CHEMICAL SAFETY REPORT

Substance Name: Lead bullion, Platinum Group Metals rich

EC Number: 931-607-7

Registrant's Identity: EPMF1

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Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

The risk management measures for all Exposure Scenarios are described in Part B, Section 9 of this Chemical Safety Report.

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

Each EU manufacturer and importer, having decided to mandate the Lead Registrant to submit this CSR on his behalf, endorses the declaration that he *implements* those risk management measures described in Part B, Chapter 9+10 of this document, that are relevant to his manufacture or import and own uses. Registrants that submit their own Part A are excluded from the afore-mentioned endorsement.

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

Each EU manufacturer, importer and Only Representative having decided to mandate the Lead Registrant to submit this CSR on his behalf endorses the declaration that he communicates to distributors and the downstream users those risk management measures that are relevant for their uses as described in Part B, Section 9+10 of this document. Registrants that submit their own Part A are excluded from the afore-mentioned endorsement.

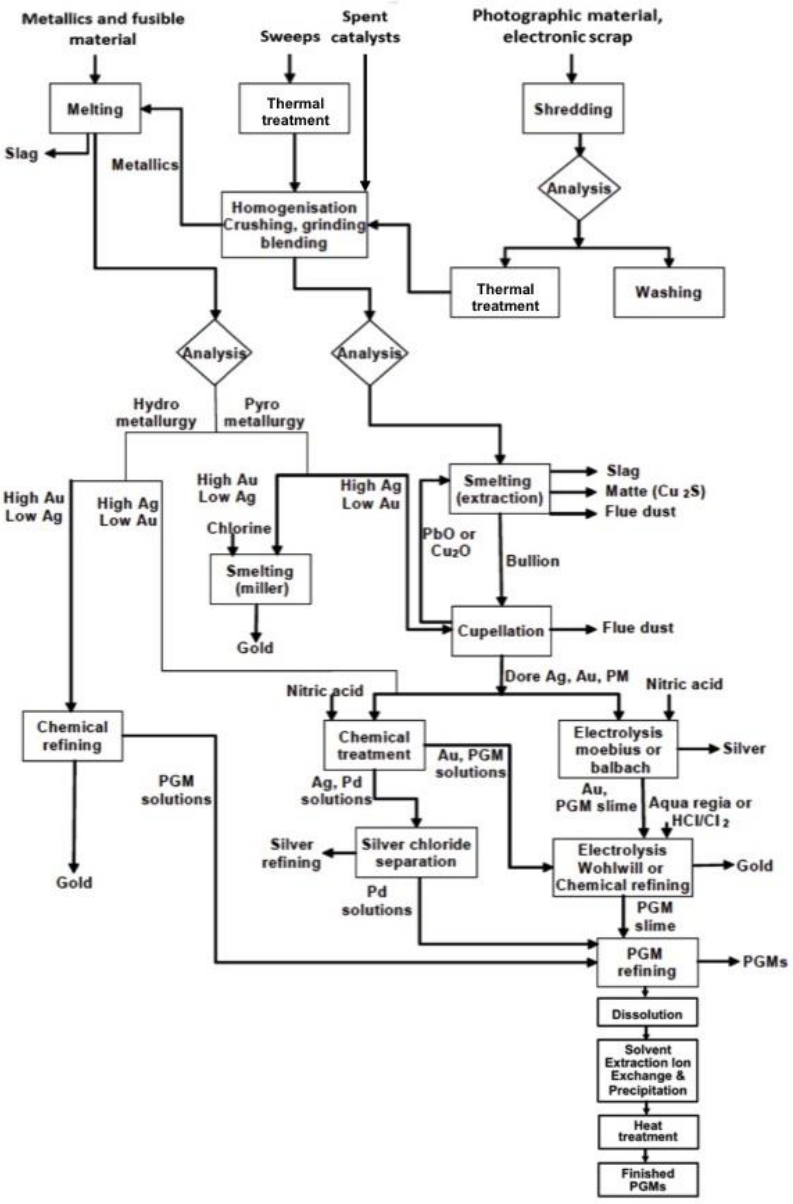
Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.0. Characterisation of the substance

Intermediates produced during the refining of precious metals (Silver (Ag), Gold (Au), and six Platinum Group Metals (PGM): Platinum (Pt), Palladium (Pd), Ruthenium (Ru), Rhodium (Rh), Iridium (Ir), and Osmium (Os)) are included in the scope of the Precious Metals and Rhenium Consortium (PMC) c/o European Precious Metals Federation, a member of Eurométaux, and are commonly referenced as Precious Metals Refinables.

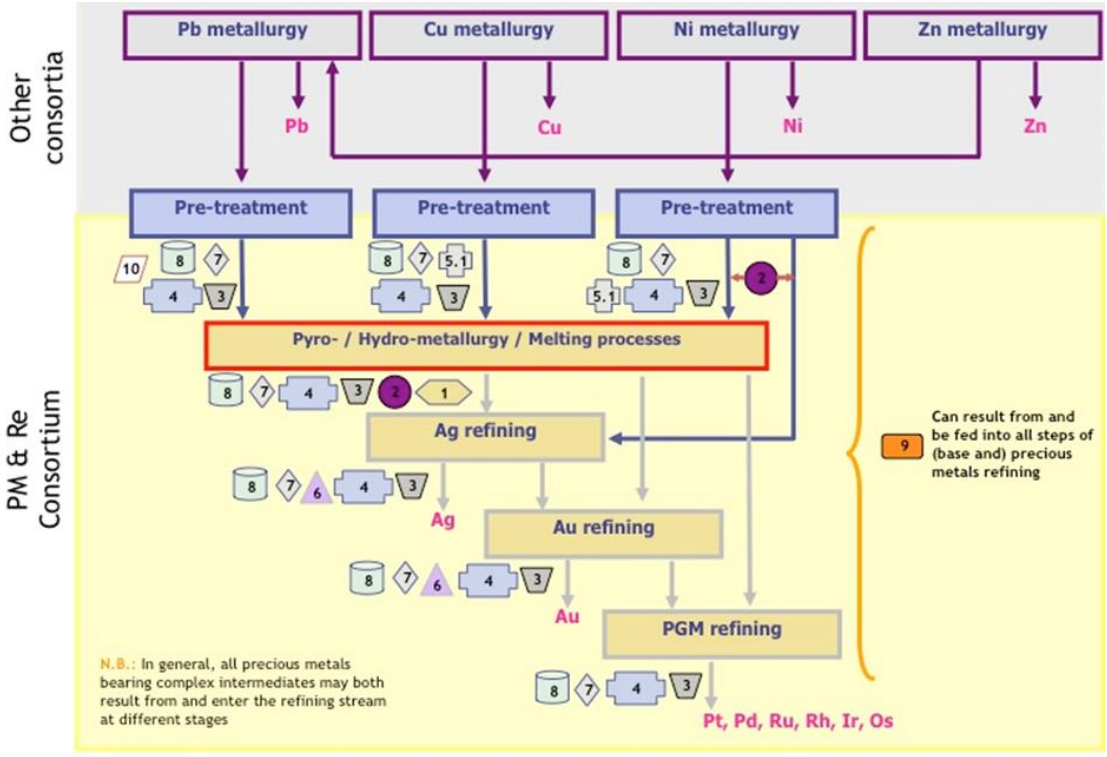
The most significant sources of precious metals are precious metal ores, by-products obtained from the processing of other non-ferrous metals (in particular anode slimes from copper production, leach residues and crude metal from zinc and lead production) and recycled material. They may be fed directly into the production process or require some level of pre-treatment, such as incineration or shredding, for instance.



Production processes are common for primary and secondary raw materials. In precious metal refining, production processes are usually carried out in various combinations to recover the precious metals that are present in a particular feedstock. Multi-purpose reactors and furnaces are used extensively and processing steps are often repeated, meaning it is difficult to identify single process steps. A variety of processes have been developed which exploit the chemical properties of precious metals. Although they are relatively inert, their reactivity varies and the various oxidation states of the metal in their compounds allows a variety of pyro- and hydro-metallurgical separation techniques to be used, as illustrated above.

Precious Metals Refinables are non-waste complex inorganic isolated intermediates resulting from the processing of a primary and/or secondary stream reclaimed for its precious metals content. Precious metals are contained in primary and secondary raw materials alone or 'embedded' or 'carried' by other metals, with whom precious metals have chemical affinity. For example, very generally summarised: copper and gold, lead and silver, and nickel and some PGM, are known to occur together, respectively. Precious Metals are hence present in most primary and secondary sources of zinc and lead, copper, and nickel.

The complexity of Precious Metals refining streams results first of all from the fact that they arise from a variety of other metals refining streams and sources, with a valuable presence of precious metals (Cf. Illustration below). These streams are collected together with other sources of precious metals by specialized refiners which apply the necessary subsequent and iterative pyro- and hydro-metallurgical processes to recover the precious metal content in the most efficient and innovative manner, in order to remain competitive.



1. Doré; 2. Matte PM; 3. Slags PM refining; 4. Slimes & sludges PM refining; 5.1. Residues matte leaching; 6. Ag electrolyte & Au electrolyte; 7. Flue dust PM refining; 8. Residues PM refining cementation & reduction; 9. Materials for reclaim PM; 10. Pb bullion PGM rich

The above illustration is a simplified scheme. A complete scheme would include additional arrows to indicate the iterative loops of base and precious metals recovery from the various process steps. Indeed, base metal rich streams are sent back to a base metal refining process, and a given precious metal-rich stream would be reused as feedstock in the various refining steps represented as discrete boxes in the illustration, according to the precious metal to be recovered and the other constituents to be removed and their affinity with the various process step conditions that exist in a given site. This is more visible in the 'simplified life-cycles' provided for each Refinable in Chapter 2 of the respective CSR, where 'black arrows' show the inputs and outputs from and to other base metals' refining, and 'green arrows' and 'red arrows' show the inputs and outputs from and to other precious metals' refining.

As precious metals are very scarce chemicals, and the precious metal refining capacity in EU is larger than the quantities of precious metals to be refined, any and all sources of precious metals are used as feedstock for

smelting. Except for some secondary raw materials which need to be pre-treated before smelting or leaching, most primary and secondary raw materials containing precious metals can be used concomitantly in any smelting phase of the precious metals production, and in particular in an early smelting phase, such as the one leading to the production of doré or matte, precious metals refining. Slags and flue dust will be produced in all smelting phases. Outputs of the subsequent pyro- or hydro-metallurgical refining steps, such as the slimes and sludges and leaching residues, will hence be inherently influenced by the variability of sources that was used in the early steps of the refining by a given producer on a given day. Because precious metals refining allows (and even requires) combining as much sources as possible right from the start (i.e. combining variable primary and secondary sources), the variability of precious metals UVCB will be large from the start of the refining process, and reduced at the end of the refining, when the precious metals are finally recovered and refined.

In summary, the variability within each type of Refinable is very much influenced by the source of the refining material as well as by the specificities and combination of the process steps which are applied to recover the precious metal content by each producer.

PMC Members have made an attempt to identify typical Refinables in line with REACH Substance Identification requirements. Considering the specific complexity of precious metal containing complex refining intermediates, a pragmatic approach has been followed to group streams resulting from similar source(s) and/or process(es).

Refinables are considered under REACH as UVCB substances in that they cannot be uniquely specified with the IUPAC name of the constituents, as not all the constituents can be identified; or that they may be generically identified on the basis of the sources and process, but with a lack of specificity due to variability of the exact composition.

The main identifiers for Refinables are related to the source of the substance and the process used, as further described in Chapter 2. Due to the lack of differentiation between constituents and impurities, the terms “main constituents” and “impurities” are not be used for Refinables, even if some constituents are known to be of no value to the actual purpose of the Refinable: to be transformed into (an)other substance(s) leading to the removal of unwanted constituents, and the concentration and recovery of (a given) precious metal(s).

The precious metal production route has therefore been used to categorise these substances. Major processes and the related intermediate types of the precious metal production have been mapped (see Chapter 2 of this CSR for more details).
In view to characterize each intermediate substance, the PMC proceeded as follows:
- For each intermediate substance, the range in elemental compositions within and across all companies has been assessed.
- Metal species were determined based on information available to registrants and/or mineralogical analysis (by means of XRD analysis).

Company-specific elemental concentration information was obtained from all participating companies. These data were aggregated into so-called generic/full compositions. Therefore, Chapter 1.2 of this CSR lists generic compositions as defined across industry. Ranges were defined based on min and max of the typicals across industry, and the typical values mentioned are average of the typicals across industry. Companies were requested to provide in their REACH files in addition their Legal Entity specific composition(s), with their typicals falling within the ranges of the generic ones (into IUCLID section 1.2 only).

1.1. Name and other identifiers of the substance

The substance **Lead bullion, Platinum Group Metals rich** is a UVCB (origin: inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

The following public name is used: Lead bullion, Platinum Group Metals rich.

Table 1. Substance identity

EC number:	931-607-7 (list number assigned by ECHA)
EC name:	Lead bullion, Platinum Group Metals rich
IUPAC name:	Lead bullion, Platinum Group Metals rich

Description:	Pre-registered as EC number: 308-011-5 Primary and secondary feed materials usually in the form of residues containing low concentrations of precious metals, together with higher and variable concentrations of base metals and refractory materials that are mixed with fluxes and smelted with a lead collector, resulting in two phases: a lead one which concentrates precious metals, and a silicate slag phase (Slags, precious metals refining). After granulation the lead phase, or Lead Bullion, Platinum Group Metal Rich is used as a feed in the hydrometallurgical upgrading of platinum group metals; it contains predominantly lead with lower concentrations of platinum group metals, silver and gold and other non-ferrous metals in varying concentrations.
Molecular formula:	
Molecular weight range:	

Remark: No separate EC entry was found in 2010 for this substance, as it is a split from EC entry 308-011-5 (registered by the Pb consortium). The list number assigned by ECHA is 931-607-7.
The name proposed by the PMC is “Lead bullion, Platinum Group Metals rich”. The above description for this substance is proposed by the PMC.

1.2. Composition of the substance

The Full/ Generic composition lists all known constituents and describes the composition across industry, derived as follows for each elemental constituent:

- Typical concentration = average of Legal Entity typical concentrations;
- Minimum concentration = minimum of Legal Entity typical concentrations;
- Maximum concentration = maximum of Legal Entity typical concentrations.

Name: Pb bullion, PGM rich (Full/Generic composition)

Description: Metallic bars/ingots and grains and their residues resulting from the smelting of primary and secondary feeds using lead as a collector. Contains lead with lower concentrations of silver, platinum group metals and other non-ferrous metals.

