical health effects

Table 24. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	No hazard identified	
Inhalation	Systemic effects - Acute	No hazard identified	
Inhalation	Local effects - Long-term	No hazard identified	
Inhalation	Local effects - Acute	No hazard identified	
Dermal	Systemic effects - Long-term	No hazard identified	
Dermal	Systemic effects - Acute	No hazard identified	
Dermal	Local effects - Long-term	No hazard identified	
Dermal	Local effects - Acute	No hazard identified	
Eyes	Local effects	Low hazard (no threshold derived)	

Further explanation on hazard conclusions:

- **Eyes Local effects:** For gold metal, the HSDB database cites Morton GW, Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974, p. 530. It is stated that metallic gold dust has been tested in rabbit eyes. The metal persisted for many months and caused invasion by leucocytes, vascularisation, and accumulation of giant cells. Particles too big to be ingested by leucocytes become encapsulated, whereas fine dust is removed. Gold (massive or dust) would not be considered a specific eye irritant, although traumatic damage by fine dust particles could be expected.

Table 25. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	No hazard identified	

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Acute	No hazard identified	
Inhalation	Local effects - Long-term	No hazard identified	
Inhalation	Local effects - Acute	No hazard identified	
Dermal	Systemic effects - Long-term	No hazard identified	
Dermal	Systemic effects - Acute	No hazard identified	
Dermal	Local effects - Long-term	No hazard identified	
Dermal	Local effects - Acute	No hazard identified	
Oral	Systemic effects - Long-term	No hazard identified	
Oral	Systemic effects - Acute	No hazard identified	
Eyes	Local effects	Low hazard (no threshold derived)	

Further explanation on hazard conclusions:

- **Eyes Local effects:** For gold metal, the HSDB database cites Morton GW, Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974, p. 530. It is stated that metallic gold dust has been tested in rabbit eyes. The metal persisted for many months and caused invasion by leucocytes, vascularisation, and accumulation of giant cells. Particles too big to be ingested by leucocytes become encapsulated, whereas fine dust is removed. Gold (massive or dust) would not be considered a specific eye irritant, although traumatic damage by fine dust particles could be expected.

Discussion

Zero valent gold is considered inert and hence there will be a lack of transformation and dissolution into soluble forms within the mammalian body. This is supported by results from a bio-elution test in artificial gastric mimetic fluid which showed no metal release above the limit of detection (1 µg/L) (Rodriguez, 2012). Consequently, the conduct of any toxicity testing by the oral route of administration is waived. In addition, gold powder was subject to particle size screening by Harlan Laboratories (Tremain and Atwal 2011). Less than 10 % of the substance passed through a 100 µm sieve, and hence a full particle size distribution assessment was not required since the powder was unlikely to be significantly inhalable (as defined by criteria contained in EUR 20268 EN 2002). However, these data were supported by a particle size distribution assessment (Rodriguez, 2012) in which the 50th and 90th percentiles of the particle size cumulative distribution for gold metal powder were 83.88 and 308.06 µm respectively. Consequently, with 50% of particles actually measured at 83.88 um the substance was confirmed as being unlikely to be significantly inhalable and studies by the inhalation route of administration were also waived. With regards to dermal exposure, there is a long history of the use of gold metal in jewellery, etc., with extensive skin contact. It is not therefore considered relevant to subject metallic gold to acute dermal toxicity testing. This decision is supported by the lack of dissolution observed in artificial sweat (Liden C et al. 1998). The Transformation/Dissolution testing of gold (Brouwers, 2012) showed that the level of dissolution was below the level of detection. Liden et al. (1998) investigated the release of gold metal from 13 different gold-containing jewellery materials stored for several weeks in artificial sweat. No release of gold was detected using ICP and atomic absorption. Consequently, it is considered that no hazard is presented to either workers or the general public via these routes of exposure to gold powder.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: gold

Related composition:
Name: Gold powder

State/form of the substance: powder

Reason for no classification: conclusive but not sufficient for classification

Name: gold

Related composition:
Name: Gold massive

State/form of the substance: solid

Reason for no classification: conclusive but not sufficient for classification

6.2. Flammability

Flammability

The available information on flammability is summarised in the following table:

Table 26. Information on flammability

Method	Results	Remarks	Reference
equivalent or similar to EC No 1272/2008 Method N.1 of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, fifth revised edition 2009	Evaluation of results: Not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test Study results: Ignition on contact with air: no Burning time (s): 0 Remarks: Test substance failed to ignite during the five minutes that the Bunsen flame was applied. Result of preliminary screening test obviated need to perform main test. Length of pile had no effect on the result as pile failed to ignite in preliminary test.	1 (reliable without restriction) key study experimental result **Test material (common name): Gold**	Tremain SP and Atwal SS (2011)

Discussion

A GLP-compliant study following UN method N1 is available for this endpoint (Harlan Laboratories 2011). This is considered suitable as the key study.

