CHEMICAL SAFETY REPORT

Substance Name: slimes and sludges, precious metal refining

EC Number: 308-516-0

CAS Number: 98072-61-8

Registrant's Identity: WCA

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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.

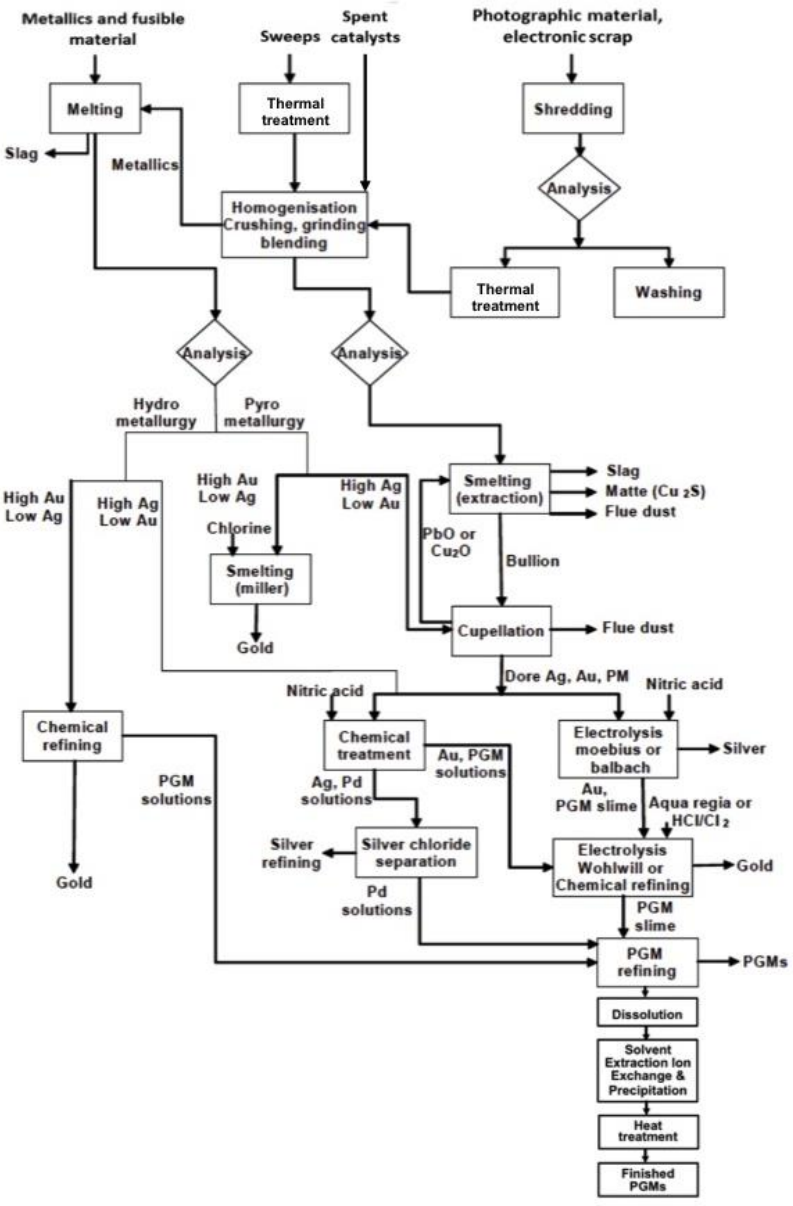
Part B

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.

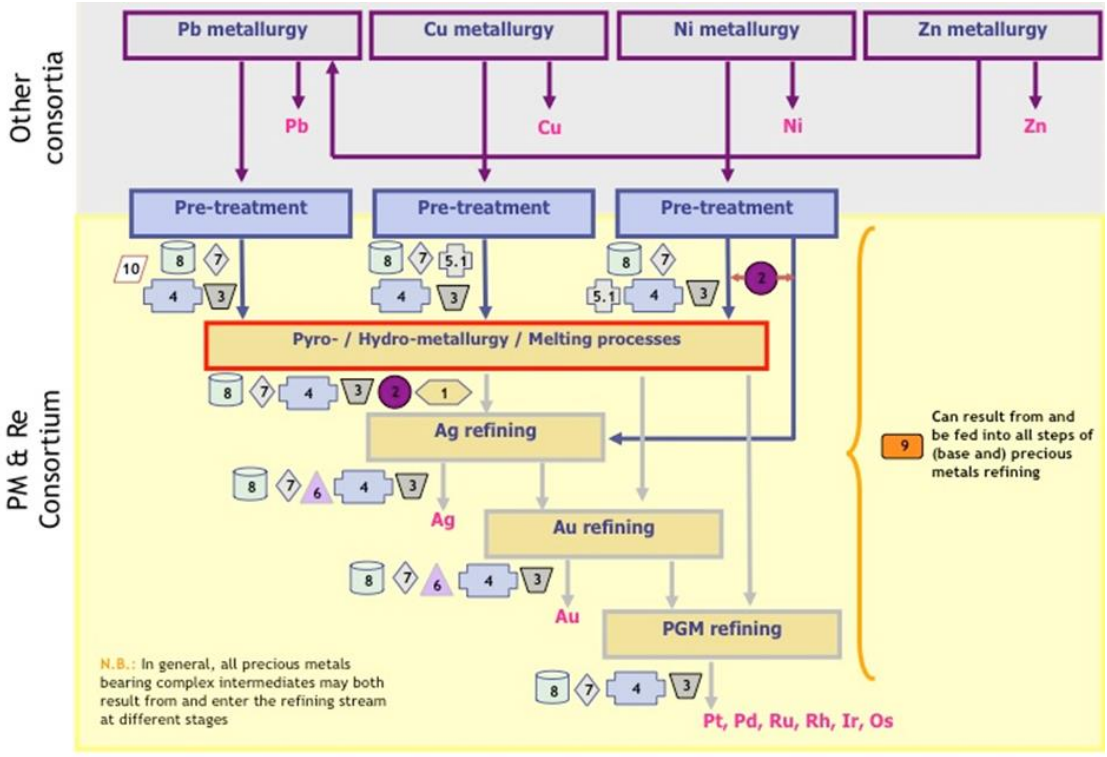
The most significant sources of precious metals are precious metal ores, by-products obtained from the processing of other non-ferrous metals (in particular anode slimes from copper production, leach residues and crude metal from zinc and lead production) and recycled material. They may be fed directly 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 **slimes and sludges, precious metal refining** is a UVCB having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

Table 1. Substance identity

EC number:	308-516-0
EC name:	Slimes and Sludges, precious metal refining
CAS number (EC inventory):	98072-61-8
IUPAC name:	Slimes and Sludges, precious metal refining

Description:	Dry or wet residues resulting from hydro-metallurgical and/or electrolysis processes used in the refining of precious metals. Slimes and sludges from precious metals refining generally contain precious and base metals, and insoluble inorganic compounds in varying concentrations.
Molecular formula:	
Molecular weight range:	

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.

The different grades (Slimes and sludges 1-4) are the compositions related to the different classifications listed under section 3.1 of this CSR. For the purpose of classification, the compositions of the Precious Metals Refinables are defined by means of formulas rather than elemental concentration ranges because in some cases, it was not possible to derive „generic“ compositions covering all companies without frequently exceeding total composition of 100%. These formulas have been added under the „Remarks“ field in IUCLID/CSR 1.2. Note that for the composition of the different grades, only those constituents relevant for classification have been reported. Other constituents are reported under the Generic/Full composition. The formulas were derived with due care, nevertheless, it is always recommended to use the freely available MeClas tool for deriving the classification of the UVCB.

Name: Slimes and sludges, precious metal refining (Full / generic composition)

Degree of purity: 100.0 % (w/w)

Table 2. Constituents

Constituent	Typical concentration	Concentration range	Remarks
silver EC no.: 231-131-3	16.0 % (w/w)	0.1 — 84.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, sulphates, sulphides and/or chlorides.
gold EC no.: 231-165-9	11.0 % (w/w)	0.0 — 95.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, sulphides and/or chlorides.
iridium EC no.: 231-095-9	1.1 % (w/w)	0.0 — 13.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, sulphides, chlorides and/or chloro-complexes.
palladium EC no.: 231-115-6	8.0 % (w/w)	0.0 — 88.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, sulphides, chlorides and/or chloro-complexes.
platinum	5.3 % (w/w)	0.0 — 60.0 % (w/w)	Refers to % element.

Constituent	Typical concentration	Concentration range	Remarks
EC no.: 231-116-1			Element is present in metallic form, as oxides, sulphides, chlorides and/or chloro-complexes.
rhodium EC no.: 231-125-0	2.6 % (w/w)	0.0 — 21.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides, sulphides, chlorides, chloro-complexes and nitro-complexes.
ruthenium EC no.: 231-127-1	3.2 % (w/w)	0.0 — 29.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides, sulphides, chlorides and chloro-complexes.
aluminium EC no.: 231-072-3	0.96 % (w/w)	0.0 — 14.0 % (w/w)	Refers to % element. Element is present as oxides.
arsenic EC no.: 231-148-6	0.93 % (w/w)	0.0 — 5.2 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides, chlorides and sulphides.
boron EC no.: 231-151-2	0.002 % (w/w)	0.0 — 0.01 % (w/w)	Refers to % element. Element is present as oxides.
barium EC no.: 231-149-1	0.96 % (w/w)	0.0 — 16.0 % (w/w)	Refers to % element. Element is present as oxides, hydroxides, chlorides and aulphates.
bismuth EC no.: 231-177-4	1.1 % (w/w)	0.0 — 9.2 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides, chlorides and sulphides.
Carbon EC no.: 231-153-3	0.48 % (w/w)	0.0 — 8.0 % (w/w)	Refers to % element.
cadmium EC no.: 231-152-8	0.02 % (w/w)	0.0 — 0.2 % (w/w)	Refers to % element. Element is present as chlorides and oxides.
cerium EC no.: 231-154-9	0.05 % (w/w)	0.0 — 1.0 % (w/w)	Refers to % element. Element is present as chrloides and oxides.
chlorine EC no.: 231-959-5	10.0 % (w/w)	0.0 — 60.0 % (w/w)	Refers to % element. Element is present as chlorides and chloro-complexes.
cobalt EC no.: 231-158-0	0.18 % (w/w)	0.0 — 3.7 % (w/w)	Refers to % element. Element is present as oxides, hydroxides and chlorides.

Constituent	Typical concentration	Concentration range	Remarks
chromium EC no.: 231-157-5	1.2 % (w/w)	0.0 — 20.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxide (Cr2O3), hydroxide and chloride.
copper EC no.: 231-159-6	5.7 % (w/w)	0.0 — 33.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides, chlorides and sulphides.
iron EC no.: 231-096-4	4.3 % (w/w)	0.0 — 40.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, chlorides, sulphides and sulphates.
potassium EC no.: 231-119-8	0.67 % (w/w)	0.0 — 17.0 % (w/w)	Refers to % element. Element is present as chlorides, oxides.
magnesium EC no.: 231-104-6	0.13 % (w/w)	0.0 — 3.0 % (w/w)	Refers to % element. Element is present as chlorides and oxides.
manganese EC no.: 231-105-1	0.03 % (w/w)	0.0 — 0.5 % (w/w)	Refers to % element. Element is present as chlorides and oxides.
sodium EC no.: 231-132-9	1.1 % (w/w)	0.0 — 15.0 % (w/w)	Refers to % element. Element is present as chlorides and oxides.
nickel EC no.: 231-111-4	1.0 % (w/w)	0.0 — 10.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides, sulphides and chlorides.
lead EC no.: 231-100-4	2.3 % (w/w)	0.0 — 14.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides, sulphates and chlorides.
sulphur	1.5 % (w/w)	0.0 — 26.0 % (w/w)	Refers to % element. Element is present in sulphates and sulphides.
antimony EC no.: 231-146-5	0.65 % (w/w)	0.0 — 8.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides and chlorides.
selenium EC no.: 231-957-4	4.0 % (w/w)	0.0 — 30.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides.
silicon EC no.: 231-130-8	1.5 % (w/w)	0.0 — 13.0 % (w/w)	Refers to % element. Element is present as oxides.
tin EC no.: 231-141-8	0.56 % (w/w)	0.0 — 5.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides and chlorides.

Constituent	Typical concentration	Concentration range	Remarks
tellurium EC no.: 236-813-4	2.3 % (w/w)	0.0 — 25.0 % (w/w)	Refers to % element. Element is present in metallic form, as oxides, hydroxides, telluric acid and sulphides.
titanium EC no.: 231-142-3	0.17 % (w/w)	0.0 — 4.0 % (w/w)	Refers to % element. Element is present as oxide.
zinc EC no.: 231-175-3	0.33 % (w/w)	0.0 — 4.5 % (w/w)	Refers to % element. Element is present as oxides, chlorides and sulphides.
zirconium EC no.: 231-176-9	0.28 % (w/w)	0.0 — 5.0 % (w/w)	Refers to % element. Element is present as oxide.