Degree of purity: 100.0 % (w/w)

Table 2. Constituents

Constituent	Typical concentration	Concentration range	Remarks
gold EC no.: 231-165-9	0.75 % (w/w)	0.5 — 1.0 % (w/w)	Refers to % element. Element is present in metallic form.
iridium EC no.: 231-095-9	14.0 % (w/w)	3.0 — 25.0 % (w/w)	Refers to % element. Present in metallic form.
palladium EC no.: 231-115-6	15.0 % (w/w)	5.5 — 25.0 % (w/w)	Refers to % element. Present in metallic form.
platinum EC no.: 231-116-1	15.0 % (w/w)	5.5 — 25.0 % (w/w)	Refers to % element. Element is present in metallic form
rhodium EC no.: 231-125-0	14.0 % (w/w)	3.0 — 25.0 % (w/w)	Refers to % element. Present in metallic form.
ruthenium	15.0 % (w/w)	5.5 — 25.0 % (w/w)	Refers to % element.

Constituent	Typical concentration	Concentration range	Remarks
EC no.: 231-127-1			Present in metallic form.
silver EC no.: 231-131-3	11.3 % (w/w)	7.5 — 15.0 % (w/w)	Refers to % element. Element is present in metallic form.
antimony EC no.: 231-146-5	3.8 % (w/w)	2.5 — 5.0 % (w/w)	Refers to % element. Element is present in metallic form.
arsenic EC no.: 231-148-6	1.5 % (w/w)	1.0 — 2.0 % (w/w)	Refers to % element. Element is present in metallic form.
bismuth EC no.: 231-177-4	7.5 % (w/w)	5.0 — 10.0 % (w/w)	Refers to % element. Element is present in metallic form.
cadmium EC no.: 231-152-8	0.045 % (w/w)	0.0 — 0.09 % (w/w)	Refers to % element. Element is present in metallic form.
copper EC no.: 231-159-6	15.0 % (w/w)	10.0 — 20.0 % (w/w)	Refers to % element. Element is present in metallic form.
iron EC no.: 231-096-4	1.0 % (w/w)	0.0 — 2.0 % (w/w)	Refers to % element. Element is present in metallic form
lead EC no.: 231-100-4	70.0 % (w/w)	60.0 — 80.0 % (w/w)	Refers to % element. Element is present in metallic form.
nickel EC no.: 231-111-4	7.5 % (w/w)	5.0 — 10.0 % (w/w)	Refers to % element. Element is present in metallic form.
selenium EC no.: 231-957-4	2.5 % (w/w)	0.0 — 5.0 % (w/w)	Refers to % element. Element is present in metallic form.
tellurium EC no.: 236-813-4	7.5 % (w/w)	5.0 — 10.0 % (w/w)	Refers to % element. Element is present in metallic form.
tin EC no.: 231-141-8	1.0 % (w/w)	0.0 — 2.0 % (w/w)	Refers to % element. Element is present in metallic form.
zinc EC no.: 231-175-3	1.0 % (w/w)	0.0 — 2.0 % (w/w)	Refers to % element. Element is present in metallic form.

NOTE: An explanation of the variable composition of this UVCB resulting from the involved sources and process is provided in Chapter 2 of the CSR.

1.3. Physicochemical properties

Table 3. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	Lead bullion, PGM rich is an odourless black/metallic solid (ingot and grain).	Data provided by a member company are considered reliable and suitable for use for this endpoint. Lead bullion, PGM rich is an odourless black/metallic solid (ingot and grain).
Melting / freezing point	The melting point of lead bullion, PGM rich is >450°C	The melting point of lead bullion, PGM rich, was determined in an experimental study (Harlan 2014). Draft results are available from this study, however the test report is still in preparation. This record will be updated once the test report is received.
Relative density	The relative density of lead bullion, PGM rich, is 9.10.	The relative density of lead bullion, PGM rich, was determined in an experimental study (Harlan 2014). Draft results are available from this study, however the test report is still in preparation. This record will be updated once the test report is received.
Granulometry	The particle size distribution study indicated a D50 of 723 µm and a D80 of 1568 µm for Lead bullion, PGM rich.	The particle size distribution of Lead bullion, PGM rich was determined in an experimental study using a sieving system. The study (Outotec 2010) is not GLP but followed sound scientific principles, was well documented and is considered suitable for use for this endpoint.
Water solubility	Transformation/dissolution tests were conducted lead bullion, PGM rich and the metals above the detection limits were copper and lead.	Water solubility testing is not appropriate for complex metal and sparingly soluble metals and metal compounds. Transformation/ dissolution testing has been conducted following OECD guideline 29 and the results are presented in section 5.6 of IUCLID and section 4.5 of the CSR.

Data waiving

Information requirement: Boiling point

Reason: study scientifically unjustified

Justification: According to Annex VII, section 7.3, column 2 of Regulation No. 1907/2006, a boiling point study is not required for solids that melt above 300°C or decompose before boiling (see results in IUCLID 4.2).

Information requirement: Vapour pressure

Reason: study scientifically unjustified

Justification: According to Annex VII, section 7.5, column 2 of Regulation No. 1907/2006, the study does not need to be conducted if the melting point is above 300°C.

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

Reason: study scientifically unjustified

Justification: According to Annex VII, section 7.8, column 2 of Regulation No. 1907/2006, the study does not need to be conducted as the substance is inorganic.

Information requirement: Water solubility

Reason: other justification

Justification: Water solubility testing is not appropriate for complex metal and sparingly soluble metals and metal compounds. Transformation dissolution testing has been conducted and is presented in IUCLID section 5.6 and CSR section 4.5.

Information requirement: Surface tension

Reason: study scientifically unjustified

Justification: According to Annex VII, section 7.6, column 2 of Regulation No. 1907/2006, surface tension is not required unless the surface activity is expected or is a desired property of the material. Based on the structure, surface activity is not expected for this inorganic substance and is not a desired property, therefore the test is not required.

Information requirement: Flash point

Reason: study scientifically unjustified

Justification: According to Annex VII, section 7.9, column 2 of Regulation No. 1907/2006, flash-point does not need to be conducted if the substance is inorganic.

Information requirement: Self-ignition temperature

Reason: study scientifically unjustified

Justification: A flammable solid means a solid which is readily combustible or may cause or contribute to fire through friction. Readily combustible solids are powdered, granular or pasty substances or mixtures which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match and if the flame spreads rapidly (CLP regulation, Annex 1, section 2.7.1). The test item is a metallic substance that is approximately 80% lead, and is manufactured in both massive form and granular form with particle size distribution of 96.2%>1mm. Therefore due to the physical form of the test item and in view of metallic lead having not been classified as flammable in respect to the CLP regulations, it is not deemed necessary for the study to be conducted as known information indicates that the test item is not flammable.

Information requirement: Flammability

Reason: study scientifically unjustified

Justification: In accordance with REACH Annex XI, testing for flammability is scientifically unjustified since the substance is a solid form containing only metals and is not manufactured or available as a powder form.

Information requirement: Explosive properties

Reason: study scientifically unjustified

Justification: According to Annex VII, section 7.11, column 2 of Regulation No. 1907/2006, the study does not need to be conducted if there are no chemical groups associated with explosive properties present in the molecule.

Information requirement: Oxidising properties

Reason: study scientifically unjustified

Justification: According to Annex VII, section 7.13, column 2 of Regulation No. 1907/2006, the study does not need to be conducted if the substance is incapable of reacting exothermically with combustible materials on the basis of the chemical structure. The test item is a metallic substance that contains no oxygen or halogen atoms and hence the study does not need to be conducted.

Information requirement: Stability in organic solvents and identity of relevant degradation products

Reason: study scientifically unjustified

Justification: According to Annex IX, section 7.15, column 2 of Regulation No. 1907/2006, the study does not need to be conducted as the substance is inorganic.

Information requirement: Dissociation constant

Reason: study technically not feasible

Justification: According to Annex IX, section 7.16, column 2 of Regulation No. 1907/2006, the study does not need to be conducted if it is scientifically not feasible to perform the test. The dissociation constant study does not need to be conducted as the substance does not contain any functional groups that dissociate and therefore testing does not appear scientifically necessary.

Information requirement: Viscosity

Reason: study technically not feasible

Justification: In accordance with ECHA (2008) Guidance on information requirements and chemical safety assessment, Chapter R7a: endpoint specific guidance, the viscosity study does not need to be conducted as this substance is a solid.

Discussion of physicochemical properties

Lead bullion, PGM rich is an odourless black/metallic solid (ingot and grain). Particle size testing determined a D50 of 723 µm and a D80 of 1568 µm. Melting point is greater than 450°C (>723 K). As water solubility testing is not appropriate for complex metal and sparingly soluble metals and metal compounds, results from the transformation/dissolution testing is presented in IUCLID section 5.6 and CSR section 4.5.

2. MANUFACTURE AND USES

No information available on quantities

2.1. Manufacture

This section of the CSR is generic and it is the responsibility of each registrant to check if the reported PROCs are appropriate and to report only such PROCs in IUCLID section 3.5. However, the current risk assessment is restricted to the list of mentioned PROCs. Thus, it is only possible to delete PROCs, whereas additional PROCs are not to be included without amending the risk assessment.

Table 4. Manufacture

Identifiers	Use descriptors	Other information
M-: Manufacture of an intermediate	**Environmental release category (ERC):** ERC 1: Manufacture of substances **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 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 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 26: Handling of solid inorganic substances at ambient temperature PROC 27b: Production of metal powders (wet processes)	

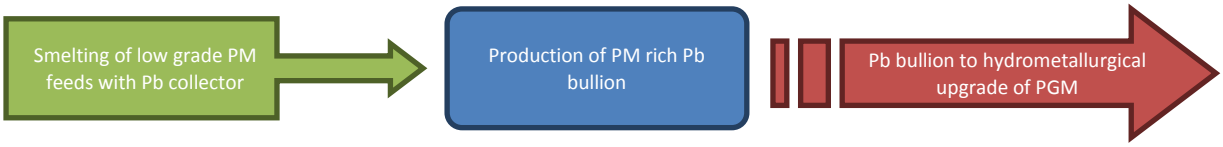
No information available on manufacture

Table 5. Manufacturing process related to the specified manufacture(s)

Related manufacture(s)	Description of manufacturing process
	Lead Bullion, Platinum Group Metals Rich are produced from primary and

Related manufacture(s)	Description of manufacturing process
	secondary feed materials usually in the form of residues containing low concentrations of precious metals, together with higher and variable concentrations of base metals and refractory materials that are mixed with fluxes and smelted with a lead collector, resulting in two phases: a lead one which concentrates precious metals, and a silicate slag phase (Slags, precious metals refining). After granulation the lead phase, or Lead Bullion, Platinum Group Metal Rich is used as a feed in the hydrometallurgical upgrading of platinum group metals; it contains predominantly lead with lower concentrations of platinum group metals, silver and gold and other non-ferrous metals in varying concentrations.

The below flowsheet identifies influx/outflux substances in the production of Lead Bullion, Platinum Group Metals Rich. Green/red arrows are used for influx from/outflux to precious metal sector.



Though the production of of a Precious Metals rich lead bullion is the result of a single process (smelting with selected fluxes), the materials that can be fed to this smelting process are typically from more than one source (copper, nickel, lead or others), and can be smelted together depending on the material available from registrant to registrant, and from day to day. Hence, the sources (because they are not necessarily pre-selected and can be smelted together) and process to produce a silver rich lead bullion or a PGM lead bullion, are the same.

The variability in composition of each constituent in this Refinable, and in particular the variability in each precious metals content, reflects the possible versions of a precious metal rich bullion that can be manufactured; if silver content is high, PGM content will be low, and vice-versa. The other constituents present will be present in lower or higher concentrations depending on the source materials' composition available for that specific smelting lot; for example, if a copper rich material was used, the concentration of copper will be high.

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

2.2. Identified uses

This section of the CSR is generic and it is the responsibility of each registrant to check if the reported PROCs are appropriate and to report only such PROCs in IUCLID section 3.5. However, the current risk assessment is restricted to the list of mentioned PROCs. Thus, it is only possible to delete PROCs, whereas additional PROCs are not to be included without amending the risk assessment.

Table 6. Uses at industrial sites

Identifiers	Use descriptors	Other information
IW-: Use as an intermediate in metal manufacturing	**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 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or	Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	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 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 26: Handling of solid inorganic substances at ambient temperature PROC 27b: Production of metal powders (wet processes) **Sector of end use:** SU 14: Manufacture of basic metals, including alloys **Technical function of the substance during formulation:** Intermediates	

3. CLASSIFICATION AND LABELLING

3.0. Introduction to classification

3.0.1. General approach

An inorganic UVCB substance is a complex substance. Its main characteristics are a known but variable elemental composition and the - in some cases - partly unknown speciation of the constituents.

The classification of the inorganic UVCB is based on the hazard of its constituents and the classification rules for the hazard assessment of mixtures under the UN Globally Harmonised System (GHS) and its EU implementation (CLP). To derive the UVCB classification, one therefore needs to have information on

- UVCB variability (elemental concentration),
- the physical form (e.g. massive, powder),
- the hazard profile for all the elemental constituents, and
- the speciation of the constituents (and the uncertainty associated if partly unknown)

The official ECHA guidance (e.g. from the European Chemicals Agency, ECHA for the CLP[1]) is used as basis for the assessment and includes metal-specific guidance.

The unknown constituents speciation and elemental variability are addressed following a precautionary and conservative approach. In practice:

- The starting point is the UVCB composition (as defined in IUCLID /CSR 1.2): the elemental composition is provided listing variability (i.e. concentration range) and reporting the available information on the chemical speciation of each constituent (i.e. specifying whether analytical tests could identify if the element is present as oxide, sulphide,…).
    - When the speciation of the elemental constituent is known, it is used as such for the classification assessment of the UVCB; when the speciation of the elemental constituent is unknown, the speciation with the worst-case classification is selected and assigned to the constituent for the UVCB classification calculation.
    - The typical UVCB variability in elemental constituents (i.e. wide range concentration of the UVCB constituents) is assessed by selecting a worst-case concentration, which is defined as the maximum of all company (across industry) typical concentrations for each constituent.

- Within one UVCB substance, the variability in elemental composition can potentially lead to different hazard profiles. Therefore, there can be a practical need (for the purpose of SDS and labelling) to differentiate more hazardous from less hazardous individual streams within the inorganic UVCB. Generic groups/grades/clusters within one UVCB - each group with a common worst-case classification profile - can be developed and reported in IUCLID to increase general understanding of the variability of the hazard of the UVCB and to allow registrants to easily derive a worst-case classification for possible new streams.

The MeClas tool (www.meclas.eu) has been developed to facilitate the classification of complex inorganic materials, considering the aspects raised above. The tool allows the use of constituent specific information to derive UVCB classification based on mixture rules (CLP).

