SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Commercial Product Name:	Silver concentrate
Chemical name:	Concentrates of lead and zinc compounds with sulphur resulting from hydrometallurgy (hot acid leaching, super-hot acid leaching and flotation)
EC number:	936-276-2
CAS number:	Not assigned
REACH registration number:	01-2120040921-64-0000

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use	Industrial use as intermediate for lead and silver production
Uses advised against:	Only the uses covered by the exposure scenarios are recommended (see Annex).

1.3 Details of the supplier of the safety data sheet

Identification of the supplier:	Boliden Kokkola Oy
Street address:	Outokummuntie 8
Post address:	P.O.Box 26
Postcode and post office:	FIN-67101 Kokkola
Country:	Finland
Telephone:	+358 6 828 6111
Telefax:	+358 6 828 6005
Email:	kemikaaliryhma.kokkola@boliden.com

1.4 Emergency telephone number

Poison Centre, Tukholmankatu 17, PL 790, 00029 HUS (Helsinki), (24h)/+358 (0)9 4711, direct number +358 (0)9 471977.
See section 16.6 for the list of telephone numbers of poison centres in the European Economic Area.

SECTION 2. HAZARDS IDENTIFICATION

This substance is classified as hazardous in accordance with the CLP regulation 1272/2008 and the Directive 67/548/EEC. This substance is harmful if swallowed and inhaled. It causes skin irritation and serious eye damage. The substance may also cause cancer and damage to unborn child. Suspected of damaging fertility. It causes damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion. It is very toxic to aquatic life with long lasting effects.

2.1 Classification of the substance:

1272/2008 (CLP):	Acute Tox. 4	H302
	Acute Tox. 4	H332
	Skin Irrit. 2	H315
	Eye Dam. 1	H318
	STOT RE 1	H372
	Repr. 1 A	H360Df
	Carc. 2	H351
	Aquatic Acute 1	H400
	Aquatic Chronic 1	H410

67/548/EEC (DSD):

Xn; 20/22
Xi; R38, R41
T; R48/23/25
Repr. Cat. 1; R61
Repr. Cat. 3; R62
Carc. Cat. 3; R40
N; R50-53

2.2 Label elements

1272/2008 (CLP)

GHS05 GHS07 GHS08 GHS09

Signal word: Danger

Hazard Statements:		
	H302	Harmful if swallowed
	H315	Causes skin irritation.
	H318	Causes serious eye damage
	H332	Harmful if inhaled
	H351	Suspected of causing cancer
	H360Df	May damage the unborn child. Suspected of damaging fertility
	H372	Causes damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion
	H410	Very toxic to aquatic life with long lasting effects

M-factors:

Aquatic Acute 1:	10
Aquatic Chronic:	1

Precautionary Statements:		
	P201	Obtain special instructions before use
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray
	P264	Wash hands thoroughly after handling
	P273	Avoid release to the environment
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	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
	P501	Dispose of contents/container to in accordance with local waste management regulations.

2.3 Other hazards

The criteria for PBT and vPvB do not apply for this substance because it is inorganic. This substance is not hazardous to ozone layer.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

This product is an UVCB substance. It is produced from the leaching residue of the zinc calcine after neutral leaching, hot acid and super-hot acid leaching and flotation. The main phases of the concentrate are lead sulphate and zinc sulphide. The product consists primarily of sulphur (ca.35 %), lead (ca.25 %) and zinc (ca.17 %) together with minor trace elements such as silver, silicon, aluminium, calcium and iron.

EC number	CAS number	Chemical name of the substance	Concentration	Classification: *EC 1272/2008 (CLP):*
936-276-2	Not assigned	Concentrates of lead and zinc compounds with sulphur resulting from hydrometallurgy (hot acid leaching, super-hot acid leaching and flotation)	100 w/w-%	Acute Tox. 4; H302 Acute Tox. 4; H332 Skin Irrit. 2 ; H315 Eye Dam. 1; H318 STOT RE 1; H372 Repr. 1 A; H360 Df Carc. 2; H351 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
				Classification: 67/548/EEC (DSD):
				Xn; 20/22 Xi; R38, R41 T; R48/23/25 Repr. Cat. 1; R61 Repr. Cat. 3; R62 Carc. Cat. 3; R40 N; R50-53

3.2 Other information

The most hazardous and readily soluble constituent of the substance is lead (Transformation/Dissolution study according to OECD guidance 29).
M-factor: Acute 1: 10
M-factor Chronic 1: 1

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: Remove from exposure to fresh air. Provide rest and warmth; keep in half-upright position. Get medical attention if any discomfort continues. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. If conscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin contact: Avoid skin contact. Remove contaminated clothing. Wash skin with plenty of soap and water. Continue to rinse for at least 10 minutes.

Eye contact: Flush eyes with plenty of water for at least 15 minutes, while lifting the upper and lower eyelids. Get medical aid if irritation occurs.

Ingestion:	Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Do not induce vomiting. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye damage and irritation of the skin. Harmful if swallowed or inhaled. Causes damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion.

4.3 Indication of immediate medical attention and special treatment needed

Show this safety data sheet to the doctor in attendance. Treat symptomatically.

SECTION 5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	The product is not flammable. Use an extinguishing agent suitable for the surrounding fire (e.g. water, foam, powder, dry sand).
Extinguishing media which must not be used for safety reasons:	None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance:	No specific hazard. This material is very toxic to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
Hazardous combustion products:	Fire can generate toxic and corrosive gases/vapours (lead oxides, sulphur oxides, zinc oxides, cadmium oxides)

5.3 Advice for fire-fighters

Special precautions for fire-fighters:	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Do not breathe vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment. Avoid skin contact.
For emergency responders:	Use appropriate personal protective equipment.

6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil and waterways. Inform the relevant Authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and materials for containment and cleaning up

Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Cleaning waters or leachates of the substance must not be discharged into soil or waterways.

6.4 Reference to other sections

See also section 8.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures:	Put on appropriate personal protective equipment. Persons with a history of skin or respiratory sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Avoid raising dust. Do not breathe vapour or mist. Do not ingest. Avoid release to the environment
Advice on general occupational hygiene:	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Keep containers tightly closed. Store in a dry area. Do not discharge to sewer or drains. Self-heating of the metal may occur. Keep away from: heat sources, acids and oxidizers. Any residues, including spills and contaminants on the floor, are to be collected as hazardous waste in enclosed appropriate containers.

7.3 Specific end use(s)

For industrial use as intermediate.
List of exposure scenarios (see exposure scenario in the annex):
ES 1: Manufacture of silver concentrate
ES 2: Industrial use as intermediate

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational exposure limits:

No exposure limits known for the substance itself. The values are given for the most critical constituent of the substance; lead and lead compounds:

Country	Limit values – 8 hours (mg/m³)
Austria	0.1 inhalable aerosol
Belgium	0.15
Denmark	0.05 inhalable aerosol
European Union	0.15 inhalable aerosol
Finland	0.1 inhalable aerosol
France	0.15 inhalable aerosol
Germany	0.1 inhalable aerosol
Hungary	0.15 inhalable aerosol 0.05 respirable aerosol
Italy	0.15 inhalable aerosol
Poland	0.05
Spain	0.15 inhalable aerosol
Sweden	0.1 inhalable aerosol 0.15 respirable aerosol
Switzerland	0.1 inhalable aerosol

United Kingdom	0.15

8.1.2 Biological limit values for inorganic lead:

Country	Binding biological exposure limit (µg/dL) male	Binding biological exposure limit (µg/dL) female
Belgium	70	70
Denmark	20	20
European Union	70	70
Finland	50	50
France	40	30
Germany	40	10*
Hungary	50	30*
Italy	60	40*
Poland	50	50
Spain	70	70
Sweden	-	-
Switzerland	70	30
United Kingdom	60	60

*for woman of reproductive capacity

8.1.3 DNELs:

The critical DNELs for workers: The DNEL values are given for the most hazardous constituent (Pb):

Long-term -systemic effects (inhalation): 0.1 mg/m^3 (OEL for lead).