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.

Name: Slimes and sludges, precious metal refining - 1 (Constituents relevant for classification)

Degree of purity: 100.0 % (w/w)

Table 3. Constituents

Constituent	Typical concentration	Concentration range	Remarks
Nickel chloride EC no.: 253-399-0	< 0.01 % (w/w)	ca. 0.0 — < 0.01 % (w/w)	
diantimony trioxide EC no.: 215-175-0	< 1.0 % (w/w)	ca. 0.0 — < 1.0 % (w/w)	
lead EC no.: 231-100-4	< 0.05 % (w/w)	ca. 0.0 — < 0.05 % (w/w)	
cobalt EC no.: 231-158-0	< 0.1 % (w/w)	ca. 0.0 — < 0.1 % (w/w)	
cadmium chloride EC no.: 233-296-7	< 0.1 % (w/w)	ca. 0.0 — < 0.1 % (w/w)	
diarsenic trioxide EC no.: 215-481-4	< 0.1 % (w/w)	ca. 0.0 — < 0.1 % (w/w)	
Borax	< 5.5 % (w/w)	ca. 0.0 — < 5.5 % (w/w)	
Selenium compounds	< 10.0 % (w/w)	ca. 0.0 — < 10.0 % (w/w)	
Manganese dioxide EC no.: 215-202-6	< 10.0 % (w/w)	ca. 0.0 — < 10.0 % (w/w)	
Other constituents influencing classification (H2SO4, As2O3, NiCl2, CaO)	< 100.0 % (w/w)		%H2SO4/5% + %As2O3/1% + %NiCl2/10% + %CaO/10% < 1

Constituent	Typical concentration	Concentration range	Remarks
Other constituents influencing classification (H2SO4, As2O3, CaO, Pd comp, Na2BO7)	< 100.0 % (w/w)		%H2SO4/5% + %As2O3/1% + %CaO/1% + %Pd comp/10% + %Na2BO7/10% < 1
Other constituents influencing classification (As2O3, Se comp, Te/Te comp, CdCl2, BaO2, Co, CuSO4, Pb comp, NiSO4, NiCl2, ZnSO4, Cu2O, MnO2, Pd comp)	> 2000.0 mg/kg		100 / ((%As2O3)/5 + (%Se comp + %Te/Te comp + %CdCl2)/100 + (%BaO2 + %Co + %CuSO4 + %Pb comp + %NiSO4 + %NiCl2 + %ZnSO4 + %Cu2O + %MnO2 + %Pd comp)/500) > 2000 mg/kg
Other constituents influencing classification (CdO, CdCl2, Se comp, BaO2, Pb comp, NiSO4, NiCl2, MnO2)	> 5.0 mg/L		100 / ((%CdO + %CdCl2)/100 + (%Se comp)/700 + (%BaO2 + %Pb comp + %NiSO4 + %NiCl2 + %MnO2 + %BaO2)/4500 > 5 mg/L
Other constituents influencing classification (As2O3, CdO, CoO, Cu2O, Pb comp, Se comp, ZnO, Ag comp, Au comp, Pd comp, Pt comp, Ti comp, Rh comp, Ru comp, CuSO4, NiSO4, ZnSO4)	> 25.0 % (w/w)	> 25.0 — <= 100.0 % (w/w)	(%As2O3 + %CdO x 10 + %CoO x 10 + %Cu2O + %Pb comp x 10 + %Se comp x 10 + %ZnO + %Ag comp x 1000 + %Au comp + %Pd comp x 10 + %Pt comp x 10 + %Ti comp + %Rh comp + %Ru comp + %CuSO4 x 10 + %NiSO4 + %ZnSO4) > 25%; (%As2O3 + %CdO x 100 + %CoO x 10 + %Cu2O + %Pb comp + %Se comp + %ZnO + %Ag comp x 100 + %Au comp + %Pd comp x 10 + %Pt comp + %Ti comp + %Rh comp + %Ru comp + %CuSO4 + %NiSO4 + %ZnSO4) > 25%

Name: Slimes and sludges, precious metal refining - 2 (low nickel, arsenic, lead) (Constituents relevant for classification)

Degree of purity: 100.0 % (w/w)

Table 4. Constituents

Constituent	Typical concentration	Concentration range	Remarks
Nickel chloride EC no.: 253-399-0		0.01 — 0.1 % (w/w)	
diantimony trioxide EC no.: 215-175-0	< 1.0 % (w/w)	ca. 0.0 — < 1.0 % (w/w)	
lead EC no.: 231-100-4	< 0.05 % (w/w)	ca. 0.0 — < 0.05 % (w/w)	

Constituent	Typical concentration	Concentration range	Remarks
cobalt EC no.: 231-158-0	< 0.1 % (w/w)	ca. 0.0 — < 0.1 % (w/w)	
cadmium chloride EC no.: 233-296-7	< 0.1 % (w/w)	ca. 0.0 — < 0.1 % (w/w)	
diarsenic trioxide EC no.: 215-481-4	< 0.1 % (w/w)	ca. 0.0 — < 0.1 % (w/w)	
Borax	< 5.5 % (w/w)	ca. 0.0 — < 5.5 % (w/w)	
Selenium compounds	< 10.0 % (w/w)	ca. 0.0 — < 10.0 % (w/w)	
Manganese dioxide EC no.: 215-202-6	< 10.0 % (w/w)	ca. 0.0 — < 10.0 % (w/w)	
Other constituents influencing classification (H2SO4, As2O3, NiCl2, CaO)	< 100.0 % (w/w)		%H2SO4/5% + %As2O3/1% + %NiCl2/10% + %CaO/10% < 1
Other constituents influencing classification (H2SO4, As2O3, CaO, Pd comp, Na2BO7)	< 100.0 % (w/w)		%H2SO4/5% + %As2O3/1% + %CaO/1% + %Pd comp/10% + %Na2BO7/10% < 1
Other constituents influencing classification (As2O3, Se comp, Te/Te comp, CdCl2, BaO2, Co, CuSO4, Pb comp, NiSO4, NiCl2, ZnSO4, Cu2O, MnO2, Pd comp)		300.0 — 2000.0 mg/kg	100 / ((%As2O3)/5 + (%Se comp + %Te/Te comp + %CdCl2)/100 + (%BaO2 + %Co + %CuSO4 + %Pb comp + %NiSO4 + %NiCl2 + %ZnSO4 + %Cu2O + %MnO2 + %Pd comp)/500) between 300 - 2000 mg/kg
Other constituents influencing classification (CdO, CdCl2, Se comp, BaO2, Pb comp, NiSO4, NiCl2, MnO2)	> 5.0 mg/L		100 / ((%CdO + %CdCl2)/100 + (%Se comp)/700 + (%BaO2 + %Pb comp + %NiSO4 + %NiCl2 + %MnO2 + %BaO2)/4500 > 5 mg/L
Other constituents influencing classification (As2O3, CdO, CoO, Cu2O, Pb comp, Se comp, ZnO, Ag comp, Au comp, Pd comp, Pt comp, Ti comp, Rh comp, Ru comp, CuSO4, NiSO4, ZnSO4)	> 25.0 % (w/w)	> 25.0 — <= 100.0 % (w/w)	(%As2O3 + %CdO x 10 + %CoO x 10 + %Cu2O + %Pb comp x 10 + %Se comp x 10 + %ZnO + %Ag comp x 1000 + %Au comp + %Pd comp x 10 + %Pt comp x 10 + %Ti comp + %Rh comp + %Ru comp + %CuSO4 x 10 + %NiSO4 + %ZnSO4) > 25% ; (%As2O3 + %CdO x 100 + %CoO x 10 + %Cu2O + %Pb comp + %Se comp + %ZnO + %Ag comp x 100 + %Au comp + %Pd comp x 10 + %Pt comp + %Ti comp +

Constituent	Typical concentration	Concentration range	Remarks
			%Rh comp + %Ru comp + %CuSO4 + %NiSO4 + %ZnSO4) > 25%

Name: Slimes and sludges, precious metal refining - 3 (medium nickel, arsenic, lead) (Constituents relevant for classification)

Degree of purity: 100.0 % (w/w)

Table 5. Constituents

Constituent	Typical concentration	Concentration range	Remarks
cobalt EC no.: 231-158-0	>= 1.0 % (w/w)		%Co >= 1% or %NiCl2: 1%-10%
Nickel chloride EC no.: 253-399-0		1.0 — 10.0 % (w/w)	%Co >= 1% or %NiCl2: 1%-10%
cadmium chloride EC no.: 233-296-7	< 0.1 % (w/w)	ca. 0.0 — < 0.1 % (w/w)	
lead EC no.: 231-100-4	< 0.3 % (w/w)	ca. 0.0 — < 0.3 % (w/w)	
Other constituents influencing classification (H2SO4, As2O3)	< 100.0 % (w/w)		%H2SO4/15% + %As2O3/5% < 1
Other constituents influencing classification (H2SO4, As2O3, NiCl2, CaO)	< 100.0 % (w/w)		%H2SO4/5% + %As2O3/1% + %NiCl2/10% + %CaO/10% >= 1
Other constituents influencing classification (H2SO4, As2O3, CaO)	< 100.0 % (w/w)		%H2SO4/15% + %As2O3/3% + %CaO/3% < 1
Other constituents influencing classification (H2SO4, As2O3, CaO, Pd comp, Na2BO7)	< 100.0 % (w/w)		%H2SO4/5% + %As2O3/1% + %CaO/1% + %Pd comp/10% + %Na2BO7/10% >= 1
Other constituents influencing classification (As2O3, Se comp, Te/Te comp, CdCl2, BaO2, Co, CuSO4, Pb comp, NiSO4, NiCl2, ZnSO4, Cu2O, MnO2, Pd comp)		300.0 — 2000.0 mg/kg	100 / ((%As2O3)/5 + (%Se comp + %Te/Te comp + %CdCl2)/100 + (%BaO2 + %Co + %CuSO4 + %Pb comp + %NiSO4 + %NiCl2 + %ZnSO4 + %Cu2O + %MnO2 + %Pd comp)/500) between 300 - 2000 mg/kg
Other constituents influencing classification (CdO, CdCl2, Se comp, BaO2, Pb comp, NiSO4, NiCl2, MnO2)		1.0 — 5.0 mg/L	100 / ((%CdO + %CdCl2)/100 + (%Se comp)/700 + (%BaO2 + %Pb comp + %NiSO4 + %NiCl2 + %MnO2 + %BaO2)/4500 between 1 and 5 mg/L

Name: Slimes and sludges, precious metal refining- 4 (high nickel, arsenic, lead) (Constituents relevant for classification)

Degree of purity: 100.0 % (w/w)

Table 6. Constituents

Constituent	Typical concentration	Concentration range	Remarks
Nickel chloride EC no.: 253-399-0	>= 1.0 % (w/w)	>= 1.0 — <= 10.0 % (w/w)	
cadmium chloride EC no.: 233-296-7	> 0.1 % (w/w)	> 0.1 — <= 0.2 % (w/w)	
lead EC no.: 231-100-4	>= 0.3 % (w/w)	>= 0.3 — <= 14.0 % (w/w)	
Other constituents influencing classification (H2SO4, As2O3)	< 100.0 % (w/w)		%H2SO4/15% + %As2O3/5% >= 1
Other constituents influencing classification (As2O3, Se comp, Te/Te comp, CdCl2, BaO2, Co, CuSO4, Pb comp, NiSO4, NiCl2, ZnSO4, Cu2O, MnO2, Pd comp)		50.0 — 300.0 mg/kg	100 / ((%As2O3)/5 + (%Se comp + %Te/Te comp + %CdCl2)/100 + (%BaO2 + %Co + %CuSO4 + %Pb comp + %NiSO4 + %NiCl2 + %ZnSO4 + %Cu2O + %MnO2 + %Pd comp)/500) between 50 - 300 mg/kg
Other constituents influencing classification (CdO, CdCl2, Se comp, BaO2, Pb comp, NiSO4, NiCl2, MnO2)		1.0 — 5.0 mg/L	100 / ((%CdO + %CdCl2)/100 + (%Se comp)/700 + (%BaO2 + %Pb comp + %NiSO4 + %NiCl2 + %MnO2 + %BaO2)/4500 between 1 and 5 mg/L

1.3. Physicochemical properties

Table 7. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	The appearance of this test item is a black, grey or yellow solid (powder).	**Value used for CSA:** solid at 20°C and 101.3 kPa The appearance of slimes and sludges, precious metal refining was described as a black solid in a study report (Harlan 2010) which is considered reliable and acceptable for use as a key study. This is supported by data received from a member company, which are considered reliable. The company-provided data indicate that slimes and sludges, precious metal refining, is an odourless solid (powder), which is grey/dark grey (sometimes black) or yellow.
Melting / freezing point	The melting point of the test item was determined to be greater than 450°C (>723K).	**Value used for CSA:** 450 °C at 101.3 kPa The study by Harlan (2010) is GLP compliant and follows a standard guideline. It is considered reliable and acceptable for use as a key study.
Relative density	The relative density of the test item has been determined to be 2.03 at 22.5±0.5°C.	**Value used for CSA:** 2.03 at 20°C The study by Harlan (2010) is GLP compliant and follows a standard guideline. It is considered reliable and acceptable for use as a key study.
Water solubility	Transformation/dissolution tests were conducted for slimes and sludges, precious metal refining and the only constituent above the detection limits was silver.	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.
Flammability	The test item is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.	The results are taken from a GLP compliant, guideline test (Harlan 2010) which is considered to be reliable and acceptable for use for this endpoint. The results indicate that the test item is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.