3.0.2. MECLAS

The classification of inorganic UVCBs is assessed using the MeClas tool (MEtal CLASsification tool, www.meclas.eu).
MeClas was developed to:

- deal with the complexity of the hazard classification of complex inorganic UVCBs;
- ensure consistent classification of complex inorganic UVCBs throughout the industry;
- provide full recognition to metal specific aspects;

[1] *ECHA, November 2013. Guidance on the Application of the CLP Criteria. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures.*

- provide a platform for relevant data centralisation between metal consortia (self-classifications and (eco)toxicity reference values) and between metal consortia and companies (read-across of speciation and bio-availability tests).

The tool allows the use of constituent specific information to derive UVCB classification based on mixture rules (CLP).

MeClas is therefore facilitating the hazard identification for complex metal materials under CLP/ DSD/GHS throughout the metal industry.
MeClas is built on a limited number of simple and basic principles:

- A **tiered and inorganic specific approach,** allowing refinement in accordance with the following (not necessarily sequential) steps/and available information:
  - Tier 0: elemental concentrations only (and worst-case speciation and worst-case 100% solubility)
  - Tier 1: speciation data and mineralogical evidence
  - Tier 2: correction based on release/solubility test data on the complex material
- **An up-to-date database** including the official EU harmonised (Annex VI of the CLP and subsequent ATPs) and self-classifications, specific concentration limits, M-factors, (eco)toxicity reference values (ERVs) values,…
- An **open building block structure**, enabling the inclusion of specific side modules if relevant (e.g. for Ores and Concentrates, for Transport Classification, additional reference lists (e.g. Japan), alloys, etc.). The core engine contains the UN-GHS, CLP (and DSD/DPD) hazard ID rulings, forming the base of the MeClas tool.
- **Confidentiality assurance** for proprietary information: Confidentiality of proprietary data is assured by having the ERVs for such substances hidden from normal users of the tool in a dedicated layer of MeClas.

Self-classification of the UVCB substance was performed using the MeClas tool based on below outline:

1. Characterization

The material is accurately described from its elemental composition (typical concentrations and concentration ranges across production sites - IUCLID Section 1.2), and the specific speciation data (mineralogical information, hazard) obtained from representative sample. This information is estimated sufficient to initiate the classification process.

2. Classification by the Mixture Approach

The UVCB is treated as a complex metal containing substance with a number of discrete constituents (i.e. chemical element with discrete speciation). The hazard classifications of each compound are then factored into a combined classification of the UVCB as a whole. For health endpoints, UVCB classifications are based on the combined hazards of the compounds (i.e. chemical element with discrete speciation) whereby additivity or key cut off levels, specified in look-up tables are used, depending on the endpoint and amount of information available for the constituting compounds. These concepts and rules are incorporated in the MeClas tool.

3. Bridging

(Eco)-toxicological data are not available for the specific UVCBs being evaluated. Considering the knowledge and variability in composition, read-across and bridging are done by using a "representative" mineralogical/speciation analysis (if available) combined with the "worst case" elemental concentration (across companies) as a basis for the classification of the UVCB substance (chemical and mineralogical surrogates with similar origin/production process and physical/chemical properties).

4. Optional correction for bio-availability (Tier 2 in MECLAS)

MeClas fulfills the OECD principles for validation of (Q)SARs model

1. **Well defined end points**
2. **Unambiguous algorithm** from EU CLP Guidance: summation/additivity formula, to determine classification and, back-calculation (via Acute Toxicity Estimate formula, etc) to derive the corresponding toxicity of the substance
3. **Clear applicability domain**: applicable to classify complex metal containing materials in a Tiered approach (see EU CLP Guidance pg 499 Annex IV.5.5, and for conceptual outline ICMM Fact Sheet “Ores & Concentrates –An industry approach to EU hazard classification”, November 2009). Input

information at tier 1: elemental composition and representative mineralogical information

4. **Mechanistic interpretation**

   Mechanistic interpretation - metal speciation:

   The tool translates the elemental composition into a mineralogical composition relevant for classification (i.e. mineralogical distribution pattern for each element/constituent of the UVCB substance).

   In the Tier 1, the classification is derived (by means of the summation formula) without taking into account any bio-availability correction. In the Tier 2, the classification is derived (e.g. for environment by means of the additivity formula) taking into account bio-availability correction.

   Mechanistic interpretation - metal-ion additivity for environment:

   (1) The additivity assumption for the toxicity of mixtures of metals was evaluated by De Schamphelaere (2009) - in JAB Bass et al. in "Environmental Quality Standards for trace metals in the aquatic environment", UK Environment Science Report 2009 (Appendix 2): No clear conclusions could be made from the literature review but a targeted experimental design with aquatic algae, showed that the additivity mode could predict the toxicity of metal mixture: the toxicity of simultaneous Cu, Zn, Ni, Cd and Pb additions to two distinct surface waters could be predicted by the additive toxic unit approach.

   (2) A. Stockdale, E Tipping, S Lofts & SJ Ormod, combined metal speciation to the additive toxicity approach and predicted the combined metal toxicity in a range of UK river systems impacted by metals: in "Modelling multiple metal toxic effects in the field - evaluation of the Toxicity Binding Model (TBM) ", ICA Report November 2009.

   The applicability of additivity at low levels (No-effects concentrations, PNECs, sometimes close to natural background levels), is currently under investigation

3.0.3. UVCB specific approach

The hazard assessment of the UVCB as such is driven by the hazard of the individual UVCB chemical elements and related speciation.

In order to address the registration data requirements (Annex VII to Annex VIII) for classification, a non-testing approach has been applied to estimate the effects for relevant toxicological and eco-toxicological endpoints of the Refinable based on read-across from its classified constituents. The principles of the method are: (1) Calculation of the classification of the UVCB substance applying the rules for mixtures as set up in EU CLP Section 4.1.4. (2) Derivation of the hazardous concentration of the UVCB corresponding to the calculated classification category using the adequate EU CLP Guidance Annex I table. This approach provides conservative hazard estimates and furthermore considers the variability in elemental (chemical) composition of the UVCB.

Reasonable worst case assumptions were made with regards to speciation: the actual speciation reported were used if available. In absence of speciation measurements or if different species co-exist (e.g. intermetallic and metal-sulfides), the species with the worst case classification in MeClas was used.

A Tier 1 classification was conducted. No bio-availability corrections are made.

Tier 1 classification
A reasonable worst-case speciation was derived (relevant for Tier 1 classification) using the Generic composition as defined in section 1.2 and information on chemistry & mineralogy of the substance. This distribution pattern for each chemical species is conservative in case speciation is unknown.

Table 7. Summary of the information for the purpose of classification

UVCB constituent		Variability of elemental composition	Classification according each relevant endpoint
Element	Speciation* taken forward for classification		

Ag	Ag compounds	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Au	Au	Maximum of typicals	Not classified, see MECLAS report in CSR Annex I
Ir	Ir/Ir compounds	Maximum of typicals	Not classified, see MECLAS report in CSR Annex I
Pd	Pd compounds	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Pt	Pt compounds with the exception of Pt compounds specified in Annex VI	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Rh	Rh compounds	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Ru	Ru compounds	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
As	As	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Bi	Bi	Maximum of typicals	Not classified, see MECLAS report in CSR Annex I
Cd	Cd (pyrophoric)	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Cu	Cu powder	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Fe	Fe/Fe compounds	Maximum of typicals	Not classified, see MECLAS report in CSR Annex I
Ni	Ni powder	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Pb	Pb powder	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Sb	Sb compounds	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Se	Se	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Sn	Sn	Maximum of typicals	Not classified, see MECLAS report in CSR Annex I
Te	Te compounds	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Zn	Zn powder-zinc dust (pyrophoric)	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I

* see IUCLID/CSR section 1.2 composition

3.1. Classification and labelling according to CLP / GHS

Name: Pb bullion, PGM rich

Implementation: EU

State/form of the substance: solid

Related composition: Pb bullion, PGM rich (Full/Generic composition), Pb Bullion, PGM rich 1 (Constituents relevant for classification)

Remarks: Ni powder >= 1%; Pb powder >= 7%; Cd < 0,1%

100 / (Te% + Se% + Sb% + As%) /100 + (Pb powder%) /500) between 300 – 2000 mg/kg
100 / (Se% + Sb% + As%) /700 + Pb powder%/4500) > 5 mg/L
(%Cu x 0,4 + %Pb x 0,14) > 1
(%Cu x 0,05 + %Pb x 0,056) > 1

Classification

The substance is classified as follows:

Table 8. Classification and labelling according to CLP / GHS for physicochemical properties

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:			conclusive but not sufficient for classification	6.1
Flammable gases:			conclusive but not sufficient for classification	6.2
Flammable 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 9. Classification and labelling according to CLP / GHS for health hazards

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Acute toxicity - oral:	Acute Tox. 4	H302: Harmful if swallowed.		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
Respiration sensitization:			conclusive but not sufficient for classification	5.5.3
Skin sensitation:	Skin Sens. 1	H317: May cause an allergic skin reaction.		5.5.3
Aspiration hazard:			conclusive but not sufficient for classification	5.2.3
Reproductive Toxicity:	Repr. 1A	H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.		5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			conclusive but not sufficient for classification	5.7.3
Carcinogenicity:	Carc. 2	H351: Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routs of exposure		5.8.3

		cause the hazard>.		
Specific target organ toxicity - single:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:	STOT Rep. Exp. 1 Affected organs: Central nervous system and systems for reproduction, or respiratory tract	H372: Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.		5.6.3

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

Table 10. Classification and labelling according to CLP / GHS for environmental hazards

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Hazards to the aquatic environment (acute/short-term):	Aquatic Acute 1	H400: Very toxic to aquatic life.		7.6
Hazards to the aquatic environment (long-term):	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects.		7.6
M-Factor acute: 1				
M-Factor chronic: 1				
Hazardous to the ozone layer:			conclusive but not sufficient for classification	7.6

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

Labelling

Signal word: Danger

Hazard pictogram:

GHS07: exclamation mark

GHS08: health hazard

GHS09: environment

Hazard statements:

H302: Harmful if swallowed.
H317: May cause an allergic skin reaction.
H351: Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routs of exposure cause the hazard>.
H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H372: Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>. (Central nervous system and systems for reproduction, or respiratory tract)
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust/fume/gas/mist/vapours/spray.
P264: Wash... thoroughly after handling.
P270: Do no eat, drink or smoke when using this product.
P272: Contaminated work clothing should not be allowed out of the workplace.
P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P281: Use personal protective equipment as required.
P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P308+P313: IF exposed or concerned: Get medical advice/attention.
P314: Get medical advice/attention if you feel unwell.
P321: Specific treatment (see... on this label).
P330: Rinse mouth.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P362+P364: Take off contaminated clothing and wash before reuse.
P391: Collect spillage.
P405: Store locked up.
P501: Dispose of contents/container to...

3.2. Classification and labelling according to DSD / DPD

3.2.1. Classification and labelling in Annex I of Directive 67/548/EEC

No relevant information available

3.2.2. Self classification(s)

No relevant information available

3.2.3. Other classification(s)

No relevant information available

4. ENVIRONMENTAL FATE PROPERTIES

4.0. Introduction to environmental fate properties

General approach

The hazard assessment of inorganic UVCBs for the purpose of classification and derivation of safe effect thresholds (e.g. PNEC) is a cumbersome and complex process. Due to the intrinsic variability of the composition of an UVCB, it is difficult to select a sample that would unambiguously be representative for the (eco)toxicological hazard profile of the UVCB and could subsequently be used for testing. Instead of direct testing, a precautionary approach is taken where the UVCB is treated as a complex metal containing substance containing a number of discrete constituents (metals, metal compounds, non-metal inorganic compounds etc.). For each of these constituents, the hazard profile is used for deriving the proper classification of the UVCB (using the mixture rules) and/or for the derivation of the PNECs of the constituent (forwarded to the risk assessment). Using the PNEC of all individual constituents circumvents indirectly the issue of varying composition of an UVCB as it implicitly assumes that each time the UVCB substance consists of the pure substance, i.e. that each constituent would be present and bioavailable at a 100% concentration in the UVCB substance. This can be considered a conservative approach. A main outcome of the constituents' based assessment is the selection of all the constituents for which any environmental hazard is identified. This selection defines the scope of the further exposure and risk assessment (CSR, Ch. 9&10).

The actual hazard profile and environmental fate properties of the inorganic UVCB substance and the individual constituents are dependent on the speciation of each and every constituent and hence this information needs to be collected and the corresponding information for the environmental fate properties will be used. Different scenarios can be encountered.

- When the speciation of a constituent is known, this is used as such for the environmental fate properties assessment.
- When the speciation is unknown or few metal species co-exist, the worst-case speciation for the purpose of environmental fate assessment and environmental hazard assessment is selected, i.e. the speciation that would lead to the most severe effects.

Conclusions on environmental fate properties are based on available and/or environmental fate worst-case speciation information for each of the UVBC constituent. Environmental fate properties for the inorganic UVCB are assessed by assessing constituents' transport and distribution, bioaccumulation potential and secondary poisoning. The other parameters, such as biodegradation or hydrolysis, are not applicable or relevant for inorganic constituents.

The UVCB classification is calculated by applying the CLP mixture rules based on the classification of the known or worst-case speciation for each constituent and worst-case constituent concentration in the UVCB (i.e. maximum of the legal entity typical value), using the MeClas tool. Depending on the availability of information, the UVCB classification can be refined following MeClas Tiered approach.

UVCB-specific approach

For environmental risk assessment purposes, information on transport / distribution, bioaccumulation and secondary poisoning is assessed for each 'driving constituent' that is considered in the risk assessment. For further information regarding how the 'driving constituents' were selected, please see the introduction to Section 7 of the CSR. An overview of the available environmental fate data for each constituent assessed in the risk assessment is presented in the table below.

Table 11. Overview of the information on aquatic environmental fate and pathways for the purpose of risk assessment.