Long-term -systemic effects (dermal): 0.03 mg/kg bw/day (route to route extrapolation from repeated dose oral study on rats, AF=50).

The critical DNELs for general population:

Long-term -systemic effects (inhalation): 500 ng/m^3 (the annual threshold value for lead emissions (2008/50/EC, VNa 38/2011).

Long-term -systemic effects (oral): 0.004 mg/kg bw/day (for the most sensitive population (children) derived from the lead blood NOAEL based on human epidemiological data).

8.1.4 PNECs: The PNEC values are given for the most critical and bioavailable constituents of the substance based on the transformation and dissolution study results:

PNEC Freshwater: 6.5 µg Pb/L (dissolved). Using the SSD approach and AF= 3.
20.6 µg/l Zn /L (dissolved). Statistical extrapolation using AF =1.

PNEC Marine water: 3.4 µg Pb/L (dissolved). Using the SSD approach and AF= 3.
6.1 µg/l Zn /L (dissolved). Statistical extrapolation using AF =3.

PNEC Freshwater sediment: 174mg Pb/kg dw. Based on the use of SSD approach and AF= 3
117.8 mg Zn/kg dw. Based on the use of SSD approach and AF= 1.

PNEC Marine water sediment: 164 mg Pb/kg dw. Based on the use of SSD approach and AF= 3.
56.5 mg Zn/kg dw. Based on the use of SSD approach and AF= 1.

PNEC Soil: 147.0 mg Pb/kg dw. Based on the use of SSD approach and AF= 2.
35.6 mg Zn/kg dw. Based on the use of SSD approach and AF= 1.

PNEC oral: 10.9 mg Pb/kg food

STP Micro-organisms: 0.1 mg/L for both constituents (Pb and Zn).

8.2 Exposure controls

Appropriate engineering controls: If user operations generate dust, fumes, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Individual protection measures:	Respiratory protection In dusty conditions use respiratory protector. Appropriate mask, self-contained breathing apparatus or air stream helmet. Hand protection Wear suitable chemical resistant protective gloves and fire resistant gloves when necessary. Eye/face protection Use chemical resistant safety glasses or face shield. Skin protection For body protection use chemical resistant protective clothing and boots and fire resistant clothing and boots when necessary.
Environmental exposure controls:	Good hygiene and housekeeping. Do not release the substance or leachates of the substance in soil or waterways. Waste waters and air emissions should be treated in proper way. All residues should be treated as hazardous waste (see annex).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Important Health Safety and Environmental Information

Appearance:	Dark grey or brownish solid with water content of ca. 15 %	
Odour:	Pungent	
Odour threshold:	No data available	
pH:	3.7 to 4 (L/S -ratio=10:1 water solution)	
Melting point/freezing point:	>400 ˚C (OECD 102)	
Initial boiling point and boiling range:	Not relevant melts > 300 ˚C	
Flash point:	Not applicable for solid substances	
Evaporation rate:	Not relevant	
Flammability (solid, gas):	Non flammable	
Explosive properties:		
	Lower explosion limit:	not applicable (Substance non-explosive)
	Upper explosion limit:	not applicable (Substance non-explosive)
Vapour pressure:	Not applicable	
Vapour density:	Not applicable	
Relative density:	3 (OECD 109)	
Solubility(ies):		
	Water solubility:	362 µg Pb/l and 3.2 µg Zn/l at pH 6 (28-d T/D study at 1 mg loading; OECD guidance 29)
	Fat solubility	No data available
Partition coefficient: n-octanol/water:	Not applicable for inorganic substances	
Auto-ignition temperature:	142 ˚C (Transport of Dangerous Goods PART III N.4)	
Decomposition temperature:	No data available	
Viscosity:	Not applicable for solid substances	
Explosive properties:	Non explosive	
Oxidising properties:	Not oxidizing	

9.2 Other information:

Mean particle size:	29 to 32 µm.

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability
The product is stable.

10.3 Possibility of hazardous reactions
Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid
No specific data.

10.5 Incompatible materials
Reactive or incompatible with the following materials: oxidizing materials and strong acids. Keep away from heat, sparks and open flame.

10.6 Hazardous decomposition products
Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Basic toxicokinetics:	There is no experimental data available on toxicokinetics for the substance itself and the assessment has been made qualitatively on the basis of the physical and chemical properties and other relevant data available for the components in silver concentrate. Main component in silver concentrate is lead sulphate ($PbSO_4$). **Toxicokinetic assessment:** Inorganic lead compounds are slowly absorbed by ingestion and inhalation and poorly absorbed through the skin. If absorbed, lead will accumulate in the body with low rates of excretion, leading to long-term build up.
Acute toxicity:	Silver concentrate is classified Acute Tox. 4; H302: Harmful if swallowed and Acute Tox. 4; H332: Harmful if inhaled based on CLP mixture rules.
Irritation and corrosion:	Silver concentrate is classified Skin Irritant 2; H315: Causes skin irritation and Eye Dam. 1; H318: Causes serious eye damage, based on CLP mixture rules.
Sensitisation:	Silver concentrate is not classified for respiratory or skin sensitisation based on CLP mixture rules.
Reproductive toxicity:	Silver concentrate is classified Repr. 1 A; H360Df: May damage the unborn child. Suspected of damaging fertility based on CLP mixture rules. Exposure to high levels of inorganic lead compounds may cause adverse effects on male and female fertility, including adverse effects on sperm quality. Prenatal exposure to inorganic lead compounds is also associated with adverse effects on neurobehavioral development in children.
Genotoxicity:	**Germ cell mutagenicity:** Silver concentrate is not classified for mutagenicity based on CLP mixture rules. The evidence for genotoxic effects of highly soluble inorganic lead compounds is contradictory, with numerous studies reporting both positive and negative effects. Responses appear to be induced by indirect mechanisms, mostly at very high concentrations that lack physiological relevance.
Carcinogenicity:	Silver concentrate is classified Carc. 2; H351: May cause cancer based on CLP mixture rules. There is evidence that highly soluble inorganic lead compounds may have a carcinogenic effect, particularly on the kidneys of rats. However, the mechanisms by which this effect occurs are still unclear. Epidemiology studies of workers exposed to inorganic lead compounds have found a limited association with stomach cancer.

	STOT-single exposure:	Silver concentrate has not been classified for STOT SE.
	STOT-repeated exposure:	Silver concentrate is classified STOT RE 1; H372: May cause damage to organs through prolonged or repeated exposure. Inorganic lead compounds are cumulative poisons and may be absorbed into the body through ingestion or inhalation. Inorganic lead compounds have been documented in observational human studies to produce toxicity in multiple organ systems and body function including the haematopoietic (blood) system, kidney function, reproductive function and the central nervous system.
	Aspiration hazard	Silver concentrate is not classified for aspiration hazard.
11.2	**Other information**	Not known.

SECTION 12. ECOLOGICAL INFORMATION

12.1 The environmental classification is based on the transformation/dissolution study results conducted for the substance. The product is very toxic to the aquatic environment and it is classified Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The following toxicity values are for the most critical constituent of the substance (lead).