The following information is taken into account for any hazard / risk assessment:

Gold is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test

Flash point

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: gold

Related composition:
Name: Gold powder

State/form of the substance: powder

Reason for no classification (Flammable gases): conclusive but not sufficient for classification

Reason for no classification (Flammable aerosols): conclusive but not sufficient for classification

Reason for no classification (Flammable liquids): conclusive but not sufficient for classification

Reason for no classification (Flammable solids): conclusive but not sufficient for classification

Name: gold

Related composition:
Name: Gold massive

State/form of the substance: solid

Reason for no classification (Flammable gases): conclusive but not sufficient for classification

Reason for no classification (Flammable aerosols): conclusive but not sufficient for classification

Reason for no classification (Flammable liquids): conclusive but not sufficient for classification

Reason for no classification (Flammable solids): conclusive but not sufficient for classification

Justification for classification or non-classification:

Based on a GLP-compliant study following a standard test guideline, gold is not classified as a readily combustible solid.

6.3. Oxidising potential

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: gold

Related composition:
Name: Gold powder

State/form of the substance: powder

Reason for no classification (Oxidising gases): conclusive but not sufficient for classification

Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification

Reason for no classification (Oxidising solids): conclusive but not sufficient for classification

Name: gold

Related composition:
Name: Gold massive

State/form of the substance: solid

Reason for no classification (Oxidising gases): conclusive but not sufficient for classification

Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification

Reason for no classification (Oxidising solids): conclusive but not sufficient for classification

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

In a GLP, guideline transformation/dissolution full test, performed at loading rates of 1, 10 and 100 mg/L and pH 6, gold showed no dissolution above the Limit of Detection of 0.3 µg/L (Brouwers, 2012). The standard approach for assessing the toxicity of a poorly soluble metal would be to compare the amount of dissolution determined in a transformation/dissolution test with the acute and chronic ecotoxicity reference values for a soluble salt of the metal in order to assess the toxicity impact of the test item in aqueous medium. However, the quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. On this basis the ecotoxicity endpoints for gold metal are waived.

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

Data waiving

Information requirement: Short-term toxicity testing on fish

Reason: study scientifically unjustified

Justification: No data are available for gold to fulfil this endpoint. In a GLP guideline transformation/dissolution full test, performed at loading rates of 1, 10 and 100 mg/L and pH 6, gold showed no dissolution above the Limit of Detection of 0.3 µg/L (Brouwers, 2012). The standard approach for assessing the toxicity of a poorly soluble metal would be to compare the amount of dissolution determined in a transformation/dissolution test with the acute and chronic ecotoxicity reference values for a soluble salt of the metal in order to assess the toxicity impact of the test item in aqueous medium. However, the quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. On this basis it is considered scientifically unjustified to conduct a short term toxicity study with fish and the study is waived.

7.1.1.2. Long-term toxicity to fish

No relevant information available

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

Data waiving

Information requirement: Short-term toxicity testing on aquatic invertebrates

Reason: study scientifically unjustified

Justification: No data are available for gold to fulfil this endpoint. In a GLP guideline transformation/dissolution full test, performed at loading rates of 1, 10 and 100 mg/L and pH 6, gold showed no dissolution above the Limit of Detection of 0.3 µg/L (Brouwers, 2012). The standard approach for assessing the toxicity of a poorly soluble metal would be to compare the amount of dissolution determined in a transformation/dissolution test with the acute and chronic ecotoxicity reference values for a soluble salt of the metal in order to assess the toxicity impact of the test item in aqueous medium. However, the quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. On this basis it is considered scientifically unjustified to conduct a short term toxicity study with aquatic invertebrates and the study is waived.

7.1.2.2. Long-term toxicity to aquatic invertebrates

No relevant information available

7.1.3. Algae and aquatic plants

Data waiving

Information requirement: Growth inhibition study with algae / cyanobacteria

Reason: study scientifically unjustified

Justification: No data are available for gold to fulfil this endpoint. In a GLP guideline transformation/dissolution full test, performed at loading rates of 1, 10 and 100 mg/L and pH 6, gold showed no dissolution above the Limit of Detection of 0.3 µg/L (Brouwers, 2012). The standard approach for assessing the toxicity of a poorly soluble metal would be to compare the amount of dissolution determined in a transformation/dissolution test with the acute and chronic ecotoxicity reference values for a soluble salt of the metal in order to assess the toxicity impact of the test item in aqueous medium. However, the quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. On this basis it is considered scientifically unjustified to conduct a short term toxicity study with algae and the study is waived.

7.1.4. Sediment organisms

No relevant information available

7.1.5. Other aquatic organisms

No relevant information available

7.2. Terrestrial compartment

7.2.1. Toxicity to soil macro-organisms

No relevant information available

7.2.2. Toxicity to terrestrial plants

No relevant information available

7.2.3. Toxicity to soil micro-organisms

No relevant information available

7.2.4. Toxicity to other terrestrial organisms

No relevant information available

7.3. Atmospheric compartment

Gold is not expected to contribute to ozone depletion, ozone formation, global warming or acidification. Therefore, the evaluation of atmospheric risk is not required.