UVCB constituent		Transport/ distribution	Bio accumulation	Secondary poisoning
Silver	Metal ion (Ag^+)	Partitioning coefficient available *(silver IUCLID files)*	BCF available *(silver IUCLID files)*	Secondary poisoning assessment not required *(silver IUCLID files)*

UVCB constituent		Transport/ distribution	Bio accumulation	Secondary poisoning
Nickel	Metal ion (Ni^{2+})	Partitioning coefficient available *(nickel IUCLID files)*	BCF available *(nickel IUCLID files)*	PNEC available *(*nickel *IUCLID files)*
Lead	Metal ion (Pb^{2+})	Partitioning coefficient available *(lead IUCLID files)*	BCF available *(lead IUCLID files)*	PNEC available *(lead IUCLID files)*
Zinc	Metal ion (Zn^{2+})	Partitioning coefficient available *(zinc IUCLID files)*	Not applicable as it is an essential element *(zinc IUCLID files)*	Secondary poisoning assessment not required *(zinc IUCLID files)*
Arsenic	Metal ion (As^{3+} and As^{5+})	Partitioning coefficient available *(diarsenic trioxide IUCLID files)*	BCF available *(diarsenic trioxide IUCLID files)*	PNEC available *(diarsenic trioxide IUCLID files)*
Cadmium	Metal ion (Cd^{2+})	Partitioning coefficient available *(cadmium IUCLID files)*	BCF available *(cadmium IUCLID files and MMD)*	PNEC available *(cadmium IUCLID files)*
Copper	Metal ion (Cu^{2+})	Partitioning coefficient available *(copper IUCLID files)*	Not applicable as it is an essential element *(copper IUCLID files)*	Secondary poisoning assessment not required *(copper IUCLID files)*

When quantitative exposure and risk assessment were conducted on a metal constituent, the environmental fate information for this individual metal is reported in the respective IUCLID endpoint summaries. The information is taken from the respective metal REACH IUCLID dossiers (see separate Annex to this CSR) and is summarized in the table below.

Table 12. Overview of solid water partition coefficients (Kd), bioaccumulation factors and the fraction of emission directed to water by STP

Endpoint		Silver (Ag^{+})	Nickel (Ni^{2+})	Lead (Pb^{2+})	Zinc (Zn^{2+})	Arsenic (As^{3+}, As^{5+})	Cadmium (Cd^{2+})	Copper (Cu^{2+})
Kd Suspended matter (freshwater)	L/kg	190546	26303	295121	110000	10000	130000	30246
Kd Suspended matter (marine)	L/kg	190546	6310	1518099	6010	ND	617	131826
Kd Sediment (freshwater)	L/kg	11092	7079	153848	73000	158	10000	24409
Soil	L/kg	4023	724	6400	158.5	2512	ND	2120
BCF/BAF (aquatic)	L/kg	70	270	1553	NA	270	233	NA
BCF/BAF (terrestrial)	kg/kg dw	0.62	0.3	0.39	NA	NA	15	NA
Removal rate STP to sludge		80.1	40	ND	ND	ND	ND	ND
Reference		Silver IUCLID	Nickel IUCLID	Lead IUCLID	Zinc IUCLID	Diarsenic trioxide IUCLID	Cadmium IUCLID	Copper IUCLID

ND: data not available
NA: data not applicable

General discussion of environmental fate and pathways:

The UVCB environmental assessment is driven by the assessment of the individual UVCB constituents. The environmental assessment is based on selected 'driving constituents'. For the environment, it is considered that it is the metal ion that is the toxic driver and that this will be the dominant form in emissions to the aquatic environment (ECHA, 2008, R.7.13-2). The parent compound of each driving constituent present in refinable substances is therefore typically not considered or relevant. Environmental fate information on the individual UVCB constituents is reported in the respective summary sheets for each constituent for which a quantitative exposure and risk assessment is conducted. The information is taken from the respective constituent IUCLID

dossiers. More information on the scope of assessment for each constituent can be found in the introductions to Section 4 and Section 7 of this CSR.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

Data waiving

Information requirement: Hydrolysis

Reason: study scientifically unjustified

Justification: According to Annex XI of Regulation 1907/2006, testing for a specific endpoint may be omitted if testing does not appear to be scientifically necessary or if it is technically not possible to conduct the study as a consequence of the properties of the substance. Under REACH (ECHA 2008, Chapter R.7B – Endpoint Specific Guidance), the term 'Hydrolysis' refers to the "decomposition or degradation of a chemical by reaction with water" as a function of pH (i. e. abiotic degradation). In the case of the current substance, the chemical safety assessment will be based on elemental metal concentrations. For indicative behaviour of the UVCB in water see IUCLID sections 4.8 and 5.6 or CSR Sections 1.3 and 4.5.

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: According to Annex VII, Column 2 of Regulation (EC) 1907/2006, a study on ready biodegradability does not need to be conducted if the substance is inorganic.

4.1.2.1.2. Simulation tests (water and sediments)

Data waiving

Information requirement: Simulation testing for biodegradation in water and sediment

Reason: study scientifically unjustified

Justification: According to Annex IX, Column 2 of Regulation (EC) 1907/2006, "further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates

the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e. g. water, sediment or soil). "The substance is inorganic so biotic degradation studies do not need to be conducted.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

4.1.2.2. Biodegradation in soil

Data waiving

Information requirement: Soil simulation testing

Reason: study scientifically unjustified

Justification: According to Annex IX, Column 2 of Regulation (EC) 1907/2006, "further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e. g. water, sediment or soil). "The substance is inorganic so biotic degradation studies do not need to be conducted.

4.1.3. Summary and discussion of degradation

No relevant information available

4.2. Environmental distribution

4.2.1. Adsorption/desorption

Data waiving

Information requirement: Adsorption/desorption

Reason: study scientifically unjustified

Justification: The UVCB adsorption/desorption is driven by the assessment of the individual UVCB constituents. Adsorption/desorption information on the individual UVCB constituents is reported, if relevant, in individual IUCLID section 5.4.1 summaries and in a separate Annex to the CSR. A summary of the Kd values for each of the relevant constituents is provided in the introduction to Section 4 of this CSR.

Discussion

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

The UVCB adsorption/desorption is driven by the assessment of the individual UVCB constituents. Adsorption/desorption information on the individual UVCB constituents is reported, if relevant, in individual IUCLID section 5.4.1 summaries and in a separate Annex to the CSR. A summary of the Kd values for each of the relevant constituents is provided in the introduction to Section 4 of this CSR.

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

The reader is referred to the upper endpoint summary of IUCLID Section 5, the introduction section of CSR

Section 4 and constituent data in a separate Annex to the CSR.

4.3. Bioaccumulation

The reader is referred to the upper endpoint summary of IUCLID Section 5, the introduction section of CSR Section 4 and constituent data in a separate Annex to the CSR.

4.3.1. Aquatic bioaccumulation

Data waiving

Information requirement: Aquatic bioaccumulation

Reason: study scientifically unjustified

Justification: The UVCB bioaccumulation is driven by the bioaccumulation of the individual UVCB constituents. Bioaccumulation of the individual UVCB constituents is reported, if relevant, in individual section 5.3 summaries and in a separate Annex to the CSR.

4.3.2. Terrestrial bioaccumulation

Data waiving

Information requirement: Terrestrial bioaccumulation

Reason: study scientifically unjustified

Justification: The UVCB bioaccumulation is driven by the bioaccumulation of the individual UVCB constituents. Bioaccumulation of the individual UVCB constituents is reported, if relevant, in individual section 5.3 summaries and in a separate Annex to the CSR.

4.3.3. Summary and discussion of bioaccumulation

Aquatic bioaccumulation

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

The UVCB bioaccumulation is driven by the bioaccumulation of the individual UVCB constituents. Bioaccumulation of the individual UVCB constituents is reported, if relevant, in individual section IUCLID 5.3 summaries and in a separate Annex to the CSR.

Terrestrial bioaccumulation

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

The UVCB bioaccumulation is driven by the bioaccumulation of the individual UVCB constituents. Bioaccumulation of the individual UVCB constituents is reported, if relevant, in individual IUCLID section 5.3 summaries and in a separate Annex to the CSR.

4.4. Secondary poisoning

The assessment of the bioaccumulation and secondary poisoning potential of the inorganic UVCB as such has not been considered. According to the CLP Guidance for complex substances (Annex III 3.2), it is not recommended to estimate an average or weighted BCF value but it is preferable to identify one or more representative constituents for further consideration.

Secondary poisoning has been assessed for those constituents that are being considered in the risk assessment. Of these, secondary poisoning is considered to be relevant for the following metal constituents based on their known bioaccumulation potential: Ni, Pb, As and Cd. The secondary poisoning approach is mainly driven by the hazard properties of the element.

For other metals, the bioaccumulation criterion is not applicable because they are either essential and well regulated in all living organisms or they do not magnify in aquatic and terrestrial systems. Where no hazard has been identified for substances such as Cu, Zn and Ag no secondary poisoning assessment has been conducted.

4.5. Additional information on environmental fate and behaviour

The results of the transformation/dissolution studies are summarised in the following table:

Table 13. Studies on transformation/dissolution

Method	Results	Remarks	Reference
Transformation/dissolution results OECD Series on Testing and Assessment No. 29 24 hour Transformation/ Dissolution Pre-test of PGM Rich Lead Bullion at a 100mg/L loading in a standard aqueous medium at pH 6 and pH 8	The worst case pH defined in this test is pH 6. Silver, copper, nickel and lead are the only elements which showed dissolution above detection limit. The results can be assumed reliable because the test conditions stayed constant during the experiment.	1 (reliable without restriction) Supporting study experimental result **Test material (common name): Lead Bullion, PGM rich**	ECTX-Consult (2010a)
Transformation/dissolution results OECD Series on Testing and Assessment No. 29 Long Term (28d) Transformation/Dissolution test of PGM Rich Lead Bullion at a 1 mg/L loading in a standard aqueous medium at pH 6	PGM Rich Lead Bullion at a loading of 1 mg/L showed an average dissolution of 5.26 µg Cu/L (CV = 26%) and 3.87 µg Pb/L (CV = 20%) after 7 days and 11.0 µg Cu/L (CV = 31%) and 7.97 µg Cu/L (CV = 36%) after 28 days of exposure to the modified OECD 203 standard medium at pH 6.	1 (reliable without restriction) Supporting study experimental result **Test material (common name): Lead Bullion, PGM rich**	ECTX-Consult (2010b)

Discussion

Water solubility testing is not appropriate for complex metal and sparingly soluble metals and metal compounds. Transformation/dissolution testing has been conducted following OECD guideline 29. Tests were conducted on lead bullion, PGM rich and the metals above the detection limits were copper and lead.

5. HUMAN HEALTH HAZARD ASSESSMENT

5.0. Introduction to human health hazard assessment

Approach followed in the hazard assessment of this UVCB

The hazard assessment of inorganic UVCBs for the purpose of classification and derivation of threshold values (i.e. DNELs) is a complex process. Due to the variability of the composition of an UVCB, it is not possible to select a sample that would be representative for the hazard profile of the UVCB and could subsequently be used for toxicity testing. Instead of testing, a precautionary approach is followed in which the UVCB nature of a complex metal containing substance having a number of constituents (metals and their compounds or other inorganic compounds) is acknowledged. The hazard profile of each individual constituent is used for deriving the classification of the UVCB (using the mixture rules) and for the derivation of the DNELs of the constituent. Using the unmodified DNEL values of all individual constituents addresses the varying composition of an UVCB on a pre-cautionary basis as it implicitly assumes that the UVCB entirely consists of the specific constituent, i.e. that each constituent would be present to 100% in the UVCB. Thus, this hazard assessment can be considered a conservative approach. The identification of constituents which are hazardous for human health also defines the scope of the exposure assessment and risk characterisation (Chapters 9 & 10).

The hazard profile of the inorganic UVCB and the individual constituents is dependent on their chemical speciation. Depending on the level of knowledge, the following situations can be distinguished:

- If chemical speciation of the constituent in the UVCB is known, this is used for classification.
- If chemical speciation of the constituent as present in the workplace is known, this is used for risk characterisation.
- When information on chemical speciation is not complete, the worst-case speciation for the purpose of risk characterisation and classification is assumed, i.e. the speciation that would lead to the most severe classification or to the lowest DNEL. It is noted that different chemical species could be relevant (see below).

Selection of toxicological information for classification

The UVCB classification is calculated by applying the CLP mixture rules based on the classification of the known or worst-case speciation of each constituent and worst-case constituent concentration in the UVCB (i.e. the maximum value of the typical concentration reported by the individual legal entities), using the MeClas tool.

Selection of toxicological information for risk assessment

For the purpose of the human health risk assessment for the UVCB, the hazards of each constituent will be assessed and DNEL values for constituents for which a hazard has been identified are compiled. As indicated above, workers may be exposed to different chemical species compared to those present in the UVCB. Hence, the information on the intrinsic properties of the UVCB constituents relevant for classification can be refined if it is known which chemical species is present in the workplace. If speciation is unknown, the chemical species of an individual constituent is considered having the lowest DNEL which could be different when compared to the species used for classification.

Assessment of combined effects of multiple constituents

Information on how combined effects are assessed in the outlined approach can be found in Chapter 9.

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

5.1.1. Non-human information

Data waiving

Reason: other justification

Justification: There is no explicit requirement to generate toxicokinetic data under Regulation (EC) 1907/2006 (REACH). However, Annex I, Section 1.0.2 of REACH states that “the human health hazard assessment shall consider the toxicokinetic profile (i.e. absorption, metabolism, distribution and elimination) of the substance”. Furthermore, REACH announces in Annex VIII, Section 8.8.1 that one should perform “assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information”.

Reasons to consider relevant available information on toxicokinetic may be to interpret other human health data, to assist in developing a testing strategy and study design and to help optimising test designs. However, Lead bullion, Platinum Group metals rich is a UVCB substance that consists of a wide range of constituents that were already tested and assessed in separate risk assessments. As such Toxicokinetic data of the individual constituent were fully discussed in the associated registration dossiers. Based on the strategy for generation of registration dossiers for Precious Metals Refinables (see CSR section 5) toxicokinetic data of the individual constituents are not presented here. Information considered relevant is reported in IUCLID Section 7 “Toxicological information_ Lead bullion, Platinum Group metals rich”.

Reason: other justification

Justification: In the absence of measured data on dermal absorption of the UVCB, current guidance suggests the assignment of either 10 % or 100 % default dermal absorption rates. In contrast, the currently available scientific evidence on dermal absorption of metals (predominantly based on the experience from previous EU risk assessments) yields substantially lower figures, which can be summarised as follows:

Measured dermal absorption values for metals or metal compounds in studies corresponding to the most recent OECD test guidelines are typically 1 % or even less. Therefore, the use of a 10 % default absorption factor is scientifically not supported for metal salts. This is corroborated by conclusions from previous EU risk assessments (Ni, Cd, Zn), which have derived dermal absorption rates of 2 % or far less from liquid media (but with considerable methodical deviations from existing OECD methods).

However, considering that in industrial settings many applications involve handling of dry powders, substances and materials, and since dissolution is a key prerequisite for any percutaneous absorption, a factor 10 lower default absorption factor may be assigned to such “dry” scenarios where handling of the product does not entail use of aqueous or other liquid media. This approach was adopted in the EU RA on zinc. A justification for this is described in detail elsewhere (Cherrie and Robertson, 1995), based on the argument that dermal uptake is dependent on the concentration of the material on the skin surface rather than its mass.