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: Granulometry

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the granulometry study does not need to be conducted as the substance is marketed or used in a non solid or granular form.

This substance is a sludge like material which is unsuitable for particle size assessment.

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: According to Annex VII, section 7.12, column 2 of Regulation No. 1907/2006, the study does not need to be conducted as preliminary results exclude self-heating of the substance up to 400°C.

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: The test item contains oxygen. According to the guidance given in Appendix 6, section six of the United Nations Recommendations on the Transport of Dangerous Goods Manual of Tests and criteria, testing is required if the test item contains oxygen and /or halogens. The oxygen is present as sulphate and therefore the oxygen is not readily available for oxidation. The metal oxides and chlorides present are

generally in small amounts or are known to be non-oxidising. Therefore, the oxidising properties of the test item can be predicted negative.

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

Slimes and sludges, precious metal refining, is a solid, with a relative density of 2.03 at 22.5°C and a melting point temperature of greater than 450°C (>723K). As water solubility testing is not appropriate for complex metal and sparingly soluble metals and metal compounds, transformation dissolution testing has been conducted and the results are 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 8. Manufacture

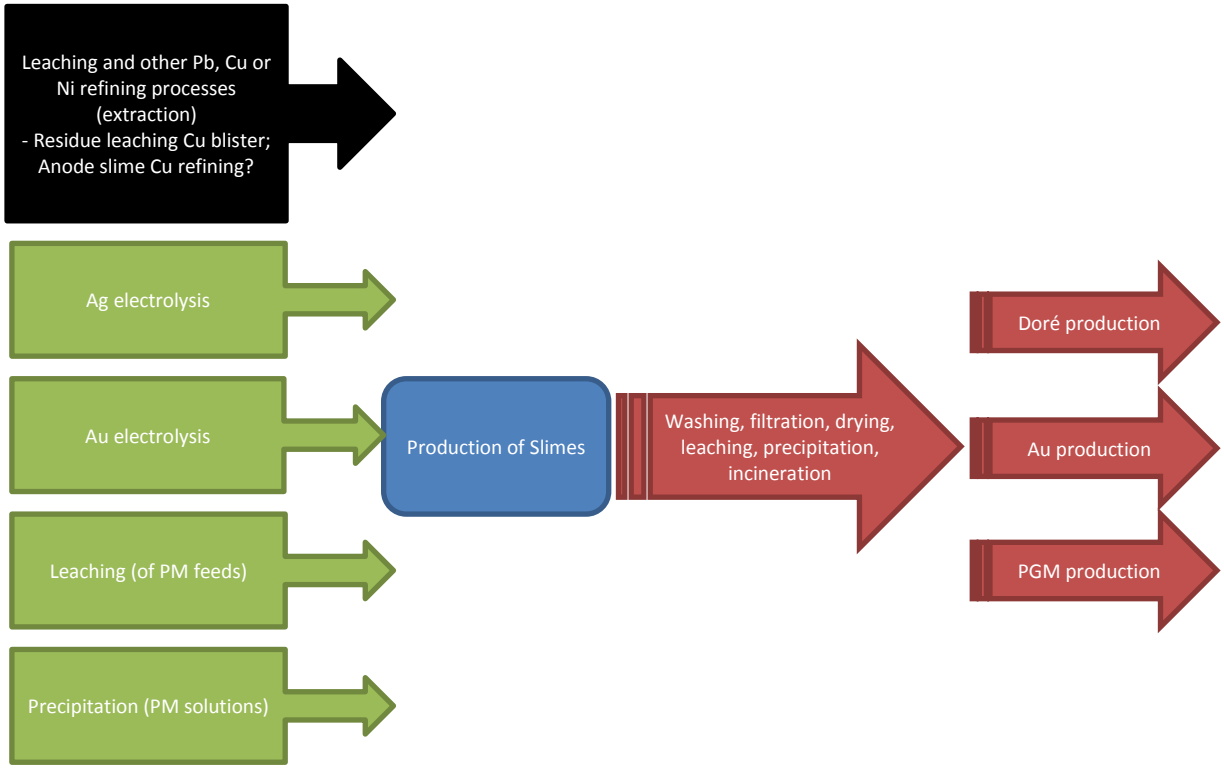
Identifiers	Use descriptors	Other information
M-: Manufacture of an intermediate	**Environmental release category (ERC):** ERC 1: Manufacture of substances **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled 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)	

Table 9. Manufacturing process related to the specified manufacture(s)

Related manufacture(s)	Description of manufacturing process
	Slimes & sludges are formed during the hydro-metallurgical and/or electrolysis processes used in the refining of precious metals (manufactured from precious metal containing primary and secondary feeds) in which precious metals are concentrated via leaching, precipitation, and other

Related manufacture(s)	Description of manufacturing process
	chemical separation techniques, from less valuable materials, in a form that can be collected and re-used as feedstock in further precious metals refining.

The below flowsheet identifies influx/outflux substances in the production of Slimes and sludges, precious metal refining. Green/red arrows are used for influx from/outflux to precious metal sector, whereas black arrows indicate influx from/outflux to other base metal sectors.



The production of slimes and sludges occurs in all sites having hydro-metallurgical or electrolytic refining operations. Slimes typically result from electrolysis steps while sludges result from chemical separation steps such as concentration/upgrading, leaching and precipitation. In both electrolysis and other hydro-metallurgical refining steps, precious metals compounds segregate into whichever phase they are most stable.

In precious metals chemistry and manufacturing, electrolysis is a method of using a direct electric current to drive an otherwise non-spontaneous chemical reaction. It consists in the passage of that current through an ionic substance that is either molten or dissolved in a suitable solvent, resulting in chemical reactions at the electrodes and separation of materials.
In that way, electrolysis does not differ from hydrometallurgical processes, which apply techniques involving the use of aqueous chemistry for the recovery of metals from ores, concentrates and recycled or residual materials.

Electrolytic as well as hydrometallurgical processes are very complex and many individual process stages may have to be repeated to achieve the required purity. Processes are designed to obtain a pure target metal(Ag, Au, PGMs) as well as to recover as much as possible PM from process residues. The number and order of the stages also depend on the constituents to be removed and the specific mix of precious metals to be separated.

The composition of slimes & sludges is intrinsically variable as they result as process residues at various stages of the precious metals refining process, multiple process conditions and exact stage of refinement step.

The composition of slimes from electrolytic refining of silver and gold does not vary as much as the composition of sludges from hydro-metallurgical refining steps as the source material and process conditions are more defined.

The composition of sludges from hydro-metallurgical refining steps is intrinsically as variable as the sources and chemical reactions they result from. Multiple reactions can be applied on a number of sources concomitantly, on the basis of the composition of the sources and the desired outcome.

Depending on material or source (i.e. whether it has already been concentrated to a certain level, is only a starting material in the refining, or a material almost fully depleted from precious metals but which retains a valuable portion that can be retrieved with a specific hydro-metallurgical reaction), the content of precious and other (unwanted) metals in the sludge will vary.

According to the ECHA Guidance for identification and naming of substances under REACH and CLP, UVCB substance "shall be identified by its name, its origin or source and the most relevant steps taken during processing". The consequence of defining a substance as UVCB is that any significant change of source or process would likely lead to a different substance that should be registered separately

However a simple differentiation between process and source in the precious metals sector is not feasible due to the significant complexity of the precious metals refining flow sheet, the fact that processes are designed to process various source materials with various levels of precious metals and base metals together and the need to repeat many individual process stages to achieve the required purity of precious metals as well as recovery of preious metasl from all process residues to the extent possible.Reality in the precious metals sector demonstrates a same Refinable can originate from different sources and process (steps) (cf. illustration in section 1 above).

Over the past years, the PMC has put extensive efforts to determine and improve the substance identification for this UVCB and considered splitting to the best of our knowledge, using ECHA guidance and taking into account the complexity of the PM refining flow sheets. So far, splitting in an objective manner has not been possible but we are further exploring criteria and approaches which could be considered to split the group.

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 10. 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 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	Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	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

3.1. Classification and labelling according to CLP / GHS

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;

[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.*

- ensure consistent classification of complex inorganic UVCBs throughout the industry;
- provide full recognition to metal specific aspects;
- 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 X) 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.

Due to the variability in elemental (chemical) composition, four different grades of Slimes and sludges (Slimes and sludges 1 - Slimes and sludges 5) with different elemental (chemical) composition and linked classification, were derived. The classifications of the different grades are grouped classifications based on cluster analysis and expert judgment (see 'Quantitative grouping' in Annex II).

For the purpose of classification, the compositions of the grades are defined by means of formulas rather than elemental concentration ranges because in some cases, it was not possible to derive 'generic' compositions covering all companies without frequently exceeding total composition of 100%. These formulas have been reported under the 'Remarks' field in IUCLID /CSR 1.2. Note that for the composition of the different grades, only those constituents relevant for classification have been reported. Other constituents are reported under the Generic/Full composition. The formulas were derived with due care, nevertheless, it is always recommended to use the freely available MeClas tool for deriving the classification of the UVCB.

For each grade, 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 11. 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 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 iin 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	As2O3/AsO3	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
B	Na2B4O7	Maximum of typicals	Harmonised and worse self-classification of the speciation, see MECLAS report in CSR Annex I
Ba	BaO2	Maximum of typicals	Harmonised and worse self-classification of the speciation, see MECLAS report in CSR Annex I
Ca	CaO	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Cd	CdCl2	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Cl	Cl/Cl compounds	Maximum of typicals	Not classified, see MECLAS report in CSR Annex I
Co	CoCl2	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Cu	Copper oxychloride	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
Mn	MnO2	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in

			CSR Annex I
Ni	NiCl2	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Pb	Pb compounds	Maximum of typicals	Harmonised and worse self-classification of the speciation, see MECLAS report in CSR Annex I
Sb	Sb2O3	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Se	Selenium compounds except cadmium sulphoselenide	Maximum of typicals	Harmonised classification of the speciation, 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
Ti	Ti (other not classified compounds, TiO2)	Maximum of typicals	Not classified, see MECLAS report in CSR Annex I
Zn	ZnO	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
Minor: Ir, Al, Bi, C, Ce, Cr, K, Mg, Na, Si, Sn, Zr	Oxides/compounds or metal	Maximum of typicals	Below 0.1% or the speciation not impacting classification, see MECLAS report in CSR Annex I
S	Metal sulphides		Taken into account in corresponding metal sulphides already

* see IUCLID/CSR section 1.2 composition

Name: Slimes and sludges, precious metal refining - 1

Related composition: Slimes and sludges, precious metal refining (Full / generic composition)

Sludges, precious metal refining, hydro-metallurgical processes – 1 (Constituents relevant for classification)

Remarks: %NiCl2 < 0,01%; %Sb2O3 < 1%; %Pb < 0,05%;
%Co < 0,1%; %CdCl2 <0,1%; %As2O3 < 0,1%
%Na2B4O7 < 5,5%; %Se comp < 10%; %MnO2 < 10%
%H2SO4/5% + %As2O3/1% + %NiCl2/10% + %CaO/10% < 1
%H2SO4/5% + %As2O3/1% + %CaO/1% + %Pd comp/10% + %Na2BO7/10% < 1
100 / ((%As2O3)/5 + (%Se comp + %Te/Te comp + %CdCl2)/100 + (%BaO2 + %Co + %CuSO4 + %Pb comp + %NiSO4 + %NiCl2 + %ZnSO4 + %Cu2O + %MnO2 + %Pd comp)/500) > 2000 mg/kg
100 / ((%CdO + %CdCl2)/100 + (%Se comp)/700 + (%BaO2 + %Pb comp + %NiSO4 + %NiCl2 + %MnO2 + %BaO2)/4500 > 5 mg/L
(%As2O3 + %CdO x 10 + %CoO x 10 + %Cu2O + %Pb comp x 10 + %Se comp x 10 + %ZnO + %Ag comp x 1000 + %Au comp + %Pd comp x 10 + %Pt comp x 10 + %Ti comp + %Rh comp + %Ru comp + %CuSO4 x 10 + %NiSO4 + %ZnSO4) > 25% *(%As2O3 + %CdO x 100 + %CoO x 10 + %Cu2O + %Pb comp + %Se comp + %ZnO + %Ag comp x 100 + %Au comp + %Pd comp x 10 + %Pt comp + %Ti comp + %Rh comp + %Ru comp + %CuSO4 + %NiSO4 + %ZnSO4) > 25%

Classification

The substance is classified as follows:

Table 12. 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	6.1

			classification	
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 13. Classification and labelling according to CLP / GHS for health hazards

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Acute toxicity - oral:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - inhalation:			conclusive but not sufficient for classification	5.2.3
Skin corrosion / irritation:			conclusive but not sufficient for classification	5.3.4 and 5.4.3
Serious damage / eye irritation:			conclusive but not sufficient for classification	5.3.4
Respiration sensitization:			conclusive but not sufficient for classification	5.5.3
Skin sensitation:			conclusive but not sufficient for classification	5.5.3
Aspiration hazard:			conclusive but not sufficient for classification	5.2.3
Reproductive Toxicity:			conclusive but not sufficient for classification	5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			conclusive but not sufficient for classification	5.7.3
Carcinogenicity:			conclusive but not sufficient for classification	5.8.3
Specific target organ toxicity - single:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:			conclusive but not sufficient for classification	5.6.3

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

Table 14. 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	Aquatic Acute 1	H400: Very toxic to aquatic life.		7.6

environment (acute/short-term):				
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: Warning

Hazard pictogram:

GHS09: environment

Hazard statements:

H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P273: Avoid release to the environment.
P391: Collect spillage.
P501: Dispose of contents/container to...