Aquatic toxicity:

<u>Short-term aquatic toxicity:</u>	
Algae (growth rate):	*Pseudokirchnerilla subcapitata*; EC50 (2 d): 21.7 - 322.9 µg Pb/L; (n=7, pH range 6.7 - 7.9; hardness (mg/l)24.2 - 262.7)
Invertebrates (immobilisation):	*Daphnia magna*; EC50 (48 h): 107.5 - 108.8 µg Pb/L; (n=4; pH range 7.6 - 8.35; hardness (mg/l) range 54 -206) *Ceriodaphnia dubia*; EC50 (48h): 26.4 - 3115.8 µg Pb/L; (n=38; pH range 5.71 - 8.25; hardness(mg/l) range5.8 - 244)
Fish (mortality):	*Pimephales promelas*; LC50 (96 h): 40.79 - 3597.5 µg Pb/L; (n=39; pH range 5.67 - 8.26; hardness (mg/l) range 4.8 - 300) *Salmo gairderi*; LC50 (96 h): 107.74 - 1170 µg Pb/L; (n=4; pH range 6.9 - 8.8; hardness (mg/l) range 32 -385).
<u>Long-term aquatic toxicity:</u>	
Aquatic plants (root length):	*Lemna minor*; NOEC (7d): 29.5 - 643.2 µg Pb/L; (n=3; pH range 7.17 - 8.06, hardness (mg/l) 29 - 56)
Invertebrates (mortality and/or reproduction):	*Ceriodaphnia dubia*; NOEC (7d; reproduction): 1.7 - 354.9 µg Pb/L; (n=19; pH range 7-8; hardness (mg/l) range 27.5 - 362) *Daphnia magna*; NOEC (21 d, reproduction): 107.0 µg Pb/L; (n=1; pH 8.1, hardness 225 mg/l) *Daphnia magna*; NOEC (21 d; mortality): 9.0 - 107 µg Pb/L; (n=4; pH range 7.4-8.1; hardness (mg/l) range 52-225)
Fish (mortality):	*Pimephales promelas*; NOEC (30 d): 39.6 - 41.8 µg Pb/L; geometric mean 40.7 µg Pb/L (pH 7.2; hardness (mg/l) range 47 -104).
<u>Toxicity to other organisms:</u>	
Sediment dwelling organisms:	Freshwater sediment**:** *Tubifex tubifex*, NOEC (28 d, reproduction): 573 mg Pb/kg dw. Marine sediment: *Neanthes arenaneodentata*; NOEC (28 d, growth): 680 mg Pb/kg dw.
Soil compartment:	Soil invertebrates: *Eisenia fetida* (adults); NOEC 400 - 1822 mg Pb/ kg d.w. (OECD art. soil or silty loam soil). Terrestrial plants: *Hordeum vulgare L*. (barley); NOEC (yields based on root): 57 mg Pb/kg dw.
STP Micro-organisms:	(Protozoa): Protozoan community; EC10: 1.0 - 7.0 mg Pb/l.

12.2 **Persistence and degradability**

Not relevant for inorganic substances.

12.3 Bioaccumulative potential
Substance contains inorganic lead compound ($PbSO_4$) and other inorganic metals which have bioaccumulation potential to aquatic and terrestrial compartments.

12.4 Mobility in soil
Substance contains lead which is readily soluble. However, based on the adsorption and bioaccumulation potential of the inorganic constituents to soil the mobility is expected to be low.

12.5 Results of PBT and vPvB assessment
The PBT and vPvB criteria in Annex XIII of the REACH Regulation do not apply for inorganic substances.

12.6 Other adverse effects
Not known.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Waste codes in accordance with the list of European Waste Catalogue (EWC) should be assigned by the user prior to final disposal. Dispose of product and product residue in accordance with the instructions of the person responsible for waste disposal. Refer to local and national waste management regulations and dispose of in accordance with the waste classification.

Waste management methods:	The primary waste management option for unused inorganic product is hazardous waste landfill if the landfill acceptance criteria are fulfilled. Recycling or re-use of uncontaminated packing is preferred to final disposal. Refer to local or national waste management regulations.
Special precautions:	This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of cleaning waters in contact with soil and waterways.
Waste from residues / unused products:	Dispose of as hazardous waste. Where possible re-use and recycling is preferred to final disposal. The proposed waste codes in accordance with the list of European Waste Catalogue EWC are: 11 02 02* sludges from zinc hydrometallurgy (including jarosite, goethite) 15 02 02* Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective Clothing contaminated by dangerous substances 19 08 13* Sludges from industrial WWT containing hazardous substances 15 01 10* Packaging containing residues of or contaminated by dangerous substance

SECTION 14. TRANSPORT INFORMATION

		ADR/RID	*ADN/ADNR*	*IMDG*	*IATA*
14.1	**UN number**	UN3077	UN3077	UN3077	UN3077
14.2	**UN proper shipping name**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Contains lead sulphate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Contains lead sulphate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Contains lead sulphate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Contains lead sulphate)
14.3	**Transport hazard class(es)**	9	9	9	9

					
14.4	**Packing group**	III	III	III	III
14.5	**Environmental hazards**	This substance is classified as hazardous to the aquatic environment to hazard class aquatic acute 1 and aquatic chronic 1.	This substance is classified as hazardous to the aquatic environment to hazard class aquatic acute 1 and aquatic chronic 1.	This substance is classified as hazardous to the aquatic environment to hazard class aquatic acute 1 and aquatic chronic 1.	This substance is classified as hazardous to the aquatic environment to hazard class aquatic acute 1 and aquatic chronic 1.
14.6	**Special precautions for users**				
	Additional information:	Hazard identification number 90 Limited quantity 5 kg Special provisions 274 335 601 Tunnel code (E)	Hazard identification number 90 Classification code M7 Special provisions 274 335 601 LQ27 E1	Emergency schedules (EmS) F-A, S-F	

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not available.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available.

15.2 Chemical safety assessment
In accordance with Regulation (EC) No. 1907/2006 (REACH) Article 14, a Chemical Safety Assessment has been carried out for this substance.

SECTION 16. OTHER INFORMATION

16.1 Additions, Deletions, Revisions
Version 3.0
This safety data sheet is drawn up to comply with the requirements Annex II of Regulation (EC) No. 1907/2006 (REACH), as amended by Annex I to Commission Regulation (EU) No. 453/2010 of 20 May 2010.

16.2 Key or legend to abbreviations and acronyms

ADNR	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AF	Assessment factor
DNEL	Derived no-effect level
DOC	Dissolved organic carbon
DSD	Council Directive 67/548/EEC (Dangerous Substances Directive)
EC50	Concentration of the substance that causes 50 % reduction of a certain effect on test organisms
EWC	European Waste Catalogue
LC50	Concentration of the substance that causes 50 % mortality of the test population
IATA	The International Air Transport Association
IMDG	INTERNATIONAL MARITIME DANGEROUS GOODS CODE
OECD	Organisation for Economic Co-operation and Development

NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
LD50	Lethal dose of the substance that causes 50 % mortality of the test population
OEL	Occupational exposure limit
PBT/vPvB	Persistent, bioaccumulative and toxic/ very persistent and very bioaccumulative
PNEC	Predicted no-effect concentration
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	International Rule for Transport of Dangerous Substances by Railway
SSD	Species sensitive approach
STOT RE	Specific Target Organ Toxicity, Repeated Exposure
STOT SE	Specific Target Organ Toxicity, Single Exposure
UVCB	Chemical substances of Unknown or Variable compositions, Complex reaction products and Biological materials
STP	Sewage treatment plant

16.3 Key literature references and sources for data

REACH Chemical Safety Report Part B Concentrates of lead and zinc compounds with sulphur resulting from hydrometallurgy (hot acid leaching, super-hot acid leaching and flotation); dated: 19.3.2014.

16.4 Classification procedure

The self-classification has been derived based on the experimental data on the substance and by applying the CLP mixture rules based on the concentrations of the individual components and their classification entries in the Annex VI of Regulation 1272/2008 (CLP).

16.5 List of relevant R phrases

Xn; R20/22:	Harmful by inhalation and if swallowed.
R38 :	Irritating to skin.
R40	Limited evidence of a carcinogenic effect.
R41:	Risk of serious damage to eyes.
T; R48/23/25:	Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
N;R50-53:	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R61:	May cause harm to the unborn child.
R62:	Possible risk of impaired fertility.