The following default dermal absorption factors for metal cations are therefore used in most of the associated REACH dossiers (reflective of full-shift exposure, i.e. 8 hours):

From exposure to liquid/wet media: 1.0 %

From dry (dust) exposure: 0.1 %

This approach is consistent with the methodology proposed in the HERAG guidance for metals (HERAG fact sheet - assessment of occupational dermal exposure and dermal absorption for metals and inorganic metal compounds; EBRC Consulting GmbH, Hannover, Germany; August 2007).

It is noted that within the constituents based approach followed for the UVCB assessment any absorption considerations are justified in the respective REACH registration files in detail. However, as "Lead bullion, Platinum Group metals rich" being of inorganic nature, it is assumed that the above consideration do also apply to the UVCB as such.

5.1.2. Human information

No relevant information available

5.1.3. Summary and discussion of toxicokinetics

Substance specific information for the UVCB substance "Lead bullion, Platinum Group metals rich" is not available for the endpoint “toxicokinetics”. However, there is no specific requirement to generate toxicokinetic data under Regulation (EC) 1907/2006 (REACH). Annex I, Section 1.0.2 of REACH regulation states that “*the human health hazard assessment shall consider the toxicokinetic profile (i.e. absorption, metabolism, distribution and elimination) of the substance*” and REACH regulation announces in Annex VIII, Section 8.8.1 that one should

perform "*assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information*".

Nevertheless, for "Lead bullion, Platinum Group metals rich", the human health (HH) hazard assessment is driven by the hazard assessment of the individual UVCB constituents which are (i) classified for HH and (ii) with a content ≥ 0.1 %. For most of the relevant constituents, toxicokinetic data are fully assessed and included in each individual REACH registration file but have not been included in the registration file of "Lead bullion, Platinum Group metals" rich (see strategy of registration for UVCB substances – Precious Metals Refinables). Relevant hazard and risk assessment information for "Lead bullion, Platinum Group metals rich" can be found in IUCLID Section 7 "Toxicological information_ Lead bullion, Platinum Group metals rich".

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of studies on acute toxicity after oral administration are summarised in the following table:

Table 14. Studies on acute toxicity after oral administration

Method	Results	Remarks	Reference
The C&L for acute oral toxicity of "Lead bullion, Platinum Group metals rich" was determined by using the "acute toxicity range estimate (ATE)" and respective rules of Regulation (EC) 1272/2006 section 3.1.3.6 "Classification of mixtures based on ingredients of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	Acute Toxicity Estimate (ATE): > 300 - ≤ 2000 mg/kg bw based on: test mat. (calculation) C&L required: Acute Tox. 4	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.2.1.2. Acute toxicity: inhalation

The results of studies on acute toxicity after inhalation exposure are summarised in the following table:

Table 15. Studies on acute toxicity after inhalation exposure

Method	Results	Remarks	Reference
The C&L for acute inhalation toxicity of "Lead bullion, Platinum Group metals rich" was determined by using the "acute toxicity range estimate (ATE)" and respective rules of Regulation (EC) 1272/2006 section 3.1.3.6 "Classification of mixtures based on ingredients of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	Acute Toxicity Estimate (ATE): > 5 mg/L air based on: test mat. (calculation) no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.2.1.3. Acute toxicity: dermal

The results of studies on acute toxicity after dermal administration are summarised in the following table:

Table 16. Studies on acute toxicity after dermal administration

Method	Results	Remarks	Reference

Method	Results	Remarks	Reference
The C&L for acute dermal toxicity of "Lead bullion, Platinum Group metals rich" was determined by using the "acute toxicity range estimate (ATE)" and respective rules of Regulation (EC) 1272/2006 section 3.1.3.6 "Classification of mixtures based on ingredients of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	Acute Toxicity Estimate (ATE): > 2000 mg/kg bw based on: test mat. (calculation) no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.2.1.4. Acute toxicity: other routes

There are no reliable reports whatsoever on acute toxicity via other routes in non-humans in the public domain.

5.2.2. Human information

No relevant information available

5.2.3. Summary and discussion of acute toxicity

Substance specific information for the UVCB substance "Lead bullion, Platinum Group metals rich" as such is not available for the endpoint "Acute Toxicity". In order to meet the requirements for Annex VII - Annex X of Regulation (EC) 1907/2006, read across information from any constituent being relevant needs to be included. Due to the high number of constituents and variability in C&L of these constituents it was decided to use the classification information from the individual constituents and to calculate the resulting classification by using the "acute toxicity range estimate (ATE)" and respective rules of Regulation (EC) 1272/2006 section 3.1.3.6 "Classification of mixtures based on ingredients of the mixture" with the aid of the MeClas tool. This approach has been presented and discussed with ECHA in several meetings.

For Lead bullion, Platinum Group metals rich one C&L entry (i.e., harmful if swallowed) for acute toxicity were calculated.

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

No information on animal testing of "Lead bullion, Platinum Group metals rich" on acute toxicity is available. The C&L was determined by using the "acute toxicity range estimate (ATE)" and respective rules of Regulation (EC) 1272/2006 section 3.1.3.6 "Classification of mixtures based on ingredients of the mixture". Applying these rules the converted acute toxicity point estimate value for acute toxicity, oral route is 500 mg/kg bw in accordance with EU CLP Guidance Annex I Table 3.1.2. No C&L for acute inhalation toxicity and toxicity via skin is required.

Value used for CSA:

Acute oral toxicity: Adverse effect observed

Acute dermal toxicity: No adverse effect observed (discriminating dose: 2000 mg/kg bw)

Acute inhalation toxicity: No adverse effect observed (discriminating conc.: 5000 mg/m³)

Justification for classification or non classification

The available information indicates that "Lead bullion, Platinum Group metals rich" is harmful via ingestion, but not acutely toxic or harmful via the dermal and inhalation route. Lead bullion, Platinum Group metals rich requires classification as harmful if swallowed (Acute Tox. 4) according to Regulation (EC) 1272/2008. Classification of "Lead bullion, Platinum Group metals rich" for acute toxicity via the dermal and inhalation route is not required according to Regulation (EC) 1272/2008.

Specific target organ toxicant (STOT) - single exposure: oral, inhalation and dermal The classification criteria according to Regulation (EC) 1272/2008 as specific target organ toxicant (STOT) – single exposure are

not met since no adverse health effects, including reversible and irreversible, were observed immediately or delayed after exposure.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

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

Table 17. Studies on skin irritation

Method	Results	Remarks	Reference
The C&L for skin irritation/corrosion of "Lead bullion, Platinum Group metals rich" was determined by using the "theory of additivity" of Regulation (EC) 1272/2006 section 3.2.3.3.2 "Classification of mixtures when data are available for all components or only for some components of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	not classified no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.3.1.2. Human information

No relevant information available

5.3.2. Eye

5.3.2.1. Non-human information

The results of studies on eye irritation are summarised in the following table:

Table 18. Studies on eye irritation

Method	Results	Remarks	Reference
The C&L for eye irritation/corrosion of "Lead bullion, Platinum Group metals rich" was determined by using the "theory of additivity" of Regulation (EC) 1272/2006 section 3.2.3.3.2 "Classification of mixtures when data are available for all components or only for some components of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	not classified no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.3.2.2. Human information

No relevant information available

5.3.3. Respiratory tract

5.3.3.1. Non-human information

Please refer to the summary and discussion of irritation.

5.3.3.2. Human information

Please refer to the summary and discussion of irritation.

5.3.4. Summary and discussion of irritation

Substance specific information for the UVCB substance of “Lead bullion, Platinum Group metals rich” is not available for the endpoint "Irritation/Corrosion". In order to meet the requirements for Annex VII - Annex X of Regulation (EC) 1907/2006, read across information from any constituent being relevant needs to be included. Due to the high number of constituents and variability in C&L of these constituents it was decided to use the classification information from the individual constituents and to calculate the resulting classification by using the “theory of additivity" (Regulation (EC) No 1272/2008, section 3.2.3. and 3.3.3) with the MeClas tool. This approach has been presented and discussed with ECHA in several meetings.

For “Lead bullion, Platinum Group metals rich” one C&L entry (i.e., no C&L) for irritation/corrosion was calculated, since either the individual constituents are not classified for irritation/corrosion or the sum of individual constituents that are classified for irritation/corrosion are not above the cut-off values given in Regulation (EC) 1272/2008.

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

No information on animal testing for skin and eye irritation of “Lead bullion, Platinum Group metals rich” is available. The approach followed on C&L of UVCB substances as irritant or corrosive to skin and eye in case where data are available on the constituents, but not on the UVCB substance as a whole, is based on the theory of additivity (CLP guideline, section 3.2.3.2.3.2, November 2013). Since, “Lead bullion, Platinum Group metals rich” does not contain any constituent ≥ 1 % (w/w) (in sum) classified as Skin Corr. 1A, 1B and 1C and/or ≥ 10 % (w/w) (in sum) classified as Skin Irrit. 2, the UVCB substance “Lead bullion, Platinum Group metals rich” does not require classification as eye irritating or corrosive substance.

Furthermore, since, “Lead bullion, Platinum Group metals rich” does not contain any constituent ≥ 1 % (w/w) (in sum) classified as Eye Damage 1 (in sum) and ≥ 3 % (w/w) (in sum) classified as Eye Irrit. 2, the UVCB substance “Lead bullion, Platinum Group metals rich” does not meet classification criteria for eye irritation/ corrosion.

Value used for CSA:

Skin irritation / corrosion:	No adverse effect observed (not irritating)
Eye irritation / corrosion:	No adverse effect observed (not irritating)
Respiratory irritation / corrosion:	No adverse effect observed (not irritating)

Justification for classification or non classification

Skin irritation:

The UVCB substance "Lead bullion, Platinum Group metals rich" does not possess a skin irritation potential (theory of additivity was applied) and does not meet classification criteria as skin irritating substance according to Regulation (EC) 1272/2008.

Eye irritation:

The UVCB substance "Lead bullion, Platinum Group metals rich" does not possess an eye irritation potential (theory of additivity was applied) and does not meet classification criteria as eye irritating substance according to Regulation (EC) 1272/2008.

Respiratory irritation:

The generic term respiratory tract irritation (RTI) covers two different effects: (i) sensory irritation and (ii) local cytotoxic effects. The classification is usually covered under the endpoint specific target organ toxicity- single exposure (endpoint IUCLID 7.2) and - repeated exposure (endpoint IUCLID 7.5). Please refer to the endpoint summaries on acute toxicity and repeated dose toxicity for further information.

5.4. Corrosivity

5.4.1. Non-human information

Results indicating non corrosivity potential to the eye or skin are summarised in section 5.3 “Irritation”.

5.4.2. Human information

No relevant information available.

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 19. Studies on skin sensitisation

Method	Results	Remarks	Reference
The C&L for skin sensitisation of Lead bullion, Platinum Group metals rich was determined by using the “Classification criteria for mixtures” of Regulation (EC) 1272/2006 section 3.4.3.3.1 “Classification of mixtures when data are available for all components or only for some components of the mixture”. For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment “PMC Classification method”).	sensitising C&L required: Skin Sens. 1 (H317)	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.5.1.2. Human information

No relevant information available.

5.5.2. Respiratory system

5.5.2.1. Non-human information

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

Table 20. Studies on respiratory sensitisation

Method	Results	Remarks	Reference
The C&L for respiratory sensitisation of Lead bullion, Platinum Group metals rich was determined by using the “Classification criteria for mixtures” of Regulation (EC) 1272/2006 section 3.4.3.3.1 “Classification of mixtures when data are available for all components or only for some components of the mixture”. For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment “PMC Classification method”).	not sensitising no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.5.2.2. Human information

No relevant information available.

5.5.3. Summary and discussion of sensitisation

Skin sensitisation

Substance specific information for the UVCB substance “Lead bullion, Platinum Group metals rich” is not available for the endpoint "Sensitisation". In order to meet the requirements for Annex VII till Annex X of Regulation (EC) 1907/2006, read across information from any constituents being relevant needs to be included. Due to the high number of constituents and variability in C&L of these constituents it was decided to use the classification information from the individual constituents and to calculate the resulting classification by using the generic concentration limits of ingredients of the mixture classified as a specific target organ toxicant that trigger classification of the mixture and respective rules of Regulation (EC) 1272/2006 section 3.4.3.2 “*Classification of mixtures when data are available for all components or only for some components of the mixture*” with the MeClas tool. This approach has been presented and discussed with ECHA in several meetings.

For “Lead bullion, Platinum Group metals rich” one C&L entry (i.e., Skin Sens. 1) for “Skin Sensitisation” were calculated.

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

No information on animal testing of "Lead bullion, Platinum Group metals rich" is available. Since, "Lead bullion, Platinum Group metals rich" contains constituent ≥ 1 % (i.e., nickel) that is itself classified for skin sensitisation; the UVCB substance requires classification as skin sensitiser, Skin Sens. 1 (H317). It is noted that no sub-categorisation was performed.

Value used for CSA: Adverse effect observed (sensitising)

Respiratory sensitisation

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

No information on animal testing of “Lead bullion, Platinum Group metals rich” is available. Since, “Lead bullion, Platinum Group metals rich” does not contain any constituent ≥ 0.1 % (w/w) that is itself classified for respiratory sensitisation, the substance must not be classified as respiratory sensitiser.

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

Justification for classification or non classification

Skin sensitisation

“Lead bullion, Platinum Group metals rich” possesses a skin sensitisation potential in accordance with Regulation (EC) 1272/2008 and requires classification as skin sensitiser, Skin Sens. 1 (H317) in accordance with Regulation (EC) 1272/2008.