Name: Slimes and sludges, precious metal refining - 2 (low Ni, As, Pb)

Related composition: Slimes and sludges, precious metal refining (Full / generic composition)

Sludges, precious metal refining, hydro-metallurgical processes - 2 (low nickel, arsenic, lead) (Constituents relevant for classification)

Remarks: %NiCl2: 0,01% - 0,1%; %Sb2O3 < 1%; %Pb < 0,05%;
%Co < 0,1%; %CdCl2 <0,1%; %As2O3 < 0,1%
%Na2B4O7 < 5,5%; %Se comp < 10%; %MnO2 < 10%
%H2SO4/5% + %As2O3/1% + %NiCl2/10% + %CaO/10% < 1
%H2SO4/5% + %As2O3/1% + %CaO/1% + %Pd comp/10% + %Na2BO7/10% < 1
100 / ((%As2O3)/5 + (%Se comp + %Te/Te comp + %CdCl2)/100 + (%BaO2 + %Co + %CuSO4 + %Pb comp + %NiSO4 + %NiCl2 + %ZnSO4 + %Cu2O + %MnO2 + %Pd comp)/500) between 300 - 2000 mg/kg
100 / ((%CdO + %CdCl2)/100 + (%Se comp)/700 + (%BaO2 + %Pb comp + %NiSO4 + %NiCl2 + %MnO2 + %BaO2)/4500 > 5 mg/L
(%As2O3 + %CdO x 10 + %CoO x 10 + %Cu2O + %Pb comp x 10 + %Se comp x 10 + %ZnO + %Ag comp x 1000 + %Au comp + %Pd comp x 10 + %Pt comp x 10 + %Ti comp + %Rh comp + %Ru comp + %CuSO4 x 10 + %NiSO4 + %ZnSO4) > 25% *
(%As2O3 + %CdO x 100 + %CoO x 10 + %Cu2O + %Pb comp + %Se comp + %ZnO + %Ag comp x 100 + %Au comp + %Pd

comp x 10 + %Pt comp + %Ti comp + %Rh comp + %Ru comp + %CuSO4 + %NiSO4 + %ZnSO4) > 25% *

Classification

The substance is classified as follows:

Table 15. 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 16. 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:			conclusive but not sufficient for classification	5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			conclusive but not sufficient for classification	5.7.3
Carcinogenicity:			conclusive but not sufficient for classification	5.8.3
Specific target organ toxicity - single:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:			conclusive but not sufficient for classification	5.6.3

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

Table 17. 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: Warning

Hazard pictogram:

GHS07: exclamation mark

GHS08: health hazard

GHS09: environment

Hazard statements:

H302: Harmful if swallowed.
H317: May cause an allergic skin reaction.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P261: Avoid breathing 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.
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.
P321: Specific treatment (see... on this label).
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P330: Rinse mouth.
P362+P364: Take off contaminated clothing and wash before reuse.
P391: Collect spillage.
P501: Dispose of contents/container to...

Name: Slimes and sludges, precious metal refining - 3 (medium Ni, As, Pb)

Related composition: Slimes and sludges, precious metal refining (Full / generic composition)

Sludges, precious metal refining, hydro-metallurgical processes - 3 (medium nickel, arsenic, lead) (Constituents relevant for classification)

Remarks: %Co >= 1% or %NiCl2: 1%-10%
%CdCl2 < 0,1%; %Pb < 0,3%;

%H2SO4/15% + %As2O3/5% < 1
%H2SO4/5% + %As2O3/1% + %NiCl2/10% + %CaO/10% >= 1
%H2SO4/15% + %As2O3/3% + %CaO/3% < 1
%H2SO4/5% + %As2O3/1% + %CaO/1% + %Pd comp/10% + %Na2BO7/10% >= 1
100 / ((%As2O3)/5 + (%Se comp + %Te/Te comp + %CdCl2)/100 + (%BaO2 + %Co + %CuSO4 + %Pb comp + %NiSO4 + %NiCl2 + %ZnSO4 + %Cu2O + %MnO2 + %Pd comp)/500) between 300 - 2000 mg/kg
100 / ((%CdO + %CdCl2)/100 + (%Se comp)/700 + (%BaO2 + %Pb comp + %NiSO4 + %NiCl2 + %MnO2 + %BaO2)/4500 between 1 and 5 mg/L

The substance is classified as follows:

Table 18. 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 19. 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:	Acute Tox. 4	H332: Harmful if inhaled.		5.2.3
Skin corrosion / irritation:	Skin Irrit. 2	H315: Causes skin irritation.		5.3.4 and 5.4.3
Serious damage / eye irritation:	Eye Irrit. 2	H319: Causes serious eye irritation.		5.3.4
Respiration sensitization:	Resp. Sens. 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.		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:			conclusive but not sufficient for classification	5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:	Muta. 2	H341: Suspected of causing genetic defects		5.7.3
Carcinogenicity:	Carc. 1A	H350: May cause cancer		5.8.3
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 through prolonged or repeated exposure		5.6.3

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

Table 20. 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.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H350: May cause cancer <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.
P271: Use only outdoors or in a well-ventilated area.
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.
P284: Wear respiratory protection.
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.
P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308+P313: IF exposed or concerned: Get medical advice/attention.
P312: Call a POISON CENTER or doctor/physician 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.
P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P362+P364: Take off contaminated clothing and wash before reuse.
P391: Collect spillage.

P405: Store locked up.
P501: Dispose of contents/container to...

Name: Slimes and sludges, precious metal refining - 4 (high Ni, As, Pb)

Related composition: Slimes and sludges, precious metal refining (Full / generic composition)

Sludges, precious metal refining, hydro-metallurgical processes - 4 (high nickel, arsenic, lead) (Constituents relevant for classification)

Remarks: %NiCl2 >= 1%; %CdCl2 > 0,1%; %Pb >= 0,3%;
%H2SO4/15% + %As2O3/5% >= 1
100 / ((%As2O3)/5 + (%Se comp + %Te/Te comp + %CdCl2)/100 + (%BaO2 + %Co + %CuSO4 + %Pb comp + %NiSO4 + %NiCl2 + %ZnSO4 + %Cu2O + %MnO2 + %Pd comp)/500) between 50 - 300 mg/kg
100 / ((%CdO + %CdCl2)/100 + (%Se comp)/700 + (%BaO2 + %Pb comp + %NiSO4 + %NiCl2 + %MnO2 + %BaO2)/4500 between 1 and 5 mg/L

Classification

The substance is classified as follows:

Table 21. 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 22. 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. 3	H301: Toxic if swallowed.		5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - inhalation:	Acute Tox. 4	H332: Harmful if inhaled.		5.2.3
Skin corrosion / irritation:	Skin Corr. 1B	H314: Causes severe skin burns and eye damage.		5.3.4 and 5.4.3
Serious damage / eye irritation:	Eye Damage 1	H318: Causes serious eye damage.		5.3.4
Respiration sensitization:	Resp. Sens. 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.		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		5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell	Muta. 1B	H340: May cause genetic		5.7.3

mutagenicity:		defects		
Carcinogenicity:	Carc. 1A	H350: May cause cancer		5.8.3
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	H372: Causes damage to organs through prolonged or repeated exposure		5.6.3

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

Table 23. 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:

GHS05: corrosion

GHS06: skull and crossbones

GHS07: exclamation mark

GHS08: health hazard

GHS09: environment

Hazard statements:

H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H332: Harmful if inhaled.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H340: May cause genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H350: May cause cancer <state route of exposure if it is conclusively proven that no other routes 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)
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.
P271: Use only outdoors or in a well-ventilated area.
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.
P284: Wear respiratory protection.
P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313: IF exposed or concerned: Get medical advice/attention.

P310: Immediately call a POISON CENTER or doctor/physician.
P312: Call a POISON CENTER or doctor/physician 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.
P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
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 24. 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 25. 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 26. 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 Slime Gold electrolysis 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. Only silver released to an important dissolved concentration from the test item (Slime Gold electrolysis) and may be important in the design of a full test for classification purposes.	1 (reliable without restriction) Supporting study experimental result **Test material (common name): Slimes and sludges, precious metal refining**	ECTX-Consult (2010a)

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 slimes and sludges, precious metal refining and the only constituent above the detection limits was silver.

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, “Slimes and Sludges, precious metal refining” 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 toxicokinetic data of the individual constituents are not presented here. Information considered relevant is reported in Section 7 “Toxicological information_Slimes and Sludges, precious metal refining".

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 “Slimes and Sludges, precious metal refining” 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 "Slimes and Sludges, precious metal refining" 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 "Slimes and Sludges, precious metal refining" 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 were not included in the registration file of "Slimes and Sludges, precious metal refining" (see strategy of registration for UVCB substances – Precious Metals Refinables). Relevant hazard and risk assessment information for Slimes and Sludges, precious metal refining" can be found in Section 7 "Toxicological information_ Slimes and Sludges, precious metal refining".

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 27. Studies on acute toxicity after oral administration

Method	Results	Remarks	Reference
Slimes and Sludges 1: The C&L for acute oral toxicity of "Slimes and Sludges, precious metal refining" 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 2 – 3: The C&L for acute oral toxicity of "Slimes and Sludges, precious metal refining" 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 (H302)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 4: The C&L for acute oral toxicity of "Slimes and Sludges, precious metal refining." 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): > 50 - ≤ 300 mg/kg bw based on: test mat. (calculation) C&L required: Acute Tox. 3 (H301)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	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 28. Studies on acute toxicity after inhalation exposure

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 2: The C&L for acute inhalation toxicity of "Slimes and Sludges, precious metal refining" 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 3 & 4: The C&L for acute inhalation toxicity of "Slimes and Sludges, precious metal refining" 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) : > 1 - ≤ 5 mg/L air based on: test mat. (calculation) C&L required: Acute Tox. 4 (H332)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	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 29. Studies on acute toxicity after dermal administration

Method	Results	Remarks	Reference
Slimes and Sludges 1 – 4: The C&L for acute dermal toxicity of "Slimes and Sludges, precious metal refining" 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	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 "Slimes and Sludges, precious metal refining" 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.

In total, four different grades of "Slimes and Sludges, precious metal refining"(composition profile 1 - composition profile 4) were identified by the consortium that could be grouped according to their calculated C&L resulting from the specific composition profile. Thus, for "Slimes and Sludges, precious metal refining" four C&L entries for acute toxicity were generated. Each group is described in a separate endpoint study record and endpoint summary.

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

(a) Slimes and Sludges, precious metal refining – composition 1:

No information on animal testing of "Slimes and Sludges, precious metal refining" on acute toxicity is available. The C&L of "Slimes and Sludges, precious metal refining" - composition profile 1 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, "Slimes and Sludges, precious metal refining" - composition profile 1 does not requires classification as acutely toxic via ingestion, inhalation and after skin contact.

Value used for CSA:

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

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)

(b) Slimes and Sludges, precious metal refining – composition 2:

No information on animal testing of "Slimes and Sludges, precious metal refining" on acute toxicity is available. The C&L of "Slimes and Sludges, precious metal refining" 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, "Slimes and Sludges, precious metal refining" - composition profile 2 meets classification criteria for acute toxicity via ingestion but does not require classification as acutely toxic after skin contact and after inhalation.

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.