16.6 Emergency telephone number

Europe-wide emergency number:	112
Contact a poison control centre. List of Telephone Numbers:	**AUSTRIA** (Vienna Wien) +43 1 406 43 43; **BELGIUM** (Brussels Bruxelles) +32 70 245 245; **BULGARIA** (Sofia) +359 2 9154 409; **CZECH REPUBLIC** (Prague Praha) +420 224 919 293; **DENMARK** (Copenhagen) 82 12 12 12; **ESTONIA** (Tallinn) 112; **FINLAND** (Helsinki) +358 9 471 977; **FRANCE** (Paris) +33 1 40 0548 48; **GERMANY** (Berlin) +49 30 19240; **GREECE** (Athens Athinai) +30 10 779 3777; **HUNGARY** (Budapest) 06 80 20 11 99; **ICELAND** (Reykjavik) +354 525 111, +354 543 2222; **IRELAND** (Dublin) +353 1 8379964; **ITALY** (Rome) +3906 305 4343; **LATVIA** (Riga) +371 704 2468; **LITHUANIA** (Vilnius) +370 5 236 20 52 or +370 687 53378; **MALTA** (Valletta) 2425 0000; **NETHERLANDS** (Bilthoven) +31 30 274 88 88; **NORWAY** (Oslo) 22 591300; **POLAND** (Gdansk) +48 58301 65 16 or +48 58 349 2831; **PORTUGAL** (Lisbon Lisboa) 808 250 143; **ROMANIA** (Bucharest) +40 21 3183606; **SLOVAKIA** (Bratislava) +421 2 54 77 4166; **SLOVENIA** (Ljubljana) + 386 41 650500; **SPAIN** (Barcelona) +34 93 227 98 33 or +34 93 227 54 00 bleep 190; **SWEDEN** (Stockholm) 112 or +46 833 12 31 (mon-fri 9.00-17.00); **UNITED KINGDOM** (London) 112 or 0845 4647 (NHS Direct).

16.7 Recommended restrictions

DISCLAIMER OF LIABILITY:

The information in this SDS was obtained from the recent information from REACH registration. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

Annex to extended Safety Data Sheet

Table of Contents

ES 1: Manufacture of silver concentrate

1. Title of Exposure scenario		
ES1: Manufacture of PbZn concentrate in the CSR		
Environment: Manufacture of the substance		ERC 1
Sector of Use: Industrial use		SU 3
Description of process(es) covered in the Exposure Scenario:		
Worker contributing scenarios		
CS 1	Hot acid leaching	PROC 27 b
CS 2	Thickener after hot acid leaching	PROC 2
CS 3	Super hot acid leaching	PROC 27b
CS 4	Thickener after super hot acid leaching	PROC 2
CS 5	Filtration of super hot acid leaching solids	PROC 3
CS 6	Flotation	PROC 2
CS 7	Filtration after flotation	PROC 3
CS 8	Handling of solid inorganic substances at ambient temperature	PROC 8b
CS9	Maintenance in case of high dustiness	PROC 8b
Description of activities covered in the Exposure Scenario:		
This exposure scenario for the manufacture of the substance includes general process exposures, material transfers, maintenance and packaging, sampling and associated laboratory activities. The above PROCs also cover the activities of waste treatment and handling. As this substance is an UVCB substance the exposure assessment and risk characterisation for workers was based on the most critical constituent in the substance, lead. The environmental assessment was conducted to two most critical and bioavailable constituents, lead and zinc.		
2. Conditions of use affecting exposure		
2.1 Control of environmental exposure manufacture of the substance **(ERC1)**		
Product characteristics		
Physical form:	Solid, moist powder. Moisture content 15%	
Water solubility:	Insoluble. Zinc and lead are soluble in water (8.3 mg Pb/L and 0.075 mg Zn /L ; OECD 29 transformation/dissolution study)	
Log Kow:	Not relevant information for inorganic substances	
Biodegradation:	Not relevant information for inorganic substances	
Adsorption coefficients	lead	zinc
Log Kd Freshwater sediment:	5.19	4.86
Log Kd Marine sediment:	5.66	3.78
Log Kd Soil compartment	3.81	2.2
Log Kd Freshwater suspended matter:	5.47	5.04
Log Kd Marine suspended matter:	6.18	-
Bioaccumulation factors: Bioconcentration is relevant only for lead.		
BCF (fresh water)	1553 L/kg	
BCF (soil)	0.39 kg/kg	
See also sections 9 and 12 in SDS		
Amounts used		
Annual manufacturing amount at a site:	≤ 5000 tonnes/year	
Daily use at a site:	≤ 14 tonnes/day	

The assessment has been conducted for the most critical constituents in the substance. The substance contains lead (conc. 25 %) and zinc (conc. 17 %):		
	lead	zinc
Daily use at site:	≤ 3.42 tonnes/day	≤ 2.33 tonnes/day
Annual use at a site:	≤ 1250 tonnes/year	≤ 850 tonnes/year
Percentage of tonnage used at regional scale:	100 %	
Frequency and duration of use		
Operating days :	continuous process	
Annual release days:	365 d/a	
Environment factors not influenced by risk management		
Handling by authorised and specially trained personnel. A combination of organisational and technical measures (spill containment and leak detection) is used to prevent and detect unexpected releases. Environmental, health and safety guidelines or written instructions on the standard operating procedure (SOP) are utilized. Good hygiene and housekeeping practices are implemented. This material must be prevented from being discharged to sewer or drain.		
Other given operational conditions affecting environmental exposure		
Effluent discharge rate:	3400 m^3/d (all emissions from the zinc plant)	
Flow rate of receiving surface water:	Not relevant for the assessment	
Receiving surface water:	Baltic Sea	
Dilution factor:	100 (default)	
Technical conditions and measures to reduce or limit discharges, air emissions and releases to soil		
Connection to WWTP:	Waste waters are discharged to on-site chemical-mechanical WWTP and further to sea and are under intensive monitoring. Quality of waste water is monitored by automated sampling every 15 minutes, analysis every 24 hour. Waste water of the zinc plant together with water from the two other industrial operators are released first to a mixing pond and further to the first precipitation pond (PP-I). Main precipitation of metals takes place in the first pond (PP-I). Continuous dredging equipment transfers solid precipitates from the bottom of pond (PP-I) to two sludge ponds (SP-I and SP-II). The sludge is dried in SP-I/II ponds and overflow water is returned back to the SP-I. Dried sludge from S-I/II is transferred to the waste pond (WP-I) of the zinc plant. The sludge from the WP-1 is disposed (pumped) to the hazardous waste landfill. After the clarification of waste water in the first precipitation pond PP-I a continuous waste water overflow stream flows to the second precipitation pond (PP-II). In the PP-II pond the final clarification takes place and water is distributed to a pipe leading to the sea.	
Discharge to water after RMM:	Release factors are based on monitored waste water emissions. On-site WWTP [Effectiveness Water: 98%]. Release factor (Pb): 0.0006% Release factor (Zn): 0.005% The emissions of the substance manufacture cover 10% of the overall emissions of the zinc plant	
Discharge to air after RMM:	The monitored air emissions are used for the assessment. The air purification techniques with efficiency (99 %) are in use at the critical point sources in the plant. Release factors are based on monitored air emissions. Release factor (Pb): 1.754E-4% Release factor (Zn): 0.069% The emissions of the substance manufacture cover 10% of the overall emissions of the zinc plant	
Soil emissions:	Application of sludge on soil: No. Hazardous sludge waste is disposed of to the onsite hazardous waste landfill. Release factor (Pb and Zn): 0 % No direct releases to soil	