Respiratory sensitisation

Furthermore, “Lead bullion, Platinum Group metals rich” does not contain any constituent ≥ 0.1 % (w/w) that is itself classified for respiratory sensitisation. Hence, the substance does not meet the classification criteria for respiratory sensitisation in accordance with Regulation (EC) 1272/2008.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of studies on repeated dose toxicity after oral administration are summarised in the following table:

Table 21. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks	Reference

Method	Results	Remarks	Reference
The C&L for toxic to specific target organ after repeated dose application of Lead bullion, Platinum Group metals rich was determined by using the “Classification criteria for mixtures” of Regulation (EC) 1272/2006 section 3.9.3.4.1 “Classification of mixtures when data are available for all components or only for some components of the mixture”. For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment “PMC Classification method”).	C&L required: STOT RE 1 (H372)	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.6.1.2. Repeated dose toxicity: inhalation

The results of studies on repeated dose toxicity after inhalation exposure are summarised in the following table:

Table 22. Studies on repeated dose toxicity after inhalation exposure

Method	Results	Remarks	Reference
The C&L for toxic to specific target organ after repeated dose application of "Lead bullion, Platinum Group metals rich" was determined by using the “Classification criteria for mixtures” of Regulation (EC) 1272/2006 section 3.9.3.4.1 “Classification of mixtures when data are available for all components or only for some components of the mixture”. For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment “PMC Classification method”).	C&L required: STOT RE 1 (H372)	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.6.1.3. Repeated dose toxicity: dermal

Data waiving

Information requirement: Repeated dose toxicity after dermal administration

Reason: study scientifically unjustified

Justification: According to Regulation (EC) 1907/2006 Annex XI (weight of evidence), testing for sub-chronic dermal toxicity is not considered to be required, for the following reasons:

- (i) “Lead bullion, Platinum Group metals rich” is a solid UVCB substance consisting of different metals and metal compounds. It is not irritating to skin and considered to be not acutely toxic after skin contact (see IUCLID section “acute toxicity”). Furthermore, a transformation/dissolution test (see IUCLID section 5.6) indicates that “Lead bullion, Platinum Group metals rich” is insoluble in environmental media (solubility < 0.1 mg/L). Hence, repeated dose toxicity study via dermal route does not need to be performed since the physico-chemical and toxicological properties do not suggest potential for a significant rate of absorption through the skin. Following the approach proposed in the HERAG guidance for metals (HERAG fact sheet - assessment of occupational dermal exposure and dermal absorption for metals and inorganic metal compounds; EBRC Consulting GmbH, Hannover, Germany; August 2007), the following default dermal absorption factors for metal cations are proposed (reflective of full-shift exposure, i.e. 8 hours):

From exposure to liquid/wet media: 1.0 %

From dry (dust) exposure: 0.1 %

For more information on absorption through the skin please refer to dermal absorption.

- (ii) “Lead bullion, Platinum Group metals rich” is characterised by a high variability in content of individual constituents, whereas the constituents as such (or at least their elemental composition) are known. Such variation in composition requires specific adoptions of the standard approach for HH hazard assessment as required under REACH. For “Lead bullion, Platinum Group metals rich”, the human health (HH) hazard assessment is driven by the hazard assessment of the individual UVCB constituents which are (i) classified for

HH and (ii) with a content ≥0.1 %. For most of the relevant constituents, toxicity data in the form of DNELs (and the required contextual information) is available from associated REACH registration files (for more information please refers to the DNEL section).

Conclusion: Since, relevant DNELs could be made available and considering that the dermal absorption is low (i.e., ≤ 1%) testing on repeated dose toxicity via dermal route is not considered to be required.

5.6.1.4. Repeated dose toxicity: other routes

There are no reliable reports whatsoever on repeated dose toxicity via other routes in non-humans in the public domain.

5.6.2. Human information

No relevant information available.

5.6.3. Summary and discussion of repeated dose toxicity

Substance specific information for the UVCB substance "Lead bullion, Platinum Group metals rich" is not available for the endpoint "Repeated Dose Toxicity". In order to meet the requirements for Annex VII till Annex X of Regulation (EC) 1907/2006, read across information from any constituents being relevant needs to be included. Due to the high number of constituents and variability in C&L of these constituents it was decided to use the classification information from the individual constituents and to calculate the resulting classification by using the generic concentration limits of ingredients of the mixture classified as a specific target organ toxicant that trigger classification of the mixture and respective rules of Regulation (EC) 1272/2006 section 3.9.3.4 "*Classification of mixtures when data are available for all components or only for some components of the mixture*" with the MeClas tool. This approach has been presented and discussed with ECHA in several meetings.

For "Lead bullion, Platinum Group metals rich" one C&L entry (i.e., STOT RE 1) for repeated dose toxicity were calculated.

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

No information on animal testing of "Lead bullion, Platinum Group metals rich" is available. However, "Lead bullion, Platinum Group metals rich" with a lead powder and nickel powder content of ≥ 1 % is considered to be toxic to specific target organs following repeated dosing via the oral route and meets classification criteria for STOT-RE 1; H372.

Value used for CSA

Via oral route - systemic effects:	Adverse effect observed
Dermal - systemic effects:	No study available
Dermal - local effects:	No study available
Inhalation - local effects:	Adverse effect observed

Justification for classification or non classification

Classification of UVCB substances as being toxic to specific target organs is based on the presence of one or more constituents ≥ 1 % classified for STOT RE 1 and the presence of one or more constituents ≥ 10 % classified for STOT RE 2. Since, "Lead bullion, Platinum Group metals rich" contains ≥ 1 % lead powder and nickel powder classified as STOT RE 1 (self-classification), "Lead bullion, Platinum Group metals rich" meets classification criteria for STOT RE 1 and requires labelling with H 372 (causes damage to organs) as required in accordance with Regulation (EC) 1272/2008.

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 23. In vitro genotoxicity studies

Method	Results	Remarks	Reference
The C&L considering mutagenicity of "Lead bullion, Platinum Group metals rich" was determined by using the "Classification criteria for mixtures" of Regulation (EC) 1272/2006 section 3.5.3.1 "Classification of mixtures when data are available for all components or only for some components of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	negative; no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)
The C&L considering genotoxicity of "Lead bullion, Platinum Group metals rich" was determined by using the "Classification criteria for mixtures" of Regulation (EC) 1272/2006 section 3.5.3.1 "Classification of mixtures when data are available for all components or only for some components of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	negative; no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.7.1.2. In vivo data

The UVCB genetic toxicity potential is driven by the assessment of the individual UVCB constituents. In-vitro and in-vivo genetic toxicity data (if available) are, in principle, considered for each individual UVCB constituent. The C&L for genetic toxicity of the UVCB is calculated using MeClas and summarized under IUCLID section 7.6.1 – in-vitro testing. For classification and labeling information, please refer to IUCLID section 7.6.1 (in-vitro testing).

5.7.2. Human information

No relevant information available

5.7.3. Summary and discussion of mutagenicity

Substance specific information for the UVCB substance "Lead bullion, Platinum Group metals rich" is not available for the endpoint "Genetic Toxicity". In order to meet the requirements for Annex VII till Annex X of Regulation (EC) 1907/2006, read across information from any constituents being relevant needs to be included. Due to the high number of constituents and variability in C&L of these constituents it was decided to use the classification information from the individual constituents and to calculate the resulting classification by using the "generic concentration limits of ingredients of a mixture classified as germ cell mutagens that trigger classification of the mixture." and respective rules of Regulation (EC) 1272/2006 section 3.5.3.1 "*Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture*" with the MeClas tool. This approach has been presented and discussed with ECHA in several meetings.

For "Lead bullion, Platinum Group metals rich" one C&L entry (i.e., no C&L) for genetic toxicity was calculated.

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

No information on animal testing of "Lead bullion, Platinum Group metals rich" is available. Since, "Lead bullion, Platinum Group metals rich" neither contains any constituent ≥ 0.1 % classified as mutagen Muta. 1, nor any constituent ≥ 1 % classified as mutagen Muta. 2, the substance must not be classified to possess germ cell mutagenicity.

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

Justification for classification or non classification

"Lead bullion, Platinum Group metals rich" neither contains any constituent ≥ 0.1 % (w/w) classified as mutagen Muta. 1, nor any constituent ≥ 1 % (w/w) classified as mutagen Muta. 2. In conclusion, "Lead bullion, Platinum Group metals rich" does not meet classification criteria for mutagenicity and/or genotoxicity in accordance with Regulation (EC) 1272/2008.

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

Please refer to the summary and discussion of carcinogenicity.

5.8.1.2. Carcinogenicity: inhalation

The results of studies on carcinogenicity via inhalation are summarised in the following table:

Table 24. Studies on carcinogenicity (inhalation)

Method	Results	Remarks	Reference
The C&L considering carcinogenicity of "Lead bullion, Platinum Group metals rich" was determined by using the "Classification criteria for mixtures" of Regulation (EC) 1272/2006 section 3.6.3.1.1 "Classification of mixtures when data are available for all components or only for some components of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	C&L required: Carc. 2 (H351)	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.8.1.3. Carcinogenicity: dermal

Please refer to the summary and discussion of carcinogenicity.

5.8.1.4. Carcinogenicity: other routes

There are no reliable reports whatsoever on carcinogenicity via other routes in non-humans in the public domain.

5.8.2. Human information

No relevant information available

5.8.3. Summary and discussion of carcinogenicity

Substance specific information for the UVCB substance "Lead bullion, Platinum Group metals rich" is not available for the endpoint "Carcinogenicity". In order to meet the requirements for Annex VII till Annex X of Regulation (EC) 1907/2006, read across information from any constituents being relevant needs to be included. Due to the high number of constituents and variability in C&L of these constituents it was decided to use the classification information from the individual constituents and to calculate the resulting classification by using the" generic concentration limits of ingredients of the mixture classified as carcinogen that trigger classification of the mixture" and respective rules of Regulation (EC) 1272/2006 section 3.6.3.1 "*Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture*" with the MeClas tool. This approach has been presented and discussed with ECHA in several meetings.

For "Lead bullion, Platinum Group metals rich" one C&L entry (i.e., carcinogenic Carc. 2) for carcinogenicity were calculated.

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

No information on animal testing of "Lead bullion, Platinum Group metals rich" is available. However, "Lead bullion, Platinum Group metals rich" does not contain any constituent ≥ 0.1 % which is classified as a Carc. 1A or Carc. 1B carcinogen but contains ≥ 1 % nickel powder, respectively, that is classified as a Car. 2 carcinogen. Hence, "Lead bullion, Platinum Group metals rich" must be classified to induce cancer (Carc. 2).

Value used for CSA

Carcinogenicity: oral: No adverse effect observed

Carcinogenicity: dermal: No adverse effect observed

Carcinogenicity: inhalation: Adverse effect observed

Justification for classification or non classification

Carcinogenicity classification of UVCB substances is based on the presence of a constituent ≥ 0.1 % classified for carcinogenicity Carc. 1A or Carc. 1B and on the presence of a constituent ≥ 1 % classified for carcinogenicity Carc .2, respectively. "Lead bullion, Platinum Group metals rich" does not contain any constituents ≥ 0.1 % classified for carcinogenicity Carc. 1A or Carc. 1B but constituents ≥ 1 % classified for carcinogenicity Carc. 2 (i.e., nickel powder). Hence, "Lead bullion, Platinum Group metals rich" is considered to induce cancer and does require classification as carcinogenic Carc. 2 (H351), in accordance with Regulation (EC) 1272/2008.

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

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

Table 25. Studies on fertility

Method	Results	Remarks	Reference
The C&L considering reproduction toxicity (effects on male or female fertility) of "Lead bullion, Platinum Group metals rich" was determined by using the "Classification criteria for mixtures" of Regulation (EC) 1272/2006 section 3.7.3.1 "Classification of mixtures when data are available for all components or only for some components of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	C&L required: Repr. 1A (H360Df)	2 (reliable with restrictions) key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	ARCHE (2013)

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

The results of studies on developmental toxicity are summarised in the following table:

Table 26. Studies on developmental toxicity

Method	Results	Remarks	Reference
The C&L considering reproduction toxicity	C&L required:	2 (reliable with restrictions)	ARCHE

Method	Results	Remarks	Reference
(developmental toxicity) of "Lead bullion, Platinum Group metals rich" was determined by using the "Classification criteria for mixtures" of Regulation (EC) 1272/2006 section 3.7.3.1 "Classification of mixtures when data are available for all components or only for some components of the mixture". For detailed information for classification strategy of UVCBs please refer to IUCLID section 13 (attachment "PMC Classification method").	Repr. 1A (H360Df)	key study estimated by calculation **Test material: Lead bullion, Platinum Group metals rich** Form: solid	(2013)

5.9.2.2. Human information

No relevant information available.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

Substance specific information for the UVCB substance "Lead bullion, Platinum Group metals rich" is not available for the endpoint "Toxicity to Reproduction" with respect to effects on fertility. In order to meet the requirements for Annex VII till Annex X of Regulation (EC) 1907/2006, read across information from any constituents being relevant needs to be included. Due to the high number of constituents and variability in C&L it was decided to use the classification information from the individual constituents and to calculate the resulting classification by using the "Generic concentration limits of ingredients of a mixture classified as reproduction toxicants or for effects on or via lactation that trigger classification of the mixture" and respective rules of Regulation (EC) 1272/2006 section 3.7.3.1 "*Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture*" with the MeClas tool. This approach has been presented and discussed with ECHA in several meetings.

For "Lead bullion, Platinum Group metals rich" one C&L entry (i.e., classification for Repr. 1A) for reproductive toxicity were calculated.

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

No information on animal testing of "Lead bullion, Platinum Group metals rich" is available. However, "Lead bullion, Platinum Group metals rich" contains amongst others lead and lead compounds ≥ 0.3 % that may possess reproduction toxicity (i.e., suspected of damaging fertility). Hence, "Lead bullion, Platinum Group metals rich" must be classified as reproductive toxicant.

Value used for CSA

Reproductive toxicity: oral: Adverse effect observed

Reproductive toxicity: dermal: No adverse effect observed

Reproductive toxicity: inhalation: No adverse effect observed

Developmental toxicity

Substance specific information for the UVCB substance "Lead bullion, Platinum Group metals rich" is not available for the endpoint "Toxicity to Reproduction" with respect to effects on developmental toxicity. In order to meet the requirements for Annex VII till Annex X of Regulation (EC) 1907/2006, read across information from any constituents being relevant needs to be included. Due to the high number of constituents and variability in C&L it was decided to use the classification information from the individual constituents and to calculate the resulting classification by using the "Generic concentration limits of ingredients of a mixture classified as reproduction toxicants or for effects on or via lactation that trigger classification of the mixture" and respective rules of Regulation (EC) 1272/2006 section 3.7.3.1 "*Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture*" with the MeClas tool. This approach has been presented and discussed with ECHA in several meetings.

For “Lead bullion, Platinum Group metals rich” one C&L entry (i.e., classification for Repr. 1A) for reproductive toxicity were calculated.

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

No information on animal testing of “Lead bullion, Platinum Group metals rich” is available. However, “Lead bullion, Platinum Group metals rich” contains lead and amongst others lead compounds ≥ 0.3 %

that may possess reproduction toxicity (i.e., may damage the unborn child). Hence, “Lead bullion, Platinum Group metals rich” must be classified as reproductive toxicant.