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)

(c) Slimes and Sludges, precious metal refining – composition 3:

No information on animal testing of "Slimes and Sludges, precious metal refining" on acute toxicity is available. The C&L of "Slimes and Sludges, precious metal refining" - composition profile 3 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. The converted acute toxicity point estimate value for acute toxicity, inhalation route is 1500 mg/m³ in accordance with EU CLP Guidance Annex I Table 3.1.2.

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

(d) Slimes and Sludges, precious metal refining – composition 4:

No information on animal testing of "Slimes and Sludges, precious metal refining" on acute toxicity is available. The C&L of "Slimes and Sludges, precious metal refining" - composition profile 4 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 100 mg/kg bw in accordance with EU CLP Guidance Annex I Table 3.1.2. The converted acute toxicity point estimate value for acute toxicity, inhalation route is 1500 mg/m³ in accordance with EU CLP Guidance Annex I Table 3.1.2.

Value used for CSA:

Acute oral toxicity: Adverse effect observed

Acute dermal toxicity: No adverse effect observed

Acute inhalation toxicity: Adverse effect observed

Justification for classification or non classification

Specific target organs toxicant (STOT) - single exposure: oral, inhalation and dermal

The classification criteria according to Regulation (EC) 1272/2008 as specific target organs toxicant (STOT) – single exposure are not met since no adverse health effects, including reversible and irreversible, were observed immediately or delayed after exposure.

(a) Slimes and Sludges, precious metal refining – composition 1:

The available information indicates that "Slimes and Sludges, precious metal refining" - composition profile 1 does not require classification as acutely toxic or harmful via ingestion and inhalation in accordance with Regulation (EC) 1272/2008. Furthermore, "Slimes and Sludges, precious metal refining" - composition profile 1 does not meet classification criteria as acutely toxic or harmful via skin exposure in accordance with Regulation (EC) 1272/2008.

(b) Slimes and Sludges, precious metal refining – composition 2:

The available information indicates that " Slimes and Sludges, precious metal refining" - composition profile2 is harmful via ingestion, but not acutely toxic or harmful via the dermal route and via inhalation. "Slimes and Sludges, precious metal refining" - composition profile 2 requires classification as harmful if swallowed (Acute Tox. 4) according to Regulation (EC) 1272/2008. Classification of " Slimes and Sludges, precious metal refining" - composition profile2 for acute toxicity via the dermal and inhalation route is not required according to Regulation (EC) 1272/2008.

(c) Slimes and Sludges, precious metal refining – composition 3:

The available information indicates that "Slimes and Sludges, precious metal refining" - composition profile 3 is harmful via ingestion and inhalation, but not acute toxic or harmful via the dermal route. "Slimes and Sludges, precious metal refining" - composition profile 3 require classification as harmful if swallowed (Acute Tox. 4) and harmful if inhaled (Acute Tox. 4) according to Regulation (EC) 1272/2008. Classification of "Slimes and Sludges, precious metal refining" - composition profile 3 for acute toxicity via dermal route is not required according to Regulation (EC) 1272/2008.

(d) Slimes and Sludges, precious metal refining – composition 4:

The available information indicates that “Slimes and Sludges, precious metal refining” - composition profile 4 is toxic via ingestion and harmful via inhalation, but not acute toxic or harmful via the dermal route. “Slimes and Sludges, precious metal refining" - composition profile 4 require classification as toxic if swallowed (Acute Tox. 3) and harmful if inhaled (Acute Tox. 4) according to Regulation (EC) 1272/2008. Classification of “Slimes and Sludges, precious metal refining” - composition profile 4 for acute toxicity via dermal route is not required according to Regulation (EC) 1272/2008.

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 30. Studies on skin irritation

Method	Results	Remarks	Reference
Slimes and Sludges – 1 & 2: The C&L for skin irritation/corrosion of "Slimes and Sludges, precious metal refining" 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges – 3: The C&L for skin irritation/corrosion of "Slimes and Sludges, precious metal refining" 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”).	irritating C&L required: Skin Irrit. 2 (H315)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)

Studies with results indicating corrosivity to the skin are summarised in section 5.4 Corrosivity.

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 31. Studies on eye irritation

Method	Results	Remarks	Reference
Slimes and Sludges – 1 & 2: The C&L for eye irritation/corrosion of "Slimes and Sludges, precious metal refining" was determined by using the “theory of additivity” of	not classified no C&L required	2 (reliable with restrictions) key study	ARCHE (2013)

Method	Results	Remarks	Reference
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”).		estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	
Slimes and Sludges – 3: The C&L for eye irritation/corrosion of "Slimes and Sludges, precious metal refining" 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”).	irritating	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)

Studies with results indicating corrosivity to the eye are summarised in section 5.4 Corrosivity.

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

No relevant information available.

5.3.4. Summary and discussion of irritation

Substance specific information for the UVCB substance of "Slimes and Sludges, precious metal refining" 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.

In total, four different grades of "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 4) were identified by the consortium that could be grouped according to their calculated C&L resulting from the specific composition profile. Thus, for "Slimes and Sludges, precious metal refining" three C&L entries for irritation/corrosion (i.e., no C&L, irritation and corrosion) were generated. Each group is described in a separate endpoint study record and endpoint summary.

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

<u>(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:</u>

No information on animal testing for skin and eye irritation of " Slimes and Sludges, precious metal refining " 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, "Slimes and Sludges, precious metal

refining" (composition profile 1 - composition profile 2) 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 " Slimes and Sludges, precious metal refining" - composition profile 1 - composition profile 2 does not require classification as eye irritating or corrosive substance.

Furthermore, since, " Slimes and Sludges, precious metal refining " (composition profile 1 - composition profile 2) 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 "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) 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)

(b) Slimes and Sludges, precious metal refining – composition 3:

No information on animal testing for skin and eye irritation of “Slimes and Sludges, precious metal refining” - composition profile 3 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). Hence, the UVCB substance “Slimes and Sludges, precious metal refining” - composition profile 3 meets classification criteria as Skin Irrit. 2 and has to be labelled with H315 (Causes skin irritation). Furthermore, “Slimes and Sludges, precious metal refining” - composition profile 3 requires classification as Eye Irrit. 2 in accordance with Regulation (EC) 1272/2008 and requires labelling with H319 (Causes serious eye irritation).

Value used for CSA:

Skin irritation / corrosion: Adverse effect observed (irritating)

Eye irritation / corrosion: Adverse effect observed (irritating)

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

(c) Slimes and Sludges, precious metal refining – composition 4:

No information on animal testing for skin and eye irritation of “Slimes and Sludges, precious metal refining” - composition profile 4 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). Hence, the UVCB substance “Slimes and Sludges, precious metal refining” - composition profile 4 meets classification criteria as skin irritant Skin Corr. 1 (Causes severe skin burns and eye damage) and has to be labelled with H314. Further, “Slimes and Sludges, precious metal refining” 4 requires classification as Eye Damage 1 (Causes serious eye damage) in accordance with Regulation (EC) 1272/2008 and requires labelling with H318.

Value used for CSA:

Skin irritation / corrosion: Adverse effect observed (corrosive)

Eye irritation / corrosion: Adverse effect observed (corrosive)

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

Justification for classification or non classification

Skin irritation:

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

The UVCB substance "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile

2) 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.

(b) Slimes and Sludges, precious metal refining – composition 3:

“Slimes and Sludges, precious metal refining” - composition profile 3 meets classification criteria for skin irritation Skin Irrit. (theory of additivity was applied) and requires labelling with H315 (causes skin irritation) as defined in Regulation (EC) 1272/2008.

(c) Slimes and Sludges, precious metal refining – composition 4:

“Slimes and Sludges, precious metal refining” - composition profile 4 meets classification criteria for skin corrosion Skin Corr. 1B (theory of additivity was applied) and requires labelling with H314 (causes severe skin burns and eye damage) as defined in Regulation (EC) 1272/2008.

Eye irritation:

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

The UVCB substance "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) 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.

(b) Slimes and Sludges, precious metal refining – composition 3:

“Slimes and Sludges, precious metal refining” - composition profile 3 meets classification criteria for Eye Irrit. 2 (theory of additivity was applied) and requires labelling with H319 (causes severe eye irritation) as defined in Regulation (EC) 1272/2008.

(c) Slimes and Sludges, precious metal refining – composition 4:

“Slimes and Sludges, precious metal refining” - composition profile 4 meets classification criteria for Eye Damage 1 (theory of additivity was applied) and requires labelling with H318 (causes severe eye damage) as defined in Regulation (EC) 1272/2008.

Respiratory irritation:

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

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 organs 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.

(b) Slimes and Sludges, precious metal refining – composition 3:

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 organs 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.

(c) Slimes and Sludges, precious metal refining – composition 4:

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

The results of studies on skin and eye irritation related to corrosivity are summarised in the following table:

Table 32. Studies on skin and eye irritation related to corrosivity

Method	Results	Remarks	Reference
Slimes and Sludges 4: The C&L for skin irritation/corrosion of "Slimes and Sludges, precious metal refining" 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”).	corrosive C&L required: Skin Corr. 1B (H314)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 4: The C&L for eye irritation/corrosion of "Slimes and Sludges, precious metal refining" 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”).	corrosive C&L required: Eye Dam. 1 (H318)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)

5.4.2. Human information

No relevant information available.

5.4.3. Summary and discussion of corrosion

The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation.

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 33. Studies on skin sensitisation

Method	Results	Remarks	Reference
Slimes and Sludges 1: The C&L for skin sensitisation of “Slimes and Sludges, precious metal refining” 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 2 - 4:	sensitising	2 (reliable with restrictions)	ARCHE

Method	Results	Remarks	Reference
The C&L for skin sensitisation of “Slimes and Sludges, precious metal refining” 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”).	C&L required: Skin Sens. 1 (H317)	key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	(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 34. Studies on respiratory sensitisation

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 2: The C&L for respiratory sensitisation of “Slimes and Sludges, precious metal refining” 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 3 & 4: The C&L for respiratory sensitisation of “Slimes and Sludges, precious metal refining" 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: Resp. Sens. 1 (H334)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	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 “Slimes and Sludges, precious metal refining” 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 organs 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.

In total, four different grades of "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 4) were identified by the consortium that could be grouped according to their calculated C&L resulting from the specific composition profile. Thus, for "Slimes and Sludges, precious metal refining" two C&L entries for skin and respiratory sensitisation (i.e., no C&L and sensitisation) were generated. Each group is described in a separate endpoint study record and endpoint summary.

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

(a) Slimes and Sludges, precious metal refining – composition 1:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. Since, "Slimes and Sludges, precious metal refining" - composition profile 1 does not contain any constituent ≥ 1 % that releases skin sensitisation (Skin Sens. 1 without sub-categorising); the substance does not meet classification criteria as skin sensitiser.

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

(b) Slimes and Sludges, precious metal refining – composition 2:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. Since, "Slimes and Sludges, precious metal refining" (composition profile 2) contains a constituent ≥ 0.1 % (i.e., soluble Pd compounds) that may cause skin sensitisation (Skin Sens. 1A); the substance must be classified as being a skin sensitiser, Skin Sens. 1 (H317). It is noted that no sub-categorisation was performed.

Value used for CSA: Adverse effect observed (sensitising)

(c) Slimes and Sludges, precious metal refining – composition 3 – composition 4:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. Since, "Slimes and Sludges, precious metal refining" (composition profile 3 - composition profile 4) contains a constituent ≥ 0.1 % (i.e., soluble Pd substances, nickel chloride) that may cause skin sensitisation (Skin Sens. 1); the substance must be classified as being a 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

(a) Slimes and Sludges, precious metal refining – composition 1:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. Since, "Slimes and Sludges, precious metal refining" - composition profile 1 does not contain any constituent ≥ 0.1 % (w/w) that releases respiratory sensitisation, the substance must not be classified as respiratory sensitiser.

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

(b) Slimes and Sludges, precious metal refining – composition 2:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. Since, "Slimes and Sludges, precious metal refining" (composition profile 2) does not contain any constituent ≥ 0.1 % (w/w) that may cause respiratory sensitisation, the substance does not meet classification criteria for respiratory sensitisation.

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

(c) Slimes and Sludges, precious metal refining – composition 3 – composition 4:

No information on animal testing of “Slimes and Sludges, precious metal refining" is available. “Slimes and Sludges, precious metal refining" (composition profile 3 - composition profile 4) contains at least one constituent ≥ 0.1 % (w/w) (i.e., nickel chloride) that may cause respiratory sensitisation “Resp. Sens. 1” (H334). Hence, the UVCB meets classification criteria for respiratory sensitisation “Resp. Sens. 1” (without sub-categorising) in accordance with Regulation (EC) 1272/2008.

Value used for CSA: Adverse effect observed (sensitising)

Justification for classification or non classification

Skin sensitization

(a) Slimes and Sludges, precious metal refining – composition 1:

“Slimes and Sludges, precious metal refining” - composition profile1 does not possess a skin sensitisation potential and does not require classification in accordance with Regulation (EC) 1272/2008.