Processing stage: Closed automatically operated continuous processes, and closed batch processes in filtration step. The reactors are equipped with exhaust system with scrubbers. Good general ventilation. Dust filters are installed in the ventilation exhausts.
Organizational measures to prevent/limit release from site
Environmental, health and safety guidelines or written instructions on the standard operating procedure (SOP) are utilized. Environment, health and safety (EHS) responsibilities are defined and assigned in writing. Emergency action plans (Rescue training for accidental emissions) are created. Personnel are trained in environment, health and safety issues, i.e. in safe handling of chemicals and good housekeeping. It is assumed that a comprehensive PPE program is implemented including selection, fit testing, training in use, maintenance and recording, as appropriate. Exposure should be controlled primarily by avoidance of contact with the substance, for instance by limiting duration of activity, minimization of manual phases and by minimization of manual process steps. Personal and static air measurements (Pb and Zn) are conducted. Biological monitoring of lead blood concentrations is performed. Good hygiene and housekeeping practices are implemented.
Conditions and measures related to municipal sewage treatment plant
The waste water is treated onsite in a chemical-mechanical treatment plant. This material must be prevented from being discharged to sewer or drain.
Conditions and measures related to external treatment of waste for disposal
Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.). All solid mineral process waste containing lead and zinc are disposed of as a hazardous waste to hazardous waste landfill, and their acceptance and quality is monitored in accordance with the acceptance criteria of waste at landfills according to Council Decision 2003/33/EC. All other wastes containing residues of the substance should be disposed of as hazardous waste to authorized hazardous waste treatment plants, operated according to Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and Best Available Techniques for Waste Incineration as described in the respective BREF of August 2006. In case of landfilling, the acceptance of waste is defined according to 2003/33/EC and disposed of only to the hazardous waste landfills operating according to waste legislation demands. Contaminated packaging should be emptied as far as possible and disposed of as hazardous waste to incineration plants in accordance with Directive 2000/76/EC. Clean packaging material should be subjected to waste management schemes (recovery recycling, and/or re-use) according to local waste management regulation. **The typical waste streams and their EWC-codes:** 11 02 02* Sludges from zinc hydrometallurgy (including jarosite, goethite) 15 02 02* Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective Clothing contaminated by dangerous substances 19 08 13* Sludges from industrial WWT containing hazardous substances 15 01 10* Packaging containing residues of or contaminated by dangerous substance
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
Good hygiene and housekeeping
2.2 Control of workers exposure
Product characteristic

Concentration of substance in product:	>25 % (lead content in the substance)
Physical form:	Solid, moist powder. Moisture content 15%
Dustiness:	Low dustiness in normal process conditions (wet process). The dust formation is possible if the product gets dry.
Molecular weight:	207.2 g/mol (Pb)
Melting point:	> 400 ˚C
Boiling point:	Not relevant because of high melting point value

Frequency and duration of use		
Contributing scenario	PROC	Duration
Hot acid leaching	PROC 27b	< 8 hours
Super hot acid leaching		
Thickener after super hot acid leaching	PROC 2	
Filtration of super hot acid leaching solids	PROC 3	
Flotation	PROC 2	
Handling of solid inorganic substances at ambient temperature	PROC 8b	< 1 hour (limited to one hour due to the dust formation)
Maintenance in case of high dustiness		< 4 hours (limited to four hours due to the dust formation)

Other conditions affecting workers exposure

The worker exposure to the substance is considered to be eliminated to the acceptable level through use of closed or covered equipment/processes to minimize dust formation. The risk of dust formation is low during normal process conditions but if the substance gets dry the dust formation is possible (manual operations, maintenance activities, sampling).

Contributing scenario	PROC	Place of use	Process temperature	Dustiness
Hot acid leaching	PROC 27b	Indoor	99 ˚C	Low dustiness because of contained wet processing
Super hot acid leaching		Indoor	99 ˚C	
Thickener after super hot acid leaching	PROC 2	Outdoor	99 ˚C	
Filtration of super hot acid leaching solids	PROC 3	Indoor	99 ˚C / 40 C˚	
Flotation	PROC 2	Indoor	20 – 40 C˚	
Handling of solid inorganic substances at ambient temperature	PROC 8b	Indoor	20 – 25 C˚	High dustiness. Risk of dust formation if the substance gets dry
Maintenance in case of high dustiness		Indoor/outdoor	Ambient	

Technical conditions and measures to control dispersion from source towards the worker

PROC 8b is describing the manual handling and maintenance activities as well as the unloading of concentrate from filters for transport to harbour. This loading/unloading process is automated process, and there is no direct contact of workers with the substance in the area except in sampling activities. Based on the current knowledge, the product will be transferred to the transport container by a telescopic handler that will be operated from its cabin. As a worst case scenario for maintenance activities the high dustiness is assumed.

Contributing scenario	PROC	Ventilation	Ventilation efficiency		Contact level	Pattern of use	Pattern of exposure control
			%	Efficiency based on			
Hot acid leaching	PROC 27 b	Enclosure	74 %	Upper confidence limit (reduction factor 26 %)	None	Closed system without breaches	Non-direct handling
Super hot acid leaching							
Thickener after super-hot acid leaching	PROC 2	General ventilation	43 %	Median estimate (reduction factor 57 %)	Incidental	Closed system without breaches	Non-direct handling
Filtration of super hot acid leaching solids	PROC 3	Enclosure	74 %	Upper confidence limit (reduction factor 26 %)	None	Closed system without breaches	Non-direct handling
Flotation	PROC 2	Enclosure	74 %	Upper confidence limit (reduction factor 26 %)	Incidental	Closed system without breaches	Non-direct handling
Handling of solid inorganic substances at ambient temperature	PROC 8b	General ventilation	74 %	Upper confidence limit (reduction factor 26 %)	Incidental	Non-dispersive use	Direct handling
Maintenance in case of high dustiness		A. Wet suppression	89 %	Upper confidence limit (reduction factor 11 %)	Intermittent	Non-dispersive use	Direct handling

		B. Integrated LEV (during maintenance work thickeners are equipped with fan)	90 %	Upper confidence limit (reduction factor 10 %)			

Conditions and measures related to personal protection, hygiene and health evaluation

This substance causes the risk of serious eye damage, is skin Irritant and is suspected of causing cancer. Lead blood concentrations of the workers are monitored and static and personal air measurements for lead and zinc are conducted according to the monitoring program. Furthermore, it is considered that the exposure to the substance via eye and skin contact is eliminated by implementing advanced Occupational Health and Safety Management System together with the RMMs and OCs presented in this assessment.

In vessel maintenance a work permit is needed. Washing of vessels is done prior to maintenance and reparation. Measurement of explosive gases and oxygen is done prior to entering the vessel. Good ventilation is applied. PPEs in maintenance work: Disposable overall, protective goggles / face shield, gloves.

During cell maintenance work respiratory protection (APF=20), disposable overall and gloves are needed. In chute maintenance protective goggles and gloves are in use.

Contributing scenario	PROC	Respiratory Protection (Effectiveness Inhal: %)	Eye/face protection:	Dermal protection (Effectiveness Dermal: %)
Hot acid leaching	PROC 27 b	Not needed in normal process conditions (Effectiveness: 0%)	Chemical resistant safety glasses or face shield.	Chemical resistant protective gloves (effectiveness 90%)
Super-hot leaching				
Thickener after super-hot acid leaching	PROC 2			
Filtration of super-hot acid leaching solids	PROC 3			
Flotation	PROC 2			
Handling of solid inorganic substances at ambient temperature	PROC 8b	Respirator (APF = 20; Effectiveness: 95%)		
Maintenance in case of high dustiness				

3. Exposure estimation and reference to its source

Worker: The recommended standard tool CHESAR version 2.2 was used as the assessment tool, and external MEASE modelled inhalation and dermal exposure estimates of the most critical constituent where exported to this tool. As this substance is an UVCB substance the exposure assessment and risk characterisation for workers was based on the most critical constituent lead. Since this substance causes the risk of serious eye damage, is skin irritant and is suspected of causing cancer, worker exposure was also assessed qualitatively. The substance produces toxicity in multiple organ systems and body function including the haematopoietic (blood) system, kidney function, reproductive function and the central nervous system. Zinc is an essential trace element for humans having no bioaccumulation properties.

Environment: The environmental exposure assessment was conducted by using the EUSES v.2.1 model. The environmental assessment was conducted to two most critical and bioavailable constituents, lead and zinc. The ERC default release rates or release factors (ERC 1) were modified based on the monitoring results and based on the assumption taken for the amount of release expected to arise from the substance use. As the monitoring data covers releases from all processes in the zinc plant, the emissions of the substance use is assumed to be 10 % of the monitored releases.

Environment

Local exposure estimation and risk characterisation

The PNEC-values are presented in SDS section 8.1.