Value used for CSA

Developmental toxicity: oral Adverse effect observed

Developmental toxicity: dermal: No adverse effect observed

Developmental toxicity: inhalation: No adverse effect observed

Justification for classification or non classification

Reproductive toxicity classification of UVCB substances is based on the presence of a constituent ≥ 0.3 % classified for reproductive toxicity. “Lead bullion, Platinum Group metals rich” contains amongst others lead and lead compounds ≥ 0.3 %. Hence, “Lead bullion, Platinum Group metals rich” is considered to induce reproductive toxicity, and should be classified as Repr. 1A (H360Df: may damage the unborn child, suspected of damaging fertility) in accordance with Regulation (EC) 1272/2008. There is not any evidence of effects on or via lactation for any constituents of “Lead bullion, Platinum Group metals rich” at a concentration ≥ 0.3 %.

5.10. Other effects

There are no reliable reports whatsoever on other effects in non-humans or humans in the public domain.

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

Specific information for the UVCB substance “Lead bullion, Platinum Group metals rich” (EC 931-607-7) for acute and long-term toxicity is not available. In order to meet the criteria for registration under Regulation (EC) 1907/2006 (REACH) for substances > 1,000 t/y (Annex VII - X), read-across to identified, registered constituents is performed.

The following constituents (metals and respective chemical species) of “Lead bullion, Platinum Group metals rich” which trigger classification were identified:

Pd	Sb	As	Pb	Ni	Se	Te
$[Pd(NH_3)_4](OH)_2$)	Sb_2O_3	As*	Pb *	Ni *	Se *	Te and Te comp.

*metallic

Constituents that are not identified as hazardous to humans are not included in the table above although included in the composition profile (IUCLID section 1.2). In addition, constituents that are included in the composition profile (IUCLID section 1.2) and that are hazardous to humans but only present in the substance below the cut-off values for mixtures given in Regulation (EC) 1272/2008 (see MeClas output sheets attached on IUCLID section 13) are also not included in the table above. Thus, the following constituents were not included in the table above: Ag, Au, Ir, Pt, Rh, Ru, Bi, Cd, Cu, Fe, Sn, Zn

General approach for inorganic UVCBs

UVCB substances are characterised by a high variability in content of individual constituents, whereas the constituents as such (or at least their elemental composition) are known. Such variation in composition requires

specific adoptions of the standard approach for HH hazard assessment as required under REACH. For “Lead bullion, Platinum Group metals rich”, the human health (HH) hazard assessment is driven by the hazard assessment of the individual UVCB constituents which are (i) identified as being hazardous for HH and (ii) with a content ≥0.1 % in the overall UVCB composition. For most of the relevant constituents, toxicity data in the form of DNELs (and the required contextual information) is available from associated REACH registration files. These toxicity data are given for each individual UVCB constituent in IUCLID section 7 “endpoint summary” provided that (i) the individual constituent is considered relevant for HH hazard assessment and (ii) IUCLID section 7 “endpoint summary” was made available to the precious metals consortium. However, in case DNELs were not made available for a specific constituent, surrogate threshold values (e.g., iOEL, MAK etc.) were used for hazard assessment. However, available values were used in the hazard assessment without modification. As a consequence, the hazard assessment will not conclude on a single threshold value for a specific combination of route and exposure duration (e.g. “chronic inhalation”) but instead has to consider all threshold values for each of the individual constituents classified for human health. As soon as further registration dossiers of relevant constituents could be made available, the UVCB dossier will be updated and the surrogate values will be replaced by the respective DNEL values.

It is noted that this approach is intrinsically conservative as a DNEL for a specific constituent was not modified according to its percentage in the UVCB as such but instead were used as were the constituent present to 100 %.

In an effort to avoid redundant information (which all would have to be constantly maintained and updated), only the constituent specific DNEL sections is included in this UVCB registration dossier. This procedure is currently under discussion between the Eurometaux and ECHA.

Furthermore, calculations with the classification tool MeClas were included in the individual HH endpoint study records based on the principles described under Regulation (EC) 1272/2008, (also referred to as “mixture rules”) e.g.:

-“acute toxicity range estimate (ATE)” and respective rules of Regulation (EC) 1272/2006 section 3.1.3.6 “Classification of mixtures based on ingredients of the mixture” and

- using the “theory of additivity" (Regulation (EC) No 1272/2008, section 3.2.3. and 3.3.3 (irritation/corrosion).

This approach ensures a conservative hazard assessment and accounts for the variability in the elemental composition of the UVCB already explained above.

5.11.1. Overview of typical dose descriptors for all endpoints

Table 27. 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	Adverse effect observed ATE: 500 mg/kg bw	ARCHE (2013) (see section 5.2.1.1)
Acute toxicity	dermal	No adverse effect observed discriminating dose: 2000 mg/kg bw	ARCHE (2013) (see section 5.2.1.3)
Acute toxicity	inhalation	No adverse effect observed discriminating conc.: 5000 mg/m³	ARCHE (2013) (see section 5.2.1.2)
Irritation / Corrosivity	skin	No adverse effect observed (not irritating)	ARCHE (2013) (see section 5.3.1.1)
Irritation / Corrosivity	eye	No adverse effect observed (not irritating)	ARCHE (2013) (see section 5.3.2.1)
Irritation / Corrosivity	respiratory tract	No adverse effect observed (not irritating)	
Sensitisation	skin	Adverse effect observed (sensitising)	ARCHE (2013)

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
			(see section 5.5.1.1)
Sensitisation	respiratory tract	No adverse effect observed (not sensitising)	(see section 5.5.2.1)
Repeated dose toxicity	oral	Adverse effect observed (based on lead compounds) Lead bullion, Platinum Group metals rich with a lead content of ≥ 0.5% must be classified as STOT RE 1 in accordance with Regulation (EC) 1272/2008.	ARCHE (2013) (see section 5.6.1.1)
Repeated dose toxicity	Inhalation (local effects)	Adverse effect observed (based on nickel constituent) Lead bullion, Platinum Group metals rich with a nickel powder content of ≥ 1% must be classified as STOT RE 1 in accordance with Regulation (EC) 1272/2008.	ARCHE (2013) (see section 5.6.1.1)
Repeated dose toxicity	dermal (local and systemic effects)	No study available	(see section 5.6.1.3)
Mutagenicity	in vitro / in vivo	No adverse effect observed (negative)	see section 5.7.1 / 5.7.2
Carcinogenicity	oral, dermal	No adverse effect observed	ARCHE (2013) (see section 5.8.1.1)
Carcinogenicity	inhalation	Adverse effect observed (based on nickel) Lead bullion, Platinum Group metals rich with a nickel content of ≥ 1% is considered to induce cancer and should be classified as Cat. 2 carcinogen in accordance with Regulation (EC) 1272/2008.	ARCHE (2013) (see section 5.8.1.2)
Reproductive toxicity: effects on fertility and developmental toxicity	oral	Adverse effect observed (based on lead and lead compounds) Lead bullion, Platinum Group metals rich contains lead and lead compounds ≥ 0.3 % that may possess reproduction toxicity (i.e., suspected of damaging fertility). Hence, Lead bullion, Platinum Group metals rich requires classification as reproductive toxicant in accordance with Regulation (EC) 1272/2008.	ARCHE (2013) (see section 5.9.1.1)
Reproductive toxicity: effects on fertility and developmental toxicity	dermal and inhalation	No adverse effect observed	ARCHE (2013) (see section 5.9.1.1)

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

5.11.2.1. Derived no effect levels (DNELs) for workers

Table 28. DNELs for workers

Route	Type of effect	As	Ni	Pb	Pd	Sb	Se	Te
Speciation		As_2O_3	Ni	Pb	Pd soluble	Sb_2O_3	Se	Te
Inhalation	Systemic long term	4 µg/m³	50 µg/m³	40 µg/dL**	20 µg/m³	no hazard	50 µg/m³	100 µg/m³
	Systemic acute	no hazard	680000 µg/m³	no hazard	no hazard	no hazard	no hazard	Qualitative assessment
	Local long term	Qualitative assessment	50 µg/m³	no hazard	no hazard	500 µg/m³	Qualitative assessment	100 µg/m³
	Local acute	Qualitative assessment	4000 µg/m³	no hazard	no hazard	no hazard	no hazard	no hazard
Dermal	Systemic long term	0.085 mg/kg bw.	no hazard	40 µg/dL**	0.6 mg/kg bw.	234.7 mg/kg bw.	7 mg/kg bw.	Qualitative assessment
	Systemic acute	no hazard	no hazard	no hazard	no hazard	no hazard	Qualitative assessment	Qualitative assessment
	Local long term	Qualitative assessment	70 µg/cm²	no hazard	no hazard	no hazard	Qualitative assessment	Qualitative assessment
	Local acute	Qualitative assessment	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard
Eye		medium hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard
Reference		RR	RR	RR	SV6	RR	RR	RR/SV8

SV: Surrogate reference value

Notes: 1. All values are given on an elemental basis, i.e. re-calculated based on the molecular weight where relevant.

2. Constituents that are not identified as hazardous to humans are not included in the table above although included in the composition profile (IUCLID section 1.2). In addition, constituents that are included in the composition profile (IUCLID section 1.2) and that are hazardous to humans but only present in the substance below the cut-off values for mixtures given in Regulation (EC) 1272/2008 (see MeClas output sheets attached on IUCLID section 13) are also not included in the table above. Thus, the following constituents were not included in the table above: Ag, Au, Ir, Pt, Rh, Ru, Bi, Cd, Cu, Fe, Sn, Zn

** Internal reference value

RR Data access to IUCLID section 7 of REACH registration dossier via LoA
SV6 Anonymous (2013): Tentative DNELs for Platinum and Palladium, bibra toxicology advice & consulting, October 2013, for the sake of this assessment, a dermal absorption factor of 1 % for palladium substances was assumed.
SV8 Anonymous (2011): Code pf practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001, (S.I. 619 of 2001), Irish Health and Safety Authority

5.11.2.2. Derived no effect levels (DNELs) for general population

DNELs for the general population are currently not included because an assessment of exposure of man via the environment is not reported but instead considered to be already included in the dossiers of the constituents. However, DNELs for the general population and the assessment of exposure of man via the environment will be amended by further analysis (please refer to Chapter 9.0.3. for further details).

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: Lead bullion, Platinum Group Metals rich

Related composition: Pb bullion, PGM rich (Full/Generic composition), Pb Bullion, PGM rich 1 (Constituents relevant for classification)

State/form of the substance: solid

Reason for no classification: conclusive but not sufficient for classification

6.2. Flammability

Flammability

Data waiving: see CSR section 1.3 Physicochemical properties.

Flash point

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: Lead bullion, Platinum Group Metals rich

Related composition: Pb bullion, PGM rich (Full/Generic composition), Pb Bullion, PGM rich 1 (Constituents relevant for classification)

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

6.3. Oxidising potential

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: Lead bullion, Platinum Group Metals rich

Related composition: Pb bullion, PGM rich (Full/Generic composition), Pb Bullion, PGM rich 1 (Constituents relevant for classification)

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

7.0. Introduction to environmental hazard assessment

General approach

The hazard assessment of inorganic UVCBs for the purpose of classification and derivation of safe effect thresholds (i.e. PNEC) is a cumbersome and complex process. Due to the intrinsic variability of the composition of an UVCB, it is difficult to select a sample that would unambiguously be representative for the (eco)toxicological hazard profile of the UVCB and could subsequently be used for testing. Instead of direct testing, a precautionary approach is taken where the UVCB is treated as a complex metal containing substance containing a number of discrete constituents (metals, metal compounds, non-metal inorganic compounds etc.). For each of these constituents, the hazard profile is used for deriving the proper classification of the UVCB (using the mixture rules) and/or for the derivation of the PNECs of the constituent (forwarded to the risk assessment). Using the PNEC of all driving constituents circumvents indirectly the issue of varying composition of an UVCB as it implicitly assumes that each time the UVCB substance consists of the pure substance, i.e. that each constituent would be present and bioavailable at a 100% concentration in the UVCB substance. This can be considered a conservative approach. A main outcome of the constituents' based assessment is the selection of all the constituents for which any environmental hazard is identified. This selection defines the scope of the further exposure and risk assessment (CSR, Ch. 9&10).

The actual hazard profile of the inorganic UVCB substance and the individual constituents is dependent on the speciation of each and every constituent and hence this information needs to be collected in order to obtain a robust classification or PNEC value used for risk assessment purposes. Different scenarios can be encountered.

- When the speciation of a constituent is known, this is used as such for the environmental hazard assessment.
- When the speciation is unknown or few metal species co-exist, the worst-case speciation for the purpose of environmental hazard assessment is selected, i.e. the speciation that would lead to the most severe effects and thus the lowest PNEC.

For most metals, it is generally assumed that the metal ion is the metal species of concern and therefore, the environmental hazard assessment is generally based on consideration of the Me-ion (ECHA, 2008. Guidance on information requirements and chemical safety assessment; Appendix R.7.13-2: Environmental risk assessment for metals and metal compounds)

Selection of the ecotoxicological information for the purpose of classification

The UVCB classification is calculated by applying the CLP mixture rules based on the classification of the known or worst-case speciation for each constituent and worst-case constituent concentration in the UVCB (i.e. maximum of the legal entity typical value), using the MeClas tool. Depending on the availability of information, the UVCB classification can be refined following MeClas Tiered approach.

Selection of the ecotoxicological information for the purpose of risk assessment

For the purpose of the environmental risk assessment for the UVCB, the hazards of each constituent will be assessed and PNEC values for all the constituents for which a hazard has been identified are compiled in order to identify the most important constituents for environmental exposure and risk characterisation (i.e. 'driving constituents').

Environmental hazard assessment of refinables

Environmental hazard assessment of the refinable substances is based on the hazards of the most important specific constituents, these driving constituents have been selected based on the following criteria:

- Classified as hazardous to the environment
- Availability of PNEC to inform hazard assessment
- Availability of monitoring data to enable exposure assessment.

Evaluation of all constituents present in refinables to determine the selection of driving constituents to include in the environmental risk assessment is provided in the Table below.