(b) Slimes and Sludges, precious metal refining – composition 2:

“Slimes and Sludges, precious metal refining” - composition profile 2 possesses a skin sensitisation potential and requires classification for skin sensitisation in accordance with Regulation (EC) 1272/2008 Skin Sens. 1 (H317).

(c) Slimes and Sludges, precious metal refining – composition 3 – composition 4:

“Slimes and Sludges, precious metal refining” (composition profile 3 - composition profile 4) possesses a skin sensitisation potential and requires classification for skin sensitisation in accordance with Regulation (EC) 1272/2008 Skins. Sens. 1 (H317: May cause an allergic skin reaction.).

Respiratory sensitisation

(a) Slimes and Sludges, precious metal refining – composition 1:

“Slimes and Sludges, precious metal refining” - composition profile 1 does not contain any constituent ≥ 0.1 % (w/w) that releases respiratory sensitisation. Hence, the substance must not be classified as respiratory sensitiser in accordance with Regulation (EC) 1272/2008.

(b) Slimes and Sludges, precious metal refining – composition 2:

“Slimes and Sludges, precious metal refining” - composition profile 2 does not contain any constituent ≥ 0.1 % (w/w) that releases respiratory sensitisation. Hence, the substance does not require classification for respiratory sensitisation in accordance with Regulation (EC) 1272/2008.

(c) Slimes and Sludges, precious metal refining – composition 3 – composition 4:

“Slimes and Sludges, precious metal refining” (composition profile 3 - composition profile 4) contains at least one constituent ≥ 0.1 % (w/w) (i. e., nickel chloride) that may cause respiratory sensitisation Category 1 (H334). Hence, the substance meets classification criteria for respiratory sensitisation “Resp. Sens. 1” (without sub-categorising) and requires labelling with H334 (may cause allergy or asthma symptoms or breathing difficulties if inhaled) 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 35. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks	Reference

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 2: The C&L for toxic to specific target organ after repeated dose application of "Slimes and Sludges, precious metal refining" 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”).	negative no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 3 & 4: The C&L for toxic to specific target organ after repeated dose application of “Slimes and Sludges, precious metal refining” 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	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 36. Studies on repeated dose toxicity after inhalation exposure

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 2: The C&L for toxic to specific target organ after repeated dose application of "Slimes and Sludges, precious metal refining" 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”).	negative no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 3 & 4: The C&L for toxic to specific target organ after repeated dose application of “Slimes and Sludges, precious metal refining" 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	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, based on the following rationale:

Slimes and Sludges, precious metal refining is a solid UVCB substance consisting of different metals and inorganic metal compounds. Three of the four grades (composition profile 1 - composition profile 4) are corrosive/irritating to skin and eye but not considered to be acutely toxic via dermal exposure (see IUCLID section “acute toxicity”).

Following the HERAG approach as proposed in the 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 %

However, due to the corrosive/irritating potential of "Slimes and Sludges, precious metal refining", wearing suitable gloves is compulsory as risk management measure (RMM). Hence, dermal absorption may be ruled out.

In conclusion, according to the data requirements as outlined in section 8.6, column 2, Annexes VIII-IX, of Regulation (EC) 1907/2006, a repeated-dose toxicity study via skin should only be performed if

(i) inhalation of the substance is unlikely, (ii) skin contact in production and/use is likely and (iii) the physico-chemical and toxicological properties suggest significant absorption through the skin. Since, (i) inhalation of "Slimes and Sludges, precious metal refining" cannot be ruled out, (ii) skin contact and a subsequent dermal absorption in production and/use will be minimised (by wearing of gloves), and (iii) physico-chemical and toxicological properties of "Slimes and Sludges, precious metal refining" do not suggest a significant absorption through the skin, derogation from testing of repeated-dose toxicity via the dermal exposure route is fully justified.

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 "Slimes and Sludges, precious metal refining" 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 organs 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.

In total, four different grades of "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 4) were identified by the consortium that could be grouped according to their calculated C&L resulting from the specific composition profile. Thus, for "Slimes and Sludges, precious metal refining" two C&L entries for specific target organs toxicity (i. e., no C&L and STOT RE 1) were generated. Each group is described in a separate endpoint study record and endpoint summary.

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

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. However, "Slimes and Sludges, precious metal refining" (composition profile 1 composition profile 2) does not meet classification criteria for STOT RE 1 or STOT RE 2.

Value used for CSA

Via oral route - systemic effects): No adverse effect observed

Dermal - systemic effects: No study available

Dermal - local effects: No study available

Inhalation - systemic effects: No adverse effect observed

Inhalation - local effects: No adverse effect observed

(b) Slimes and Sludges, precious metal refining – composition 3 – composition 4:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. "Slimes and Sludges, precious metal refining" (composition 3) contains ≥ 1 % nickel chloride (specific concentration limits of nickel chloride; see "justification for classification and non-classification" below). Hence, "Slimes and Sludges, precious metal refining" (composition 3) meets classification criteria for STOT RE 1 via the inhalation route.

"Slimes and Sludges, precious metal refining" (composition 4) contains ≥ 1 % nickel chloride and ≥ 0.3 % lead and lead compounds relevant for C&L of grade 4. For all constituents there are specific concentration limits (*SCL*s) given for STOT RE classification (see discussion). Based on the SCLs and the specific rules for mixtures of Regulation (EC) 1272/2008 "Slimes and Sludges, precious metal refining" (composition 4) requires classification as STOT RE 1.

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

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

Classification of UVCB substances as being toxic to specific target organs after repeated dose application is based on the presence of a constituent ≥ 1 % classified as STOT-RE 1 and of a constituent ≥ 10 % classified as STOT-RE 2, respectively. Since, "Slimes and Sludges, precious metal refining" 1&2 does not contain any constituents in concentrations relevant for C&L, "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) does neither meet classification criteria as STOT-RE 1 nor STOT-RE 2, in accordance with Regulation (EC) 1272/2008.

(b) Slimes and Sludges, precious metal refining – composition 3 – composition 4:

Classification driver for STOT RE 1 are:

(i) Lead and lead compounds – oral (grade 4)

According to the self-classification of lead compounds the specific concentration limits (SCL) for STOT RE classification are as follows:

STOT RE 1; H372: C ≥ 0.5%

STOT RE 2; H373: 0.05% ≤ C < 0.5%

(ii) Nickel dichloride – inhalation (grade 3 & 4)

According to the self-classification of nickel chloride the specific concentration limits (*SCL*) for STOT RE classification (inhalation) are as follows:

STOT RE 1; H372: C ≥ 1 %

STOT RE 2; H373: 1 % ≤ C < 7 %

Classification of UVCB substances as being toxic to specific target organs after repeated dose application is based on the presence of a constituent ≥ 1 % classified as STOT-RE 1 and of a constituent ≥ 10 % classified as STOT-RE 2, respectively. However, for lead compounds and nickel dichloride there are specific concentration limits given for STOT RE classification assigned by the lead/nickel industry. According to Regulation (EC) 1272/2008 "specific concentration limits" should take precedence over any other concentration limits for the purpose of classification.

The classification driver for STOT RE classification of "Slimes and Sludges, precious metal refining" (composition 3) is nickel dichloride in concentration relevant for C&L as STOT RE 1. The classification drivers for STOT RE classification of "Slimes and Sludges, precious metal refining" (composition 4) are nickel dichloride and lead and lead compounds in concentration relevant for C&L as STOT RE 1.

Hence, "Slimes and Sludges, precious metal refining" (composition 3 – composition 4) meets classification criteria as STOT RE 1 and requires labelling with H372 (causes damage to organs).

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 37. In vitro genotoxicity studies

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 2: The C&L considering mutagenicity of "Slimes and Sludges, precious metal refining" 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 1 & 2: The C&L considering genotoxicity of "Slimes and Sludges, precious metal refining" 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 (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 3: The C&L considering mutagenicity of "Slimes	C&L required: Muta. 2	2 (reliable with restrictions)	ARCHE (2013)

Method	Results	Remarks	Reference
and Sludges, precious metal refining" 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”).	(H341)	key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	
Slimes and Sludges 3: The C&L considering genotoxicity of "Slimes and Sludges, precious metal refining" 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”).	C&L required: Muta. 2 (H341)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 4: The C&L considering mutagenicity of "Slimes and Sludges, precious metal refining" 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”).	C&L required: Muta. 1B (H340)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 4: The C&L considering genotoxicity of "Slimes and Sludges, precious metal refining" 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”).	C&L required: Muta. 1B (H340)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	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 labelling information, please refer to 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 "Slimes and Sludges, precious metal refining" 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.

In total, four different grades of " Slimes and Sludges, precious metal refining"(composition profile 1 - composition profile 4) were identified by the consortium that could be grouped according to their calculated C&L resulting from the specific composition profile. Thus, for " Slimes and Sludges, precious metal refining" three C&L entries for genetic toxicity (i. e., no C&L and mutagenicity 2 and 1B) were generated. Each group is described in a separate endpoint study record and endpoint summary.

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

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. Since, "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) neither contains any constituent ≥ 0.1 % classified as mutagen Muta. 1, nor any constituent ≥ 1 % classified as mutagen Muta. 2, the substance does not require classification for germ cell mutagenicity.

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

(b) Slimes and Sludges, precious metal refining – composition 3:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. "Slimes and Sludges, precious metal refining" (composition profile 3) contains one constituent ≥ 1 % (w/w) classified as mutagen Muta. 2 ($NiCl_2$), but no constituent ≥ 0.1 % (w/w) classified as mutagen Muta. 1A/B. In conclusion, "Slimes and Sludges, precious metal refining" (composition profile 3) requires classification as Muta. 2 (H341) in accordance with Regulation (EC) 1272/2008.

Value used for CSA: Genetic toxicity: Adverse effect observed (positive)

(c) Slimes and Sludges, precious metal refining – composition 4:

No information on animal testing of "Slimes and Sludges, precious metal refining" (composition profile 4) is available. "Slimes and Sludges, precious metal refining" (composition profile 4) contains two constituent ≥ 1 % (w/w) classified as mutagen Muta. 2 (i.e., $NiCl_2$ and $CoCl_2$), and one constituent ≥ 0.1 % (w/w) classified as mutagen Muta. 1B (i.e., $CdCl_2$). Thus, the substance should be classified as germ cell mutagen Muta. 1B (H340).

Value used for CSA: Genetic toxicity: Adverse effect observed (positive)

Justification for classification or non classification

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

"Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) 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, "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) does not possess mutagenicity and/or genotoxicity in accordance with Regulation (EC) 1272/2008.

(b) Slimes and Sludges, precious metal refining – composition 3:

"Slimes and Sludges, precious metal refining" (composition profile 3) contains one constituent ≥ 1 % (w/w) classified as mutagen Muta. 2 ($NiCl_2$), but no constituent ≥ 0.1 % (w/w) classified as mutagen Muta. 1A/B. In conclusion, "Slimes and Sludges, precious metal refining" (composition profile 3) requires classification as Muta. 2 (H341) in accordance with Regulation (EC) 1272/2008.

(c) Slimes and Sludges, precious metal refining – composition 4:

"Slimes and Sludges, precious metal refining" (composition profile 4) contains two constituent ≥ 1 % (w/w) classified as mutagen Muta. 2 (i.e., $NiCl_2$ and $CoCl_2$), and one constituent ≥ 0.1 % (w/w) classified as mutagen Muta. 1B (i.e., $CdCl_2$). Thus, the substance should be classified as germ cell mutagen Muta. 1B (H340).

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

The results of studies on carcinogenicity (oral route) are summarised in the following table:

Table 38. Studies on carcinogenicity (oral)

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 2: The C&L considering carcinogenicity of "Slimes and Sludges, precious metal refining" 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").	negative no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 3 & 4: The C&L considering genotoxicity of "Slimes and Sludges, precious metal refining" was determined by using the "Classification criteria for mixtures" of Regulation (EC) 1272/2006 section 3.6.3.1 "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: Carc. 1A (H350)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)

5.8.1.2. Carcinogenicity: inhalation

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

Table 39. Studies on carcinogenicity (inhalation)

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 2: The C&L considering carcinogenicity of "Slimes and Sludges, precious metal refining" 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").	negative no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 3 & 4:	C&L required:	2 (reliable with restrictions)	ARCHE

Method	Results	Remarks	Reference
The C&L considering genotoxicity of "Slimes and Sludges, precious metal refining" was determined by using the "Classification criteria for mixtures" of Regulation (EC) 1272/2006 section 3.6.3.1 "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").	Carc. 1A (H350)	key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	(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 "Slimes and Sludges, precious metal refining" 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.

In total, four different grades of "Slimes and Sludges, precious metal refining"(composition profile 1 - composition profile 4) were identified by the consortium that could be grouped according to their calculated C&L resulting from the specific composition profile. Thus, for "Slimes and Sludges, precious metal refining" two C&L entries for carcinogenicity (i.e., no C&L and carcinogen) were generated. Each group is described in a separate endpoint study record and endpoint summary.