Release	**Release factor % / Release rate (kg/d)**	**Explanation / Justification**
Water	**Local release rate (kg/d):** 0.00041 kg Pb/d 0.108 kg Zn /d	The average annual zinc release (394 kg/a) divided by the release days (365 d/a). Based on the annual monitored release (2002-2012) from the whole plant. 10 % is assumed to be emitted from the new silver recovery line. As lead water emissions are low, lead concentrations of effluents are not required to be monitored according to the environmental permit. The assumption for the estimated release factor of 0.06 % is based on the expert judgement.
Air	**Local release rate (kg/d):**	The average annual zinc and lead release in air (22.4 kg Pb/a and 5918 kg Zn/a) divided by

	0.006 kg Pb /d 1.6 kg Zn /d	the release days (365 d/a). Based on the annual monitored release from the whole plant. 10 % is assumed to be emitted from the new silver recovery line.
Soil	**Final release factor:** 0 %	No direct release to natural or agricultural soil. The emissions via air deposits have been taken into account in the assessment.

Protection target	Exposure estimate Local PEC Lead	Exposure estimate Local PEC Zinc	Risk characterisation ratio (RCR) Lead	Risk characterisation ratio (RCR) Zinc
Fresh water	Not relevant, no releases to fresh water			Not relevant
Marine water	1.315E-6 mg/L	2.764E-4 mg/L	< 0.01	0.045
Sediment (Fresh water)	Not relevant, no releases to fresh water			Not relevant
Sediment (Marine water)	0.039 mg/kg	3.042 mg/kg	< 0.01	0.054
Sewage treatment plant	No on-site relevancy, no biological WWT			Not relevant
Agricultural soil	0.016 mg/kg	0.352 mg/kg	< 0.01	< 0.01

Risk characterisation for man via the environment

The substance contains lead and zinc. Lead may cause cancer and may be damaging to unborn child. It is also suspected of damaging fertility. The substance produces toxicity in multiple organ systems and body function including the hematopoietic (blood) system, kidney function, reproductive function and the central nervous system. It is very toxic to aquatic life with long lasting effects. Zinc is an essential trace element for humans. It is vital for many biological functions and plays a crucial role in cell growth and division, fertility and immune system function. Thus, the human exposure via the environment was assessed for lead releases.

Exposure via inhalation:	1.67E-6 mg/m³
Exposure via food consumption:	2.869E-4 mg/kg/d
Risk characterisation (RCR) – combined routes:	0.07

Worker exposure

Quantitative assessment (long-term systemic effects)

Inhalation: Derived no effect level (DNEL) (mg/m^3) = 0.1 mg/m3 (OEL for lead).
Dermal: Derived no effect level (DNEL) (mg/kg) = 0.03 mg/kg bw/day

Contributing scenario	PROC	Inhalation				Dermal			
		duration	respiratory protection	Exposure estimate (mg/m^3)	RCR	gloves	Exposure estimate (mg/kg)	RCR	Risk characterisation ratio (RCR) combined routes
Hot acid leaching	PROC 27 b	< 8h	No	0.026	0.26	Yes Eff. 90%	0.002	0.066	0.327
Super hot acid leaching									
Thickener after super hot acid leaching	PROC 2			0.006	0.06		4E-5	0.001	0.061
Filtration of super hot acid leaching solids	PROC 3			0.026	0.26		2E-4	0.007	0.267
Flotation	PROC 2			0.003	0.03		4E-4	0.01	0.04
Handling of solid inorganic substances at ambient temperature	PROC 8b	< 1h	Yes (APF=20) Eff. 95%	0.065	0.65		8E-4	0.03	0.68
Maintenance in case of high dustiness		< 4h		Vessel maintenance 0.083	0.83		0.002	0.07	0.82 - 0.90
				Filter and cell maintenance 0.075	0.75				

Qualitative assessment
Since no short-term, high peak exposures are expected from the processes, the risk characterisation for acute effects is considered unnecessary. The hazard class for the substance is based on the classification of the substance and is described in ECHA CSA guidance Part E Table E 3-1. This substance is classified for severely damaging to eyes, skin irritant and is suspected of causing cancer. Based on this classification the substance is assigned to moderate hazard class. The worker exposure is controlled with appropriate RMMs and use of PPEs (see sections 2.1 and 2.2).
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES
This exposure scenario does not address consumers or professional workers. The exposure assessment and risk characterization of workers were conducted by using MEASE –model. Based on the exposure assessment, the respiratory protection is needed in maintenance activities (cell and filter maintenance) when potential inhalation exposure is expected. During normal process conditions the use of respiratory protection is not necessary since the processes are closed and automated. Since this substance causes the risk of serious eye damage and is skin irritant dermal contact should be avoided using PPEs. Personal and static air measurements of lead and zinc are conducted during worst case situations at process areas where exposure to dust is expected. In addition, monitoring of lead blood concentrations of the workers would confirm the conditions of safe use of the substance. The environmental exposure assessment was conducted by using the EUSES v.2.1 model. The ERC default release rates and release factors were modified based on the monitoring results and based on the assumption taken for the amount of release expected to arise from the substance use. No monitoring data of the manufacturing process of this substance is currently available. As the available monitoring data covers releases from all processes in the zinc plant, the emissions of the substance use is assumed to be 10 % of the monitored releases. Scaling of worker exposure can be done by modifying the default parameters and recalculating the exposures using MEASE –model. The compliance can be also verified by comparing the monitored occupational measures with the DNEL value (section 3). Scaling of environmental exposure scenario conducted for this process can be done by modifiying the releases parameters based on the measured emissions of lead and zinc and re-claculating the emissions by using the EUSES. The recalculated values can then be compared with the PNEC values (section 3). The use is considered safe if the scaled results divided by the DNEL or PNEC –values are resulting a risk characterisation ratio (RCR) less than 1.

ES 2: Industrial use as intermediate

1. Title of Exposure scenario		
ES2: Industrial use as intermediate (CSR)		
Environment: Industrial use as intermediate		ERC 6a
Sector of Use: Industrial use. Manufacture of basic metals including alloys		SU 3, SU14
Description of process(es) covered in the Exposure Scenario:		
Worker contributing scenarios		
CS 1	Raw material handling	PROC 26
CS 2	Drying and smelting	PROC 1
CS 3	Maintenance and sampling	PROC 8b
Description of activities covered in the Exposure Scenario:		
This exposure scenario for the downstream use of the substance describes the activities to produce lead and silver. This exposure scenario includes general process exposures, material transfers, maintenance, cleaning and control walks/sampling activities. The life-cycle of the substance ends up to smelting. Therefore, the exposure scenario does not cover the activities and processes after smelting. As this substance is an UVCB substance the exposure assessment and risk characterisation for workers was based on the most critical constituent in the substance, lead. The environmental assessment was conducted to two most critical and bioavailable constituents, lead and zinc.		