Table 29. Selection of driving constituents

UVCB constituent Element	Speciation most relevant for environmental risk assessment	Environmental classification	PNEC available	Constituent included in risk assessment?
Silver	Metal ion	Yes	Yes	Yes
Gold	Metal ion	Not classified	No	No (Not classified)
Iridium	Metal ion	Not classified	No	No (Not classified)
Palladium	Metal ion	Yes	No	No PNEC currently available, will be reviewed in future updates
Platinum	Metal ion	Yes	No	No PNEC currently available, will be reviewed in future updates
Rhodium	Metal ion	Yes	No	No PNEC currently available, will be reviewed in future updates
Ruthenium	Metal ion	Yes	No	No PNEC currently available, will be reviewed in future updates
Antimony	Metal ion	Not classified	Yes	No (Not classified)
Arsenic	Metal ion	Yes	Yes	Yes
Bismuth	Metal ion	Not classified	Yes	No (Not classified)
Cadmium	Metal ion	Yes	Yes	Yes
Copper	Metal ion	Yes	Yes	Yes
Iron	Metal ion	Not classified	No	No (Not classified)
Lead	Metal ion	Yes	Yes	Yes
Nickel	Metal ion	Yes	Yes	Yes
Selenium	Se ion	Yes	Yes	No monitoring data currently available, but will be assessed in future updates*
Tellurium	Metal ion	Yes	Yes	No monitoring data currently available, but will be assessed in future updates*
Tin	Metal ion	Yes	Yes	No monitoring data currently available, but will be assessed in future updates*
Zinc	Metal ion	Yes	Yes	Yes

* Risk addressed by risk assessment of other constituents present at higher concentrations, and with lower PNECs

There is an absence of exposure monitoring data for some constituents and for these metals and metalloids an evaluation has been made as to whether any potential risk could be adequately predicted using hazard and exposure data for other constituents. For example, where there are no monitoring data for a specific constituent, evaluation was made as to whether any potential risk could be predicted by assessment of another constituent on the basis that it occurs at higher concentrations and has a lower PNEC. Monitoring data for these constituents will be incorporated in subsequent updates to the CSR.

For the majority of the refinable substances there is very limited information available on the speciation of

constituents in either the refinable or the form in which they are discharged to the environment. It is assumed that for inorganic constituents discharged to the aqautic environment that following waste water treatment the metal or metalloid will be in soluble form that any observable effects will be due to the metal ion.

Exposure assessment has been undertaken separately for each of the driving constituents identified as relevant to the environmental hazard of the refinables substances, these are:

- Arsenic
- Cadmium
- Copper
- Lead
- Nickel
- Silver
- Zinc

The refinable substances have variable composition and may not contain all of the environmentally hazardous constituents so assessment of each refinable substance only considers the relevant constituents.

For each of the driving constituents considered in the risk assessment, the Predicted No Effect Concentrations (PNECs) have been obtained from the relevant IUCLID datasets. PNECs for each constituent considered in the risk assessment are presented in Section 7.6 of this CSR.

7.1. Aquatic compartment (including sediment)

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 30. Short-term effects on fish

Method	Results	Remarks	Reference
Aquatic toxicity of the UVCB substance was determined by classifying based on mixture rules from EU CLP (Tier 1: summation of classified components or Tier 2: additivity of soluble components to derive Hazard class) and back calculation to the corresponding L(E)C50 range.	EC50 (96 h): <= 1 mg/L test mat. (estimated) based on: most sensitive species	2 (reliable with restrictions) key study estimated by calculation **Test material (common name): Lead bullion, PGM rich**	ARCHE (2013)

Discussion

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

No PNEC is derived for the UVCB itself. The short-term toxicity to fish is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR. Individual UVCB constituents-specific information is used for classification and risk assessment.

7.1.1.2. Long-term toxicity to fish

The results are summarised in the following table:

Table 31. Long-term effects on fish

Method	Results	Remarks	Reference
Aquatic toxicity of the UVCB substance was determined by classifying based on mixture rules from EU CLP (Tier 1: summation of classified components or Tier 2: additivity of soluble components to derive Hazard class) and back calculation to the corresponding EC10/NOEC range.	NOEC (28 d): <= 0.1 mg/L test mat. (estimated) based on: most sensitive species	2 (reliable with restrictions) key study estimated by calculation **Test material (common name): Lead bullion, PGM rich**	ARCHE (2013)

Discussion

The following information is taken into account for long-term fish toxicity for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Long-term toxicity to fish is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR. Individual UVCB constituents-specific information is used for classification and risk assessment.

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 32. Short-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Aquatic toxicity of the UVCB substance was determined by classifying based on mixture rules from EU CLP (Tier 1: summation of classified components or Tier 2: additivity of soluble components to derive Hazard class) and back calculation to the corresponding L(E)C50 range.	EC50 (48 h): <= 1 mg/L test mat. (estimated) based on: most sensitive species	2 (reliable with restrictions) key study estimated by calculation **Test material (common name): Lead bullion, PGM rich**	ARCHE (2013)

Discussion

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Short-term toxicity to aquatic invertebrates is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR. Individual UVCB constituents-specific information is used for classification and risk assessment.

7.1.2.2. Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 33. Long-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Aquatic toxicity of the UVCB substance was determined by classifying based on mixture rules from EU CLP (Tier 1: summation of classified components or Tier 2: additivity of soluble components to derive Hazard class) and back calculation to the corresponding EC10/NOEC range.	NOEC (21 d): <= 0.1 mg/L test mat. (estimated) based on: most sensitive species	2 (reliable with restrictions) key study estimated by calculation **Test material (common name): Lead bullion, PGM rich**	ARCHE (2013)

Discussion

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Long-term toxicity to aquatic invertebrates is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR. Individual UVCB constituents-specific information is used for classification and risk assessment.

7.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 34. Effects on algae and aquatic plants

Method	Results	Remarks	Reference
Aquatic toxicity of the UVCB substance was determined by classifying based on mixture rules from EU CLP (Tier 1: summation of classified components or Tier 2: additivity of soluble components to derive Hazard class) and back calculation to the corresponding L(E)C50 range.	EC50 (72 h): < 1 mg/L test mat. (estimated) based on: most sensitive species	2 (reliable with restrictions) key study estimated by calculation **Test material (common name): Lead bullion, PGM rich**	ARCHE (2013)
Aquatic toxicity of the UVCB substance was determined by classifying based on mixture rules from EU CLP (Tier 1: summation of classified components or Tier 2: additivity of soluble components to derive Hazard class) and back calculation to the corresponding EC10/NOEC range.	EC10 (72 h): <= 0.1 mg/L test mat. (estimated) based on: most sensitive species	2 (reliable with restrictions) key study estimated by calculation **Test material (common name): Lead bullion, PGM rich**	ARCHE (2013)

Discussion

Effects on algae / cyanobacteria

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Toxicity to algae and cyanobacteria is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR. Individual UVCB constituents-specific information is used for classification and risk assessment.

7.1.4. Sediment organisms

Data waiving

Information requirement: Effects on sediment organisms

Reason: other justification

Justification: This endpoint is not used to assess classification of the UVCB and therefore classification testing/modeling (MeClas) for this endpoint is not required. Data on the substance toxicity to sediment is driven by the UVCB constituents. Relevant information is reported in the IUCLID summary 6 and 6.2.

Discussion

The following information is taken into account for sediment toxicity for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Sediment toxicity is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR.

7.1.5. Other aquatic organisms

No relevant information available

7.2. Terrestrial compartment

7.2.1. Toxicity to soil macro-organisms

Data waiving

Information requirement: Toxicity to soil macro-organisms except arthropods

Reason: other justification

Justification: This endpoint is not used to assess classification of the UVCB and therefore classification testing/modeling (MeClas) for this endpoint is not required. The toxicity to soil macroorganisms is driven by the UVCB constituents. Relevant information is reported in the IUCLID summary 6 and 6.3.1.

Information requirement: Toxicity to soil arthropods

Reason: other justification

Justification: This endpoint is not used to assess classification of the UVCB and therefore classification testing/modeling (MeClas) for this endpoint is not required. The toxicity to terrestrial arthropods is driven by the UVCB constituents. Relevant information is reported in the IUCLID summary 6 and 6.3.2.

Discussion of effects on soil macro-organisms except arthropods

The following information is taken into account for effects on soil macro-organisms except arthropods for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Toxicity to soil macro-organisms is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR.

Discussion of effects on soil dwelling arthropods

The following information is taken into account for effects on soil dwelling arthropods for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Toxicity to terrestrial arthropods is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR.

7.2.2. Toxicity to terrestrial plants

Data waiving

Reason: other justification

Justification: This endpoint is not used to assess classification of the UVCB and therefore classification testing/modeling (MeClas) for this endpoint is not required. The toxicity to terrestrial plants is driven by the UVCB constituents. Relevant information is reported in the IUCLID summary 6 and 6.3.3.

Discussion

The following information is taken into account for toxicity on terrestrial plants for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Toxicity to terrestrial plants is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR.

7.2.3. Toxicity to soil micro-organisms

Data waiving

Information requirement: Effects on soil micro-organisms

Reason: other justification

Justification: This endpoint is not used to assess classification of the UVCB and therefore classification testing/modeling (MeClas) for this endpoint is not required. The toxicity to soil microorganisms is driven by the UVCB constituents. Relevant information is reported in the IUCLID summary 6 and 6.3.4.

Discussion

The following information is taken into account for toxicity on soil micro-organisms for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Toxicity to soil microorganisms is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR.

7.2.4. Toxicity to other terrestrial organisms

No relevant information available

7.3. Atmospheric compartment

Lead bullion, Platinum Group Metals rich 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: other justification

Justification: This endpoint is not used to assess classification of the UVCB and therefore classification testing/modeling (MeClas) for this endpoint is not required. Data on the substance toxicity to STP microorganisms is driven by the UVCB constituents. Relevant information is reported in the IUCLID summary 6 and 6.1.7, if relevant.

Discussion

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Toxicity to microorganisms is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR.

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

7.5.1. Toxicity to birds

Data waiving

Information requirement: Toxicity to birds

Reason: other justification

Justification: This endpoint is not used to assess classification of the UVCB and therefore classification testing/modeling (MeClas) for this endpoint is not required. The toxicity to birds is driven by the UVCB constituents. Relevant information is reported in the IUCLID summary 6 and 6.3.5.

Discussion

The following information is taken into account for effects on birds for the derivation of PNEC:

No PNEC is derived for the UVCB itself. Toxicity to birds is driven by the characteristics of the individual UVCB constituents. Relevant information on the individual UVCB constituents is reported in the IUCLID Section 6 Summary and in a separate annex of the CSR.

7.5.2. Toxicity to mammals

No relevant information available

7.6. PNEC derivation and other hazard conclusions

The UVCB ecotoxicological assessment is driven by the assessment of the individual UVCB constituents. PNECs for the individual UVCB constituents are reported in each constituent summary in IUCLID section 6 and in a separate Annex to the CSR. A summary of the PNECs for the UVCB constituents which are considered in the risk assessment are presented in below Table.

Table 35. Hazard assessment conclusion for the environment

PNEC	Unit	Silver	Nickel	Lead	Zinc	Arsenic	Cadmium	Copper
Freshwater	µg/L	0.04	3.6	3.1	20.6	13	0.19	7.8
Marine water	µg/L	0.86	8.6	3.5	6.1	0.91	1.14	5.2
Freshwater sediment	mg/kg_{dw}	438.13	NA	174	117.8	179.5	1.8	87
Marine sediment	mg/kg_{dw}	438.13	NA	164	56.5	9.1	0.64	676
Soil	mg/kg_{dw}	1.41	34	212	35.6	0.53	0.9	65
STP	µg/L	25	330	100	52	60.8	20	230
Secondary poisoning	mg/kg food	NR	See Table below	10.9	NR	0.99	0.16	NR

*Speciation assumed to be Cr(III) following on-site waste water treatment
NR – not relevant

Concentration ($PNEC_{oral}$) for secondary poisoning assessment of nickel

Protection target	**PNECoral (**mg/kg $food_{ww}$)
Freshwater (aquatic bird)	12.3
Freshwater (aquatic mammal)	2.3
Marine	4.6
Terrestrial bird	8.5
Terrestrial mammal	0.12

Environmental classification justification

The environmental classification for this substance has been derived using the MeCLAS tool. The classifications for Lead bullion, PGM rich, are grouped classifications based on the composition profiles. This approach has been used for lead bullion, precious metal rich, as it consists of a small and relatively uniform (yet still sufficiently variable to be considered a UVCB) group, where a number of composition profiles are expected to be manufactured and/or imported.

Notes:

- For the speciation used for classification, please refer to the table in CSR Section 3.0.3.
- Classification drivers are (worst case) assumptions and do not necessarily represent real species/mineralogical composition.

Lead bullion, PGM rich

The MeCLAS tool has been used to derive the classification for lead bullion, precious metal rich, on the basis of its composition, showing that it would be classified for the environment under CLP as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

General discussion

For classification purposes, the classification of the UVCB is based on the hazard of the constituents. This has been determined following CLP mixture toxicity rules using the MeClas tool.

For risk assessment purposes, the assessment covers the risks posed to all relevant environmental compartments by releases of selected environmental driving constituents during the production and use of the refinable substances. Exposure assessment has been undertaken separately for each of the driving constituents. These are arsenic, cadmium, chromium, copper, lead, nickel, silver and zinc. The refinable substances have variable composition and may not contain all of the environmentally hazardous constituents so the generic exposure assessment for each refinable substance only considers the relevant constituents.

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

8.1.2. Summary and overall conclusions on PBT or vPvB properties

Overall conclusion:

PBT assessment does not apply.

Justification:

The UVCB is an inorganic substance for which PBT assessment does not apply.

9. EXPOSURE ASSESSMENT (and related risk characterisation)

The exposure assessments are provided in a separate Annex to the CSR and are attached to Section 13 of IUCLID.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

The exposure assessments are provided in a separate Annex to the CSR and are attached to Section 13 of IUCLID.

REFERENCES

ARCHE (2013). MECLAS: Metals Classification Tool. MECLAS webpage: www. meclas. eu. Report no.: See version number MECLAS report. Owner company: ARCHE cvba, Stapelplein 70, box 104, 9000 Gent + Eurometaux, Avenue de Broqueville 12, 1150 Brussels, Belgium + REACH Consortium License.

ECTX-Consult (2010). 24-h Transformation/Dissolution Pre-test of PGM Rich Lead Bullion at a 100mg/L loading in a standard aqueous medium at pH 6 and pH 8. Testing laboratory: ECTX-Consult bvba (Ecotoxicology and Biodegradation). Report no.: X01-051. Owner company: Precious Metals and Rhenium Consortium (PMC), c/o European Precious Metals Federation.

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Vale Inco (2010). Collection of Appearance/Physical State Colour Data (IUCLID Endpoint 4.1). Owner company: Vale Inco Europe Limited, London, UK

Annex I: MECLAS export sheets

See IUCLID section 13 attachments CSR Annex I

Annex II: PMC classification method

See IUCLID section 13 attachment CSR Annex II

Annex III: Generic Environmental Exposure Scenario

See IUCLID section 13 attachment CSR Annex III

Annex IVa: Methodology for Occupational Exposure Assessment

See IUCLID section 13 attachment CSR Annex IVa

Annex IVb: Company-specific Occupational Exposure Scenarios

See IUCLID section 13 attachment CSR Annex IVb

Annex V: Annex of environmental constituent text

See IUCLID section 13 attachment CSR Annex V

Annex VI: Annex of human health constituent text

See IUCLID section 13 attachment CSR Annex VI