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

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. Since, "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) does not contain any constituent ≥ 0.1 % which is classified as a Carc. 1A or Carc. 1B carcinogen and ≥ 1 % which is classified as a Carc. 2 carcinogen, "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) does not require classification for carcinogenicity.

Value used for CSA

Carcinogenicity via oral route: No adverse effect observed

Carcinogenicity via dermal route: No adverse effect observed

Carcinogenicity via inhalation route: No adverse effect observed

(b) Slimes and Sludges, precious metal refining – composition 3 – composition 4:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. However, "Slimes and Sludges, precious metal refining" (composition profile 3 - composition profile 4) contains constituents ≥ 0.1 % that are classified as a Carc. 1A carcinogen (i.e., As_2O_3 or $NiCl_2$). Hence, "Slimes and Sludges, precious metal refining" (composition profile 3 - composition profile 4) meets classification criteria for carcinogenicity and requires classification as "Carc. 1A", H350 (May cause cancer).

Value used for CSA

Carcinogenicity via oral route: Adverse effect observed

Carcinogenicity via dermal route: No adverse effect observed

Carcinogenicity via inhalation route: Adverse effect observed

Justification for classification or non classification

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 2:

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. Since, "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) does not contain any constituent ≥ 0.1 % classified for carcinogenicity Car. 1A or Carc. 1B and no constituent ≥ 1 % classified for carcinogenicity Carc. 2, "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 2) is considered not to induce carcinogenicity and does not require classification for carcinogenicity (neither in Carc. 1A and Carc. 1B nor in Carc. 2) in accordance with Regulation (EC) 1272/2008.

(b) Slimes and Sludges, precious metal refining – composition 3 – composition 4:

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. "Slimes and Sludges, precious metal refining" (composition profile 3) contains constituents ≥ 0.1 % classified for carcinogenicity Carc. 1A (i.e., $NiCl_2$ (inhalation)). "Slimes and Sludges, precious metal refining" (composition profile 4) contains constituents ≥ 0.1 % classified for carcinogenicity Carc. 1A (i.e., As_2O_3 (oral)) and constituents ≥ 1 % classified for carcinogenicity Carc. 2 (i.e., lead and lead compounds). Hence, "Slimes and Sludges, precious metal" (composition profile 3 - composition profile 4) is considered to induce cancer and meets classification criteria as carcinogenic Carc. 1A (H350), 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 40. Studies on fertility

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 3: The C&L considering reproduction toxicity (effects on male or female fertility) of "Slimes and Sludges, precious metal refining" 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	negative no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)

Method	Results	Remarks	Reference
(attachment “PMC Classification method”).			
Slimes and Sludges 4: The C&L considering reproduction toxicity (effects on male or female fertility) of “Slimes and Sludges, precious metal refining"” 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 (H360)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	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 41. Studies on developmental toxicity

Method	Results	Remarks	Reference
Slimes and Sludges 1 & 3: The C&L considering reproduction toxicity (developmental toxicity) of “Slimes and Sludges, precious metal refining" 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”).	negative no C&L required	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (2013)
Slimes and Sludges 4: The C&L considering reproduction toxicity (developmental toxicity) of “Slimes and Sludges, precious metal refining” 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 (H360)	2 (reliable with restrictions) key study estimated by calculation **Test material (IUPAC name): Slimes and Sludges, precious metal refining** Form: powder	ARCHE (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 "Slimes and Sludges, precious metal refining" 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.

In total, four different grades of "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 4) were identified by the consortium that could be grouped according to their calculated C&L resulting from the specific composition profile. Thus, for "Slimes and Sludges, precious metal refining" two C&L entries for carcinogenicity (i.e., no C&L and reproductive toxicant) were generated. Each group is described in a separate endpoint study record and endpoint summary.

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

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 3:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. Since, "Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 3) does not contain any constituent ≥ 0.3 % which possesses reproduction toxicity and/or induce effects on or via lactation, the substance does not require classification for reproductive toxicity.

Value used for CSA

Reproductive toxicity: oral: No adverse effect observed

Reproductive toxicity: dermal: No adverse effect observed

Reproductive toxicity: inhalation: No adverse effect observed

(b) Slimes and Sludges, precious metal refining –composition 4:

No information on animal testing of "Slimes and Sludges, precious metal refining" is available. However, "Slimes and Sludges, precious metal refining" (composition profile 4) contains lead and lead compounds ≥ 0.3 % that may possess reproduction toxicity potential (i.e., suspected of damaging fertility). Nevertheless, "Slimes and Sludges, precious metal refining" (composition profile 4) also contains cobalt dichloride and cadmium dichloride classified as reproductive toxicant "Repr. 1B" (H360) with a content ≥ 0.3 %, but the classification driver for "Slimes and Sludges, precious metal refining" is lead and lead compounds that requires classification as reproductive toxicant "Repr. 1A" (H360).

Value used for CSA

Reproductive toxicity: oral: Adverse effect observed

Reproductive toxicity: dermal: No adverse effect observed

Developmental toxicity

Substance specific information for the UVCB substance "Slimes and Sludges, precious metal refining" 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.

In total, four different grades of “Slimes and Sludges, precious metal refining” (composition profile 1 - composition profile 4) were identified by the consortium that could be grouped according to their calculated C&L resulting from the specific composition profile. Thus, for "Slimes and Sludges, precious metal refining" two C&L entries for carcinogenicity (i.e., no C&L and reproductive toxicant) were generated. Each group is described in a separate endpoint study record and endpoint summary.

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

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 3:

No information on animal testing of “Slimes and Sludges, precious metal refining” is available. Since, “Slimes and Sludges, precious metal refining” (composition profile 4) does not contain any constituent ≥ 0.3 % which possesses reproduction toxicity and/or induce effects on or via lactation, the substance does not require classification for reproductive toxicity.

Value used for CSA

Developmental toxicity: oral	No adverse effect observed
Developmental toxicity: dermal:	No adverse effect observed
Developmental toxicity: inhalation:	No adverse effect observed

(b) Slimes and Sludges, precious metal refining –composition 4:

“Slimes and Sludges, precious metal refining" (composition profile 4) contains lead and lead compounds ≥ 0.3 % that may possess reproduction toxicity potential (i.e., may damage the unborn child). However, “Slimes and Sludges, precious metal refining" also contains cobalt dichloride and cadmium dichloride classified as reproductive toxicant “Repr. 1B” (H360) with a content ≥ 0.3 %. Nevertheless, the classification driver for “Slimes and Sludges, precious metal refining" (composition profile 4) is lead and lead compounds that requires classification as reproductive toxicant “Repr. 1A” (H360).

Value used for CSA

Developmental toxicity: oral	Adverse effect observed
Developmental toxicity: dermal:	Adverse effect observed

Justification for classification or non classification

(a) Slimes and Sludges, precious metal refining – composition 1 – composition 3:

Reproductive toxicity classification of UVCB substances is based on the presence of a constituent ≥ 0.3 % classified for reproductive toxicity. Since, " Slimes and Sludges, precious metal refining" (composition profile 1 - composition profile 3) is considered neither to induce reproductive toxicity nor induce effects on or via lactation, the substance does not have to be classified as such (neither in Cat. 1A and Cat. B nor in Cat. 2) in accordance with Regulation (EC) 1272/2008.

(b) Slimes and Sludges, precious metal refining –composition 4:

Reproductive toxicity classification of UVCB substances is based on the presence of a constituent ≥ 0.3 % classified for reproductive toxicity. “Slimes and Sludges, precious metal refining" (composition profile 4) contains lead and lead compounds (Repr. 1A) and cobalt dichloride and cadmium dichloride (Repro. 1B) ≥ 0.3%. Hence, “Slimes and Sludges, precious metal refining" (composition profile 4) is considered to induce reproductive toxicity, and requires classification as Repr. 1A (H360Df: may damage the unborn child, suspected of damaging fertility) based on lead and lead compounds in accordance with Regulation (EC) 1272/2008. There is not any evidence of effects on or via lactation for any constituents of “Slimes and Sludges, precious metal refining" 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 "Slimes and Sludges, precious metal refining" (CAS 98072-61-8; EC 308-516-0) 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 "Slimes and Sludges, precious metal refining" which trigger classification were identified:

Pd	**As**	**B**	**Ca**	**Cd**	**Co**	**Cu**	**Mn**	**Ni**	**Pb**	**Sb**	**Se**	**Te**
Pd sol.	As_2O_3	Borate	CaO	Cd*	Co*	Cu_2O $CuSO_4$	MnO_2	$NiSO_4$	Pb* Pb comp.	Sb_2O_3	Se*	Te*

*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, Ag comp., Au, Au comp., Ir, Ir comp., Pt, Pt comp., Rh, Rh comp., Ru, Ru comp., Al comp., BaO, Bi, Bi comp., C, Ce comp., Cl comp., Cr, Cr(III) comp., Fe, Fe comp., K comp., Mg comp., Na comp., Si comp., Sn, Sn comp., Ti comp., Zn comp., Zr comp.

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 "Slimes and Sludges, precious metal refining", 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 42. 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	**Slimes & Sludges 1:** No adverse effect observed discriminating dose: 2000 mg/kg bw	ARCHE (2013) (see section 5.2.1.1)
Acute toxicity	oral	**Slimes & Sludges 2 - Slimes & Sludges 3:** Adverse effect observed ATE: 500 mg/kg bw.	ARCHE (2013) (see section 5.2.1.1)
Acute toxicity	oral	**Slimes & Sludges 4:** Adverse effect observed ATE: 100 mg/kg bw.	ARCHE (2013) (see section 5.2.1.1)
Acute toxicity	dermal	**Slimes & Sludges 1 - Slimes & Sludges 4:** No adverse effect observed discriminating dose: 2000 mg/kg bw	ARCHE (2013) (see section 5.2.1.3)
Acute toxicity	inhalation	**Slimes & Sludges 2 - Slimes & Sludges 2:** No adverse effect observed discriminating conc.: 5000 mg/m³	ARCHE (2013) (see section 5.2.1.2)
Acute toxicity	inhalation	**Slimes & Sludges 3 - Slimes & Sludges 4:** No adverse effect observed ATE: 1500 mg/m³	ARCHE (2013) (see section 5.2.1.2)
Irritation / Corrosivity	skin	**Slimes & Sludges 1 - Slimes & Sludges 2:** No adverse effect observed (not irritating)	ARCHE (2013) (see section 5.3.1.1)
Irritation / Corrosivity	skin	**Slimes & Sludges 3:** Adverse effect observed irritating	ARCHE (2013) (see section 5.3.1.1)
Irritation / Corrosivity	skin	**Slimes & Sludges 4:** Adverse effect observed corrosive	ARCHE (2013) (see section 5.3.1.1)
Irritation / Corrosivity	eye	**Slimes & Sludges 1 - Slimes & Sludges 2:** No adverse effect observed (not irritating)	ARCHE (2013) (see section 5.3.2.1)
Irritation / Corrosivity	eye	**Slimes & Sludges 3:** Adverse effect observed irritating	ARCHE (2013) (see section 5.3.2.1)
Irritation /	eye	**Slimes & Sludges 4:**	ARCHE (2013)

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
Corrosivity		Adverse effect observed corrosive	(see section 5.3.2.1)
Irritation / Corrosivity	respiratory tract	**Slimes & Sludges 1 - Slimes & Sludges 4:** No adverse effect observed (not irritating)	
Sensitisation	skin	**Slimes & Sludges 1:** No adverse effect observed (not sensitising)	ARCHE (2013) (see section 5.5.1.1)
Sensitisation	skin	**Slimes & Sludges 2 - Slimes & Sludges 4:** Adverse effect observed (sensitising)	ARCHE (2013) (see section 5.5.1.1)
Sensitisation	respiratory tract	**Slimes & Sludges 1 - Slimes & Sludges 2:** No adverse effect observed (not sensitising)	(see section 5.5.2.1)
Sensitisation	respiratory tract	**Slimes & Sludges 3 - Slimes & Sludges 4:** Adverse effect observed (sensitising)	(see section 5.5.2.1)
Repeated dose toxicity	oral	**Slimes & Sludges 1 - Slimes & Sludges 2:** No adverse effect observed	ARCHE (2013) (see section 5.6.1.1)
Repeated dose toxicity	oral	**Slimes & Sludges 3 - Slimes & Sludges 4:** Adverse effect observed Lead and lead compounds; but not the C&L driver	ARCHE (2013) (see section 5.6.1.1)
Repeated dose toxicity	dermal (systemic and local effects)	**Slimes & Sludges 1 - Slimes & Sludges 4:** No study available	(see section 5.6.1.3)
Repeated dose toxicity	inhalation (systemic and local effects)	**Slimes & Sludges 1 - Slimes & Sludges 2:** No adverse effect observed	ARCHE (2013) (see section 5.6.1.2)
Repeated dose toxicity	inhalation (local effects)	**Slimes & Sludges 3 - Slimes & Sludges 4:** Adverse effect observed STOT RE 1: nickel chloride	ARCHE (2013) (see section 5.6.1.2)
Mutagenicity	in vitro / in vivo	**Slimes & Sludges 1 - Slimes & Sludges 2:** No adverse effect observed (negative)	see section 5.7.1 / 5.7.2
Mutagenicity	in vitro / in vivo	**Slimes & Sludges 3:** Adverse effect observed (positive) Muta. Cat. 2 (nickel chloride)	see section 5.7.1 / 5.7.2
Mutagenicity	in vitro / in vivo	**Slimes & Sludges 4:** Adverse effect observed (positive) Muta. Cat. 2 (cadmium chloride)	see section 5.7.1 / 5.7.2
Carcinogenicity	oral	**Slimes & Sludges 1 - Slimes & Sludges 2:** No adverse effect observed	ARCHE (2013) (see section 5.8.1.1)
Carcinogenicity	oral	**Slimes & Sludges 3 - Slimes & Sludges 4:** Adverse effect observed Carc. Cat. 1A (arsenic trioxide, lead and lead compounds)	ARCHE (2013) (see section 5.8.1.1)
Carcinogenicity	dermal	**Slimes & Sludges 1 - Slimes & Sludges 4:** No adverse effect observed	ARCHE (2013)