2. Conditions of use affecting exposure		
2.1 Control of environmental exposure Industrial use as intermediate **(ERC6a)**		
Product characteristics		
Physical form:	Solid, moist powder. Moisture content 15%	
Water solubility:	Insoluble. Zinc and lead are soluble in water (8.3 mg Pb/L and 0.075 mg Zn /L ; OECD 29 transformation/dissolution study)	
Log Kow:	Not relevant information for inorganic substances	
Biodegradation:	Not relevant information for inorganic substances	
Adsorption coefficients		
	Lead	Zinc
Log Kd Freshwater sediment:	5.19	4.86
Log Kd Marine sediment:	5.66	3.78
Log Kd Soil compartment	3.81	2.2
Log Kd Freshwater suspended matter:	5.47	5.04
Log Kd Marine suspended matter:	6.18	-
Bioaccumulation factors: Bioconcentration is relevant only for lead.		
BCF (fresh water)	1553 L/kg	
BCF (soil)	0.39 kg/kg	
See also sections 9 and 12 in SDS		
Amounts used		
Annual manufacturing amount at a site:	≤ 5000 tonnes/year	
Daily use at a site:	≤ 14 tonnes/day	
The assessment has been conducted for the most critical constituents in the substance. The substance contains lead (conc. 25 %) and zinc (conc. 17 %):		
	Lead	Zinc
Daily use at site:	≤ 3.42 tonnes/day	≤ 2.33 tonnes/day
Annual use at a site:	≤ 1250 tonnes/year	≤ 850 tonnes/year

Percentage of tonnage used at regional scale:	100 %
Frequency and duration of use	
Operating days :	continuous process
Annual release days:	365 d/a
Environment factors not influenced by risk management	
Handling by authorised and specially trained personnel. A combination of organisational and technical measures (spill containment and leak detection) is used to prevent and detect unexpected releases.	
Other given operational conditions affecting environmental exposure	
Effluent discharge rate:	3300 m^3/d
Flow rate of receiving surface water:	18 000 m^3/d (default)
Receiving surface water:	Fresh water or marine water
Dilution factor (fresh water):	10 (default)
Dilution factor (marine water):	100 (default)
Technical conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Connection to WWTP:	Waste waters are discharged to on-site WWTP and further to sea and are under intensive monitoring. Quality of waste water is monitored by automated sampling (ca. 52/year), analysis are conducted from composite sample once a month. Water emissions for this intermediate use are arising from process gas purification and conducted to onsite treatment. The water from the venturi scrubber is led to two serially connected thickeners where the sludge settles. The sludge is dewatered in a filter press. The filter cakes are temporarily stored and returned to the Kaldo furnace by mixing into lead concentrate before drying. Flushing water and condensate from the scrubber is conducted to first thickener. Also condensation from the gas line is returned to the thickener. The water from other thickener is conducted to onsite WWTP. One or more of the following measures (as set out in the BAT Reference Document on Non-Ferrous Metal Processes) are used to reduce emissions to water: - Chemical precipitation: used primarily to remove the metal ions - Sedimentation - Filtration: used as final clarification step - Electrolysis: for low metal concentration - Reverse osmosis: extensively used for the removal of dissolved metals - Ion exchange: final cleaning step in the removal of heavy metal from process wastewater In case of on-site waste water emissions, the efficiency of the implemented risk management measures vary between 95 to 98%.
Discharge to water after RMM:	Release factors are based on monitored waste water emissions. The emissions of the substance use cover 10 % of the overall emissions of the process steps up to smelting. Release factor (Pb): 9.649E-5 % Release factor (Zn): 0.007 %
Discharge to air after RMM:	The monitored air emissions are used for the assessment. The emissions of the substance use cover 10 % of the overall emissions of the process steps up to smelting. The air purification techniques with efficiency (99 %) are in use at the critical point sources in the plant. Release factors are based on monitored air emissions. The air emissions are continuously monitored with the sampling frequency of 12 samples/ year. Release factor (Pb): 0.001% Release factor (Zn): 2.146E-4% One or more of the following measures (as set out in the BAT Reference Document on Non-Ferrous Metal Processes) are used to reduce emissions to air: - Electrostatic precipitators using wide electrode spacing: Wet electrostatic precipitators: - Cyclones, but as primary collector - Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission

	values -Membrane filtration techniques can achieve - Ceramic and metal mesh filters. PM10 particles are removed - Wet scrubbers. In case of stack air emissions, the efficiency of the implemented risk management measures vary between 95 to 99.95%.
Emissions to soil:	No direct releases to soil. Application of sludge on soil: No. Slag and air purification filter wastes from smelting are recycled back to the process. Other hazardous wastes are disposed of to the onsite hazardous waste landfill or incinerated. Release factor (Pb and Zn): 0 %
Processing stage: Closed automatically operated continuous processes Lead static and personal measures are conducted. Biological monitoring of lead blood concentrations.	
Organizational measures to prevent/limit release from site	
Environmental, health and safety guidelines or written instructions on the standard operating procedure (SOP) are utilized. Environment, health and safety (EHS) responsibilities are defined and assigned in writing. Emergency action plans (Rescue training for accidental emissions) are created. Personnel are trained in environment, health and safety issues, i.e. in safe handling of chemicals and good housekeeping. It is assumed that a comprehensive PPE program is implemented including selection, fit testing, training in use, maintenance and recording, as appropriate. Exposure should be controlled primarily by avoidance of contact with the substance, for instance by limiting duration of activity, minimization of manual phases and by minimization of manual process steps. Good hygiene and housekeeping practices are implemented.	
Conditions and measures related to municipal sewage treatment plant	
No connection to municipal STP. Waste waters are discharged to on-site WWTP. This material must be prevented from being discharged to sewer or drain.	
Conditions and measures related to external treatment of waste for disposal	
Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.). All solid mineral process waste containing lead and zinc are disposed of as a hazardous waste to hazardous waste landfill, and their acceptance and quality is monitored in accordance with the acceptance criteria of waste at landfills according to Council Decision 2003/33/EC. All other wastes containing residues of the substance should be disposed of as hazardous waste to authorized hazardous waste treatment plants, operated according to Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and Best Available Techniques for Waste Incineration as described in the respective BREF of August 2006. In case of landfilling, the acceptance of waste is defined according to 2003/33/EC and disposed of only to the hazardous waste landfills operating according to waste legislation demands. Contaminated packaging should be emptied as far as possible and disposed of as hazardous waste to incineration plants in accordance with Directive 2000/76/EC. Clean packaging material should be subjected to waste management schemes (recovery recycling, and/or re-use) according to local waste management regulation.	
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
Good hygiene and housekeeping	
2.2 Control of workers exposure	
Product characteristic	
Concentration of substance in product:	>25 % (lead content in the substance)
Physical form:	Solid, moist powder. Moisture content 15%
Dustiness:	Low dustiness in normal process conditions (wet process). The dust formation is possible if the product gets dry.
Molecular weight:	207.2 g/mol (Pb)
Melting point:	> 400 ˚C
Boiling point:	Not relevant because of high melting point value

Frequency and duration of use		
Contributing scenario	PROC	Duration
Raw material handling	PROC 26	< 1 hour
Drying and smelting	PROC 1	< 8 hours
Maintenance and sampling	PROC 8b	< 1 hour

Other conditions affecting workers exposure

The scenario (PROC 8b) is conducted as a worst case scenario for the activities describing the conditions of use during smelter control walks and minor maintenance activities, manual/semi-automated transfer operations and maintenance works activities where the exposure of workers might be expected. High dustiness is assumed as a worst case scenario as the substance might dry up during storage. The state of the substance at normal conditions is a wet powder (ca. 15 % moisture). At the elevated process temperatures the formation of fumes is possible.

Contributing scenario	PROC	Place of use	Process temperature	Dustiness
Raw material handling	PROC 26	outdoor/indoor	Ambient	High dustiness
Drying and smelting	PROC 1	outdoor/indoor	>400 ˚C	Low dustiness during normal operations; (High dustiness during control walks and minor maintenance activities)
Maintenance and sampling	PROC 8b	indoor	20 – 25 ˚C	High dustiness

Technical conditions and measures to control dispersion from source towards the worker

The processes are enclosed and automated. The following risk management measures are assessed in conditions with the high risk of dust or fume formation. In normal process conditions the workers are separated from emission source and supervision and crane/vehicle operations are done from ventilated control rooms. Ventilation efficiency of 78% is implemented.

Contributing scenario	PROC	Ventilation	Ventilation efficiency		Contact level	Pattern of use	Pattern of exposure control
			Eff. %	Based on			
Raw material handling	PROC 26	General ventilation	78	Lower confidence limit (reduction factor 22 %)	None	Closed system without breaches	Incidental
Drying and smelting	PROC 1	Enclosure	74	Upper confidence limit (reduction factor 26 %)	None	Closed system without breaches	Non-direct handling
Maintenance and sampling	PROC 8b	Generic LEV (exhaust ventilation systems located in close proximity of and directed to the emission source)	78	Lower confidence limit (reduction factor 22 %)	Incidental	Non-dispersive use	Direct handling

Conditions and measures related to personal protection, hygiene and health evaluation

This substance causes the risk of serious eye damage, is skin irritant and is suspected of causing cancer. Heat and fire resistant work clothes, boots and gloves are used for certain jobs. Lead blood concentrations of the workers are monitored and static and personal air measurements for lead and zinc are conducted. The PPEs presented below is recommended to be worn during the high risk activities (manual transfers, control walks, maintenance work).