7.4. Microbiological activity in sewage treatment systems

Data waiving

Information requirement: Effects on aquatic micro-organisms

Reason: study scientifically unjustified

Justification: No data are available for gold to fulfil this endpoint. In a GLP guideline transformation/dissolution full test, performed at loading rates of 1, 10 and 100 mg/L and pH 6, gold showed no dissolution above the Limit of Detection of 0.3 µg/L (Brouwers, 2012). The standard approach for assessing the toxicity of a poorly soluble metal would be to compare the amount of dissolution determined in

a transformation/dissolution test with the acute and chronic ecotoxicity reference values for a soluble salt of the metal in order to assess the toxicity impact of the test item in aqueous medium. However, the quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. On this basis it is considered scientifically unjustified to conduct a toxicity study with microorganisms and the study is waived.

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

No relevant information available

7.5.2. Toxicity to mammals

No relevant information available

7.6. PNEC derivation and other hazard conclusions

Table 27. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	No hazard identified	No hazard is presented to aquatic environment from gold. Gold showed no dissolution above the Limit of Detection of 0.3 µg/L in a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6. The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it is considered that no hazard is presented to aquatic environment from gold.
Marine water	No hazard identified	It is considered that no hazard is presented to marine environment from gold. Gold showed no dissolution above the Limit of Detection of 0.3 µg/L in a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6. The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it can be concluded that no hazard is presented to marine environment from gold.
Intermittent releases to water	No hazard identified	It is considered that no hazard is presented to the environment from intermittent releases of gold. Gold showed no dissolution above the Limit of Detection of 0.3 µg/L in a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6. The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it can be concluded that no hazard is presented from intermittent releases of gold.
Sediments (freshwater)	No hazard identified	It is considered that no hazard is presented to freshwater sediment from gold. Gold showed no dissolution above the Limit of Detection of 0.3 µg/L in a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6. The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it can be concluded that no hazard is presented to

Compartment	Hazard conclusion	Remarks/Justification
		freshwater sediment from gold.
Sediments (marine water)	No hazard identified	It is considered that no hazard is presented to marine sediment from gold. Gold showed no dissolution above the Limit of Detection of 0.3 µg/L in a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6. The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it can be concluded that no hazard is presented to marine sediment from gold.
Sewage treatment plant	No hazard identified	It is considered that no hazard is presented to microorganisms from gold. Gold showed no dissolution above the Limit of Detection of 0.3 µg/L in a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6. The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it can be concluded that no hazard is presented to microorganisms from gold.
Soil	No hazard identified	It is considered that no hazard is presented to soil organisms from gold. Gold showed no dissolution above the Limit of Detection of 0.3 µg/L in a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6. The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it can be concluded that no hazard is presented to soil organisms from gold.
Air	No hazard identified	It is considered that no hazard is presented to air from gold.
Secondary poisoning	No potential for bioaccumulation	Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant.

Environmental classification justification

Acute classification under CLP / GHS

Gold showed no dissolution above the Limit of Detection of 0.3 µg/L after 7 days in a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6. The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it is considered that no acute hazard is presented to environment from gold and, according to ECHA guidance, gold should not be classified for acute hazard.

Chronic classification under CLP / GHS

Similar to the results of 7-day T/D testing, the results of 28-day T/D testing at loading rates of 1, 10 and 100 mg/L were also below the analytical limit of detection (0.3 µg/L). The quantities of gold which are released into solution from gold metal during a transformation/dissolution test are diminishingly small (<0.3 µg/L) and it is unlikely to be possible to determine the speciation of any dissolved metal. Therefore, it is considered that no chronic hazard is presented to environment from gold and, according to ECHA guidance, gold should not be classified for chronic hazard.

General discussion

In a GLP, guideline transformation/dissolution test performed at loading rates of 1, 10 and 100 mg/L and pH 6 gold showed no dissolution above the Limit of Detection of 0.3 µg/L after 7 and 28 days (Brouwers 2012).

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

8.1.1.1. Assessed substance: Substance itself

Reference substance: gold

8.1.1.1.1. Persistence assessment

Other evidence of non-P / non-vP properties

PBT assessment is unjustified as the substance is inorganic.

Conclusion on P / vP properties: P not vP

PBT assessment is unjustified as the substance is inorganic.

8.1.1.1.2. Bioaccumulation assessment

Other evidence of non-B / non-vB properties

PBT assessment is unjustified as the substance is inorganic.

Conclusion on B / vB properties: not B/vB

PBT assessment is unjustified as the substance is inorganic.

8.1.1.1.3. Toxicity assessment

Other evidence of non-T properties

PBT assessment is unjustified as the substance is inorganic.

Conclusion on T properties: not T

PBT assessment is unjustified as the substance is inorganic.

8.1.2. Summary and overall conclusions on PBT or vPvB properties

Overall conclusion:

Based on the assessment described in the subsections above the substance is not a PBT / vPvB substance.

Justification:

Gold is an inorganic and therefore the PBT assessment is unjustified.

9. EXPOSURE ASSESSMENT (and related risk characterisation)

Section 9 is not required as gold is a non-classified substance.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

Section 10 is not required as gold is a non-classified substance.

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