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
			(see section 5.8.1.3)
Carcinogenicity	inhalation	**Slimes & Sludges 1 - Slimes & Sludges 2:** No adverse effect observed	ARCHE (2013) (see section 5.8.1.2)
Carcinogenicity	inhalation	**Slimes & Sludges 3 - Slimes & Sludges 4:** Adverse effect observed Carc. Cat. 1A (nickel chloride)	ARCHE (2013) (see section 5.8.1.2)
Reproductive toxicity: effects on fertility and developmental toxicity	oral	**Slimes & Sludges 1 - Slimes & Sludges 3:** No adverse effect observed	ARCHE (2013) (see section 5.9.1.1)
Reproductive toxicity: effects on fertility and developmental toxicity	oral	**Slimes & Sludges 4:** Adverse effect observed Repr. Cat. 1A (H360Df): lead and lead compounds	ARCHE (2013) (see section 5.9.1.1)
Reproductive toxicity: effects on fertility and developmental toxicity	dermal and inhalation	**Slimes & Sludges 1 - Slimes & Sludges 4:** 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 43. DNELs for workers

Route	Type of effect	As	B	Ca	Cd	Co	Cu		Mn	Ni	Pb		Se	Te	Sb
Speciation		As_2O_3	Borate	CaO	Cd	Co	Cu_2O	$CuSO_4$	MnO_2	$NiSO_4$	Pb	Pb comp.	Se	Te	Sb_2O_3
Inhalation	Systemic long term	4 µg/m³	SV0	no hazard	4 µg/m³	SV0	1000 µg/m³	1000 µg/m³	SV0	50 µg/m³	40 µg/dL**	40 µg/dL**	50 µg/m³	100 µg/m³	no hazard
	Systemic acute	no hazard	SV0	no hazard	no hazard	SV0	no hazard	4000 µg/m³	SV0	16000 µg/m³	no hazard	no hazard	no hazard	QA	no hazard
	Local long term	QA	SV0	1000 µg/m³	no hazard	SV0	1000 µg/m³	1000 µg/m³	SV0	50 µg/m³	no hazard	no hazard	QA	100 µg/m³	500 µg/m³
	Local acute	QA	SV0	4000 µg/m³	no hazard	SV0	no hazard	4000 µg/m³	SV0	700 µg/m³	no hazard	no hazard	no hazard	no hazard	no hazard
Dermal	Systemic long term	0.085 mg/kg bw.	SV0	no hazard	QA*	SV0	no hazard	no hazard	SV0	no hazard	40 µg/dL**	40 µg/dL**	7 mg/kg bw.	QA	234.7 mg/kg bw.
	Systemic acute	no hazard	SV0	no hazard	QA*	SV0	no hazard	no hazard	SV0	no hazard	no hazard	no hazard	QA	QA	no hazard
	Local long term	QA	SV0	no hazard	QA*	SV0	no hazard	no hazard	SV0	0.44 µg/cm²	no hazard	no hazard	QA	QA	no hazard
	Local acute	QA	SV0	QA	QA*	SV0	no hazard	no hazard	SV0	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard
Eye		medium hazard	SV0	medium hazard	no hazard	SV0	low hazard	no hazard	SV0	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard
Reference		RR	SV0	SV10	RR	SV0	SV3	SV3	SV0	RR	RR	RR	RR	RR/SV8	RR

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, Ag comp., Au, Au comp., Ir, Ir comp., Pt, Pt comp., Rh, Rh comp., Ru, Ru comp., Al comp., BaO, Bi, Bi comp., C, Ce comp., Cl comp., Cr, Cr(III) comp., Fe, Fe comp., K comp., Mg comp., Na comp., Si comp., Sn, Sn comp., Ti comp., Zn comp., Zr comp.

* Exposure based waiving as indicated in the REACH registration dossier is addressed with a qualitative assessment (including quantification of exposure)
** Internal reference value

QA Qualitative assessment
RR Data access to IUCLID section 7 of REACH registration dossier via LoA
SV0 ECHA dissemination website; no official data access yet, value currently deleted for copyright issues
SV3 Former MAK value; values for acute inhalation DNEL: extrapolation from long term value multiplied with 4
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.
SV10 Anonymous (2008): Recommendation from the Scientific Committee on occupational exposure limits for calcium oxide (CaO) and calcium hydroxide (Ca(OH)2, SCOEL/SUM/137, February 2008.

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: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 1 (Constituents relevant for classification)

Reason for no classification: conclusive but not sufficient for classification

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 2 (low nickel, arsenic, lead) (Constituents relevant for classification)Reason for no classification: conclusive but not sufficient for classification

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 3 (medium nickel, arsenic, lead) (Constituents relevant for classification)

Reason for no classification: conclusive but not sufficient for classification

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining- 4 (high nickel, arsenic, lead) (Constituents relevant for classification)

Reason for no classification: conclusive but not sufficient for classification

6.2. Flammability

Flammability

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

Table 44. Information on flammability

Method	Results	Remarks	Reference
Method N.1 specified in the United Nations, Recommedations on the Transport of Dangerous Goods, Manual of Tests and Criteria, fourth revised edition, 2003.	Evaluation of results: non flammable Study results: Ignition on contact with air: no Burning time (s): (The pile failed to ignite during the five minutes that the Bunsen flame was applied.)	1 (reliable without restriction) key study experimental result **Test material (common name): Slimes and sludges, precious metal refining**	Tremain SP, Atwal SS (2010)

Discussion

The results are taken from a GLP compliant, guideline test (Harlan 2010) which are considered to be reliable and acceptable for use for this endpoint. The results indicate that the test item is not classified as a readily combustible solid under Division 4.1 as it failed to ignite in the preliminary screening test.

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

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

Flash point

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 1 (Constituents relevant for classification)

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

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

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

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

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 2 (low nickel, arsenic, lead) (Constituents relevant for classification)

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

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

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

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

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 3 (medium nickel, arsenic, lead) (Constituents relevant for classification)

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

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

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

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

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining- 4 (high nickel, arsenic, lead) (Constituents relevant for classification)

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: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 1 (Constituents relevant for classification)

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

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

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

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 2 (low nickel, arsenic, lead) (Constituents relevant for classification)

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

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

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

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining - 3 (medium nickel, arsenic, lead) (Constituents relevant for classification)

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

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

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

Name: slimes and sludges, precious metal refining

Related composition: Slimes and sludges, precious metal refining- 4 (high nickel, arsenic, lead) (Constituents relevant for classification)

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 45. 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
Aluminium	Metal ion	Not classified	Yes	No (Not classified)
Antimony	Metal ion	Not classified	Yes	No (Not classified)
Arsenic	Metal ion	Yes	Yes	Yes
Barium	Metal ion	Not classified	Yes	No (Not classified)
Boron	borate anion	Not classified	Yes	No
Bismuth	Metal ion	Not classified	Yes	No (Not classified)
Cadmium	Metal ion	Yes	Yes	Yes
Calcium	Metal ion	Not classified	Yes	No (Not classified)
Carbon	Inorganic C	Not classified	No	No (Not classified)
Cerium	Metal ion	Not classified	Yes	No (Not classified)
Chlorine	chloride anion	Not classified	No	No (Effects dominated by chloride anion, not classified)
Chromium	Metal ion (Cr3+)	No	Yes	No (Not classified)
Cobalt	Metal ion	Yes	Yes	No monitoring data currently available, but will be assessed in future updates*
Copper	Metal ion	Yes	Yes	Yes
Iron	Metal ion	Not classified	No	No (Not classified)
Lead	Metal ion	Yes	Yes	Yes
Magnesium	Metal ion	Not classified	Yes	No (Not classified)
Manganese	Metal ion	Not classified (Mn or MnO_2)	Yes	No (Not classified)
Nickel	Metal ion	Yes	Yes	Yes
Potassium	Metal ion	Not classified	No	No (Not classified)
Selenium	Se ion	Yes	Yes	No monitoring data currently available, but will be assessed in future updates*
Silicon		Not classified	Yes	No (Not classified)
Sodium	Metal ion	Not classified	No	No (Not classified)
Sulphur		Not classified	No	No (Not classified)
Tellurium	Metal ion	Yes	Yes	No monitoring data currently available, but

UVCB constituent Element	Speciation most relevant for environmental risk assessment	Environmental classification	PNEC available	Constituent included in risk assessment?
				will be assessed in future updates*
Tin	Metal ion	Yes	Yes	No monitoring data currently available, but will be assessed in future updates*
Titanium	Metal ion	Not classified	Yes	No (Not classified)
Zinc	Metal ion	Yes	Yes	Yes
Zirconium	Metal ion	Not classified	No	No (Not classified)

* 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 46. Short-term effects on fish

Method	Results	Remarks	Reference
Aquatic toxicity of the UVCB substance was determined by	EC50 (96 h): <= 1 mg/L test mat. (estimated) based	2 (reliable with restrictions)	ARCHE (2013)

Method	Results	Remarks	Reference
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.	on: most sensitive species	key study estimated by calculation **Test material (common name): Slimes and sludges, precious metal refining 1-4**	

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 47. 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): Slimes and sludges, precious metal refining 1-4**	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 48. 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): Slimes and sludges, precious metal refining 1-4**	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 49. 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): Slimes and sludges, precious metal refining 1-4**	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 50. 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): Slimes and sludges, precious metal refining 1-4**	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): Slimes and sludges, precious metal refining 1-4**	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

Slimes and sludges, precious metal refining 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 the Table below.

Table 51. 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 Slimes and sludges, precious metal refining, are grouped classifications based on cluster analysis and expert judgement. This approach has been used for Slimes and sludges, precious metal refining, as it consists of a large and variable group, where many combinations are possible and hence there was a need to apply cluster analysis to identify conservative classification profiles to arrive at a reasonable number of possible classifications of the

individual streams belonging to each UVCB substance.

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.

There are four different grades of Slimes and sludges, precious metal refining, and the environmental classification for each grade is presented below.

Slimes and sludges, precious metal refining 1

The MeCLAS tool has been used to derive the classification for Slimes and sludges, precious metal refining 1, 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).

Slimes and sludges, precious metal refining 2 (Low Ni, As, Pb)

The MeCLAS tool has been used to derive the classification for Slimes and sludges, precious metal refining 2 (low Ni, As, Pb), 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).

Slimes and sludges, precious metal refining 3 (Med Ni, As, Pb)

The MeCLAS tool has been used to derive the classification for Slimes and sludges, precious metal refining 3 (Med Ni, As, Pb), 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).

Slimes and sludges, precious metal refining 4 (High Ni, As, Pb)

The MeCLAS tool has been used to derive the classification for Slimes and sludges, precious metal refining 4 (High Ni, As, Pb), 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.

Tremain SP, Atwal SS (2010). Refinable No 4: Slimes and sludges, precious metal refining: Determination of hazardous physico-chemical properties. Testing laboratory: Harlan Laboratories Ltd, Shardlow Business Park, Shardlow, Derbyshire. DE72 2GD. UK. Report no.: 3099/0008. Owner company: Precious Metals and Rhenium Consortium (PMC), c/o EPMF.

White DF, Woolley SM (2010) Refinable No 4: Slimes and sludges, precious metal refining - Determination of general physico-chemical properties. Testing laboratory: Harlan Laboratories Ltd., Shardlow Business Park, Shradlow, Derbyshire. DE72 2GD. UK. Reoprt No.: 3099/0007. Owner company: Precious Metals and Rhenium Consortium (PMC), c/o EPMF

Annex I: MECLAS export sheets

See IUCLID section 13 attachments CSR Annex I.A – CSR Annex I.D

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