Contributing scenario	PROC	Respiratory Protection (Effectiveness Inhal: %)	Eye/face protection:	Dermal protection (Effectiveness Dermal: %)
Raw material handling	PROC 26	Not needed at normal process conditions. Respirator (APF of 20) (Effectiveness 95%) for manual handling	Face shield/air stream helmet	Chemical or fire resistant gloves (Effectiveness 90 %) chemical resistant protective clothing and boots. Fire resistant gloves, clothes, shoes and protective overall (overall usage before cleaning approx. 60 min)
Drying and smelting	PROC 1	Not needed at normal process conditions.	No workers are separated from emission source	

Maintenance and sampling	PROC 8b	Respirator (APF of 20) (Effectiveness 95%)	Face shield/air stream helmet	Leather gloves: Breakthrough time: approx. 30 min. Low risk gloves for daily use, Heat and fire resistant gloves for certain jobs. Gloves lifespan approx. 1-16 hours depends on the activity.

3. Exposure estimation and reference to its source

Worker: The recommended standard tool CHESAR version 2.2 was used as the assessment tool, and external MEASE modelled inhalation and dermal exposure estimates of the most critical constituent where exported to this tool. As this substance is an UVCB substance the exposure assessment and risk characterisation for workers was based on the most critical constituent in the substance, lead. Since this substance causes the risk of serious eye damage, is skin irritant and is suspected of causing cancer, worker exposure was also assessed qualitatively. The substance produces toxicity in multiple organ systems and body function including the haematopoietic (blood) system, kidney function, reproductive function and the central nervous system. Zinc is an essential trace element for humans having no bioaccumulation properties.

Environment: The environmental exposure assessment was conducted by using the EUSES v.2.1 model. The environmental assessment was conducted to two most critical and bioavailable constituents, lead and zinc. The ERC default release rates or release factors (ERC 6a) were modified based on the monitoring results and based on the assumption taken for the amount of release expected to arise from the substance use. As the monitoring data covers releases from all processes in the factory, the emissions of the substance use is assumed to be 10 % of the monitored releases.

Environment

Local exposure estimation and risk characterisation

The PNEC-values are presented in SDS section 8.1.

Release	**Release factor % / Release rate (kg/d)**	**Explanation / Justification**
Water	**Local release rate (kg/d):** 0.003 kg Pb/d 0.156 kg Zn/d.	Based on the monitored zinc and lead releases. Since monitoring data contains also releases from other lead refinery processes, 10 % is assumed to be released from the downstream use of the substance.
Air	**Local release rate (kg/d):** 0.047 kg Pb/d 0.005 kg Zn/d	The average annual zinc and lead release in air (173 kg Pb/a and 17 kg Zn/a) divided by the release days (365 d/a) based on the annual monitored release from the whole lead refinery process. 10 % is assumed to be released from the downstream use of the substance.
Soil	**Final release factor:** 0 %	No direct release to natural or agricultural soil. The emissions via air deposits have been taken into account in this assessment.

Protection target	Exposure estimate Local PEC Lead	Exposure estimate Local PEC Zinc	Risk characterisation ratio (RCR) Lead	Risk characterisation ratio (RCR) Zinc
Fresh water	1.114E-4 mg/L	0.006 mg/L	0.017	0.307
Marine water	6.986E-6 mg/L	4.096E-4 mg/L	< 0.01	0.067
Sediment (Fresh water)	3.288 mg/kg	69.56 mg/kg	<0.01	0.59
Sediment (Marine water)	0.206 mg/kg	4.507 mg/kg	< 0.01	0.08
Sewage treatment plant	No on-site relevancy, no biological WWT		Not relevant	Not relevant
Agricultural soil	0.016 mg/kg	0.388 mg/kg	< 0.01	< 0.01

Risk characterisation for man via the environment

The substance contains lead and zinc. Lead may cause cancer and may be damaging to unborn child. It is also suspected of damaging fertility. The substance produces toxicity in multiple organ systems and body functions including the hematopoietic (blood) system, kidney function, reproductive function and the central nervous system if inhaled or ingested. It is very toxic to aquatic life with long lasting effects. Zinc is an essential trace element for humans. It is vital for many biological functions and plays a crucial role in cell growth and division, fertility and immune system function. Thus, the human exposure via the environment was assessed for lead releases.

Exposure via inhalation:	1.308E-5 mg/m³
Exposure via food consumption:	0.002 mg/kg/d
Risk characterisation (RCR) –	0.53

combined routes:	

Worker exposure

Quantitative assessment (long-term systemic effects)

Inhalation: Derived no effect level (DNEL) (mg/m^3) = 0.1 mg/m3 (OEL for lead).
Dermal: Derived no effect level (DNEL) (mg/kg) = 0.03 mg/kg bw/day.
The scenario (PROC 8b) is conducted as a worst case scenario for the activities describing the conditions of use during smelter control walks and minor maintenance activities, manual/semi-automated transfer operations and maintenance works activities where the exposure of workers might be expected (see section 2.2).

Contributing scenario	PROC	Inhalation				Dermal			
		duration (h)	respiratory protection	Exposure estimate (mg/m^3)	RCR	gloves	Exposure estimate (mg/kg)	RCR	Risk characterisation ratio (RCR)combined routes
Raw material handling	PROC 26	< 1	Yes (APF 20) Eff. 95 %	0.022	0.22	Yes Eff. 90 %	3.3 E-4	0.11	0.231
Drying and smelting	PROC 1	< 8	No Eff. 0 %	0.01	0.1		2E-4	0.007	0.107
Maintenance and sampling	PROC 8b	< 1	Yes (APF 20) Eff. 95 %	0.055	0.55		8E-4	0.03	0.577

Qualitative assessment

Since no short-term, high peak exposures are expected from the processes, the risk characterisation for acute effects is considered unnecessary. The hazard class for the substance is based on the classification of the substance and is described in ECHA CSA guidance Part E Table E 3-1. This substance is classified for severely damaging to eyes, skin irritant and is suspected of causing cancer. Based on this classification the substance is assigned to moderate hazard class. The worker exposure is controlled with appropriate RMMs and use of PPEs (see sections 2.1 and 2.2).

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

This exposure scenario does not address consumers or professional workers. The exposure assessment and risk characterization of workers were conducted by using MEASE –model. Based on the exposure assessment the respiratory protection and limitation of activity durations are required for manual operations, control walks and maintenance activities when potential inhalation exposure is expected. During normal process conditions the use of respiratory protection is not necessary since the processes are closed and automated and the workers are separated from emission source and supervision and crane/vehicle operations are done from ventilated control rooms. Since this substance causes the risk of serious eye damage and is skin irritant dermal contact should be avoided using PPEs. Personal and static air measurements and biological monitoring of lead blood concentrations of the workers confirm the conditions of safe use of the substance.

The environmental exposure assessment was conducted by using the EUSES v.2.1 model. The ERC default release rates and release factors were modified based on the monitoring results and based on the assumption taken for the amount of release expected to arise from the substance use. The emissions of the substance use are assumed to be 10 % of the monitored releases from the process steps up to smelting.

Scaling of exposure assessment can be done by modifying the default parameters and recalculating the exposures using the same models. The compliance can be also verified by comparing the monitored occupational exposure measurements with the DNEL value (section 3). Scaling of environmental exposure scenario conducted for this process can be done by modifiying the releases parameters based on the measured emissions of lead and zinc and re-claculating the emissions by using the EUSES. The recalculated values can then be compared with the PNEC values (section 3). The use is considered safe if the scaled results divided by the DNEL or PNEC –values are resulting a risk characterisation ratio (RCR) less than 1.